

Independent State of Samoa

Samoa's National Biosafety Framework

FINAL DRAFT



United Nations Environment Programme



Government of Samoa



Global Environment Facility

Minister's message

On behalf of the Government of Samoa, it gives me great pleasure to endorse Samoa's National Biosafety Framework for the safe transfer, handling and use of Genetically Modified Organisms (GMOs) resulting from modern biotechnology.

Samoa has made some significant achievements in environmental protection and conservation in recent years. Our National Biodiversity Strategy and Action Plan has set the direction for Samoa's implementation of the Convention on Biological Diversity, which we signed at the Rio Summit in 1992 and ratified in February 1994.

Our firm commitment to the development and support of biodiversity policy has seen Samoa leading the region in this area. This political commitment is further shown by the formulation and endorsement of our National Biosafety Framework.

The Framework has been developed within the context of Samoa's national development priorities and takes into account the need to protect the environment and human health. It will enable Samoa to fulfil its obligations as a Party to the Cartagena Protocol on Biosafety which we ratified on 30 May 2002.

As a small island developing state that is heavily dependent on agriculture and fisheries, Samoa is particularly vulnerable to the potential adverse affects of GMOs. At the same time, we also recognise the potential development gains from the use of modern biotechnology. However, it is important to strike a careful balance to ensure that our environment, health and culture is not damaged in the process.

The implementation of this Framework is an important opportunity to increase public awareness and understanding about GMOs, their impact and the system the Framework sets in place to manage these issues. It will also be important to gather further information about the current use of GMOs in Samoa, and to assess their environmental impact.

Given the capacity constraints that Samoa faces, support from our key stakeholders is crucial. The development and implementation of the Framework relies on input and assistance from the Samoan community, private sector, international donor community and our bilateral partners. We acknowledge with thanks the assistance provided so far, and hope that we can continue these relationships to ensure the effective implementation of the Framework.

I would like to take this opportunity to encourage the people of Samoa to "come on board". Together as a community we can face the challenges and maximise the benefits that GMOs bring.



Hon. Tagaloa Tuala Sale Tagaloa
Minister of Natural Resources and Environment
November 2004

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1. Introduction

1.1 Context for Samoa's National Biosafety Framework

Biotechnology has been used by Samoan farmers for many years to crossbreed plants and animals. However, modern biotechnology, where genes are transferred between species, is a relatively new concept in Samoa. The products of modern biotechnology are often referred to as Genetically Modified Organisms (GMOs). Biosafety is a way of reducing the potential risks that may result from modern biotechnology and its products. It is a way of protecting a country's biodiversity, or its environment and human health from any possible adverse effects of GMOs.

The international community has put in place a framework to deal with these issues through the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Samoa ratified the Cartagena Protocol on 30 May 2002 and the Convention on Biological Diversity on 9 February 1994. Since 2002, the Government of Samoa has been developing the National Biosafety Framework to address biosafety issues and to implement its obligations under the Cartagena Protocol.

The potential risks and benefits of GMOs are exacerbated by Samoa's environment and socio-economic factors. Samoa is a least developed country located in the South West Pacific. Its population of 176,710 (2001 figures) lives on two main islands, Upolu and Savai'i, and seven small islands. Samoa's GDP per capita is approximately \$USD1,750.

As a small island developing state with an economy based on agriculture and fisheries, Samoa recognises the risks associated with the importation of GMOs. Samoa also recognises the potential benefits offered by modern biotechnology and its products in both subsistence and export based agriculture and fisheries. Further risk assessment and risk management needs to be carried out to investigate potential risks to biodiversity. This should also take into account socio-economic considerations and the limited existing capabilities to cope with known and potential risks associated with GMOs.

Samoa's National Biosafety Framework has been developed within the context of Samoa's national environment policies, development priorities and obligations as a party to the Cartagena Protocol. The National Biodiversity Strategy and Action Plan sets in place a framework for addressing a range of environmental issues, including biosafety. Biosafety must also be considered in light of the broader development goals set by the Strategy for the Development of Samoa 2002-2004.

The National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that ensure an adequate level of protection for the safe transfer, handling and use of GMOs resulting from modern biotechnology. In particular, it aims to safely manage GMOs that may have adverse effects on conservation and the sustainable use of biological diversity, also taking into account possible risks to human health.

1.2 Key elements

There are five key elements to the National Biosafety Framework

1. A national **biosafety policy**;
2. A **regulatory regime**;
3. A **system to handle requests** (administrative, risk assessment, risk management and decision making processes);
4. **Follow up actions** (monitoring, inspections and enforcement); and
5. Systems for **public awareness and participation**.

Each of these various elements is considered in turn below.

2. Status of modern biotechnology in Samoa

2.1 Modern biotechnology surveys

In order to assess the existing status of modern biotechnology in Samoa, two surveys were undertaken in 2003 to analyse the:

- extent and impact of the release of GMOs and commercial products; and
- existing cooperative programmes in capacity building, research and development and existing uses and application of modern biotechnology.

The scope of the surveys included consultations with government ministries, private sector organisations, academic institutions, inter-governmental organisations, non-government organisations and communities.

The studies found that there were no official records concerning the release of any GMOs in Samoa. However, the possibility of actual use, handling, release and transboundary movements of GMOs could not be excluded. For example, there were commercial products that could potentially be regarded as GMO products or derivatives. However, a lack of labelling requirements meant it was difficult to determine with any precision whether these products did in fact contain GMOs. Imported living organisms, such as livestock and plants, could also potentially be the result of modern biotechnology activities, however, there were no records regarding their genetic profiles. A list of GMOs, their products and derivatives that could impact on Samoa is provided in Annex 1 (Survey on the Extent and Impact of Release of GMOs and Commercial Product).

In addition to importation of GMO products or derivatives, the surveys considered domestic use of gene technology in Samoa. Capacity building with regard to modern biotechnology is relatively new to Samoa. At the time of the survey, there was no research on GMOs at the national level. However, institutions, such as the University of the South Pacific School of Agriculture, the National University of Samoa and the Ministry of Agriculture's Research Station at Nuu, have laboratory facilities that could be utilized for such activities.

2.2 Legislation survey

The surveys found that while there were a number of laws that potentially impact on GMO products and derivatives, there was no legislation that specifically addressed the issue of modern biotechnology. A legislation survey undertaken in August 2004 (see Annex 3) identified existing and proposed laws of Samoa that could impact on the implementation of fundamental concepts arising from the CBD and the Cartagena Protocol.

(a) *The Constitution of Samoa*

Samoa's Constitution is the supreme law of the country. It deals with a wide range of matters including fundamental rights and freedoms and the system of government. Amongst other provisions, it recognises the institutions of traditional governance, customary or chiefly titles and land ownership in Samoa. The preservation of culture and traditional values is fundamental for Samoa's approach to biosafety issues.

(b) *Lands, Surveys and Environment Act 1989*

The *Lands, Surveys and Environment Act 1989* is the principal law relating to the management and protection of the environment currently in force in Samoa. It establishes the Department of Lands, Surveys and Environment (since renamed the Ministry of Natural Resources and Environment) and makes comprehensive provision in relation to land and environmental management. Its provisions relating to conservation and protection of the environment include:

- appointment of a Principal Environment Officer as a deputy to the Director of Lands;
- establishment of the Department with broad ranging functions and powers for conservation and environment protection;
- establishment of an Environment Board;
- broad powers given to the Minister in relation to environmental management, including assessments, monitoring, the approval of guidelines and authorization of special investigations;
- appointment of conservation officers;
- preparation of draft Management Plans in relation to a range of environmental issues. These must be considered by the Board and can be approved by the Minister;
- protection of foreshores and coastal waters;
- control of pollution of Samoa's waters;
- establishment of an environment fund; and
- provision for litter control.

(c) *Ministry of Natural Resources and Environment Bill 2003*

This Bill establishes the Ministry of Natural Resources and Environment and defines its functions and responsibilities. It has yet to be introduced into Parliament. The Bill includes provisions relating to:

- responsibilities vested in the Ministry, including environment and conservation functions, the implementation of Samoa's obligations under environment related international conventions and responsibilities for Samoa's other natural resources;

- Ministerial appointment of advisory bodies;
- powers to monitor, investigate and enforce, including taking samples and seizing items; and
- giving technical evidence by certificate.

(d) *Agriculture, Forests and Fisheries Ordinance 1959*

This Ordinance establishes the Department of Agriculture, Forests and Fisheries (now Ministry of Agriculture). It establishes the Ministry's various functions that relate to conservation and management of the environment and quarantine matters. The Ministry is tasked to:

- promote, in conjunction with Lands, Surveys and Environment, the conservation, production and development of the natural resources of Samoa, especially soil, water and forest;
- regulate fishing and promote the conservation of fish; and
- regulate, control and supervise the storage and use of pesticides.

(e) *Ministry of Primary Industries Development Bill 2003*

This Bill establishes the Ministry of Primary Industries Development and defines its functions and responsibilities. It has yet to be introduced into Parliament. The Bill includes provisions relating to:

- responsibilities vested in the Ministry, including crops and horticulture, animal production and health, responsibilities relating to Samoa's other natural resources including forest and fisheries, quarantine and policy and planning;
- Ministerial appointment of advisory bodies;
- powers to monitor, investigate and enforce, including taking samples and seizing items; and
- giving technical evidence by certificate.

(f) *Health Ordinance 1959*

The *Health Ordinance 1959* establishes the Department (now Ministry) of Health. It deals with a number of matters relating to public health, including the Ministry's functions to provide advice, information, research and investigations relating to public health. The Board of Health advises the Minister of Health in relation to matters that may affect the health of the people of Samoa. The Director-General of Health also has very broad powers to act in relation to infectious diseases including powers to isolate and quarantine. Persons, ships, aircraft, animals or things may be prevented from coming into Samoa.

(g) *Quarantine (Biosecurity) Bill 2003*

This Bill replaces existing biosecurity legislation with a comprehensive quarantine regime to regulate imports and associated biosecurity risks. It also controls pests and diseases in animals, plants and the wider environment. It has yet to be introduced into Parliament.

(h) *Plants Act 1984*

The *Plants Act 1984* makes comprehensive provision in relation to plants and plant diseases. It regulates the importation and exportation of plants and quarantine-related issues. Regulations made under this Act may impose controls on the export of any plant and may require the masters of ships and aircraft to provide prescribed information. The Quarantine (Biosecurity) Bill 2003 proposes to repeal and replace this Act.

(i) *Business Licences Act 1998*

This Act makes comprehensive provision for the licensing of businesses in Samoa, including the prohibition of certain business activities. Prohibited business activities include nuclear and toxic waste disposal, export of products that are prohibited under any law and processing and export of endangered species.

(j) *Consumer Information Act 1988*

The *Consumer Information Act 1988* makes provision for informative labeling and marking of goods. It also prevents misleading and deceptive packaging, labeling and advertising of goods. This Act may be used to require the disclosure of the use of GMOs in packaged food products.

(k) *Fair Trading Act 1998*

The *Fair Trading Act 1998* regulates consumer protection including permitting standards to be applied to goods offered for sale, and other arrangements for the protection of consumers' rights. The Minister for Trade and Commerce may apply product safety or quality standards for any specified goods. The standards must be aimed at preventing or reducing risk or injury to persons. The requirements may relate to methods of manufacture, testing of goods and labelling. Goods must not be supplied unless they conform to an approved standard. The CEO of the Ministry of Commerce, Industry and Labour may conduct inquiries into any matter involving the sale of goods to which approved standards apply. The Minister may order the recall of any goods that do not comply with an approved standard.

(l) *National University of Samoa Act 1997*

This Act provides for the administration of the National University of Samoa (NUS), one of two tertiary academic institutions established under Samoan law that provides teaching and research at tertiary level. A primary function of NUS is as a centre of excellence in the study of Samoa, the Samoan language and Samoan culture.

(m) *The University of the South Pacific School of Agriculture Act 1977*

This law establishes the University of the South Pacific (USP) School of Agriculture in Samoa and endows lands for its purposes. USP's functions include undertaking research and advisory services relating to agriculture and agriculture science for the communities of the South Pacific,

governments and other institutions. The USP Campus retains the function of providing and extending pest-control, animal health and related services for the people of Samoa.

(n) Fisheries Act 1988

The *Fisheries Act 1988* provides for the conservation, management and development of Samoa's fisheries and for the licensing of foreign fishing vessels. This includes protection and preservation of the marine environment and potential regulation of marine scientific research and exploration. The Act includes mechanisms for government consultation with industry and village representatives to make by-laws aimed at the conservation and management of fisheries. Amendments made in 1998 provide for licensing of commercial and experimental aquaculture operations, the export or import of certain fish or fish products and fish processing establishments.

(o) Forests Act 1967

The *Forests Act 1967* provides for the conservation, protection and development of the soil, water and forests of Samoa. It includes some provisions dealing with quarantine issues relating to the import of trees, seeds, timber and timber products.

(p) Food and Drugs Act 1967

This legislation deals with the sale, adulteration and analysis of food and drugs. It includes provisions relating to food standards, labelling and packaging. Ministry of Health officers are given powers of entry, inspection, seizure and destruction. Provision is made for taking samples for analysis and consequent certificates. Regulations may be made under this Act for the licensing and control of the manufacture, importation, sale, distribution or use of sera, vaccines, antigens, toxins, antitoxins or other biological preparations.

(q) Poisons Act 1968

The *Poisons Act 1968* regulates the importation, carriage, custody and sale of poisons and prohibited substances. While GMOs cannot be described as "poisons", this Act regulates anything that is declared by regulations to be a "prohibited substance".

(r) Customs Act 1977

This legislation makes provision for the collection of duties and the importation and exportation of goods. Specified goods can be declared to be prohibited imports on grounds including the public interest. This may have general application or be limited to the importation of goods from any specified person or place. Conditions may be imposed on imports. Prohibition Orders may be made in relation to the export of goods on grounds of the public interest, if the goods have not been prepared or manufactured in accordance with law, or if they do not conform to conditions as to purity and soundness.

(s) *Maritime Zones Act 1999*

The *Maritime Zones Act 1999* makes provision in relation to the sovereignty of Samoa's maritime areas in accordance with international law. It addresses internal waters, the contiguous zone, the exclusive economic zone and the continental shelf. The legislation controls certain acts within the territorial sea by foreign vessels that may harm the environment or affect its resources. Prior approval must be given for vessels carrying hazardous substances or substances harmful to the environment in the territorial sea.

(t) *Carriage by Air Act 1964*

This law applies the Warsaw Convention to international air carriage to and from Samoa. It requires that the consignor of items provide necessary information and documentation to enable clearance of the goods to the consignee.

(u) *Internal Affairs Act 1995*

This legislation establishes the Ministry of Internal Affairs (now part of the Ministry of Women, Community and Social Development). It also makes provision for the recognition and organisation of village authority to stand as a system of local government throughout Samoa.

(v) *Village Fono Act 1990*

The *Village Fono Act 1990* empowers the Village Fono (or council of chiefs) to exercise authority within a village in accordance with Samoan custom and tradition. Village Fonos have specific power to make rules for the maintenance of hygiene and the development and use of village land for the village's economic betterment. This power includes requiring people ordinarily resident in the village to perform work relating to these activities. Village Fonos also have the authority to impose punishments including a fine in money, fine mats, animals or food or ordering an offender to undertake work on village land.

(w) *Foreign Affairs Act 1976*

This Act makes provision for the administration of foreign affairs for the Government of Samoa. It does not, however, contain substantive provisions prescribing the means by which Samoa is to fulfill its international obligations, or by which it might form international alliances and partnerships to pursue these ends.

2.2.1 Interface between biosafety and other laws

The interface between biosafety and other laws has been taken into account in the development of biosafety legislation. As a result, the biosafety law expressly preserves the operation of other laws dealing with issues such as quarantine, pesticides, human health and food labelling. The laws mentioned above are summarised in the Table below along with their scope, responsible agencies, and their status.

Legislation	Relevant Scope of Act	Responsible Agencies
Agriculture, Forests and Fisheries Ordinance 1959 and Regulations	<ul style="list-style-type: none"> To strengthen the capabilities of agricultural inspection and quarantine services 	MAFFM
Animal Ordinances 1960 and Regulations	<ul style="list-style-type: none"> To develop control measures to protect and conserve biodiversity To control and/or prevent the introduction of inappropriate foreign plants and animals 	MAFFM
Noxious Weeds Ordinance 1961	<ul style="list-style-type: none"> To control the propagation of harmful plants 	MAFFM
Forest Act 1967	<ul style="list-style-type: none"> To develop control measures to protect and conserve biodiversity 	MAFFM - Forestry
Development Bank Act 1974	<ul style="list-style-type: none"> To encourage new cash crops To encourage local entrepreneurial activities 	Development Bank
National Parks & Reserves Act 1974	<ul style="list-style-type: none"> To preserve native species 	MAFFM
Customs Act 1977	<ul style="list-style-type: none"> To control and/or prevent the introduction of inappropriate foreign plants and animals 	MR - Customs
Plants Act 1984 and Regulations	<ul style="list-style-type: none"> To prevent the introduction of inappropriate foreign plants 	MAFFM MR-Customs
Lands, Survey and Environment Act 1989	<ul style="list-style-type: none"> To ensure and promote the conservation and protection of the natural resources and environment of Samoa 	MNRE
Trade, Commerce & Industry Act 1990	<ul style="list-style-type: none"> To encourage new cash crops To develop resource-based industries To encourage local entrepreneurial activities To attract foreign investment To negotiate trade agreements 	TCI
Enterprise Incentives & Export Promotion Act 1992	<ul style="list-style-type: none"> To encourage new cash crops To encourage local entrepreneurial activities 	TCI
Protection and Conservation of Wild Animals Amendment Regulations 1993	<ul style="list-style-type: none"> To develop planning controls to protect and conserve biodiversity 	MNRE
	PROPOSED	
Environment Impact Assessment Regulation 1998	<ul style="list-style-type: none"> To regulate and guide impact assessments in Samoa for both private and public development proposals 	MNRE - PUMA
Environment Bio-Prospecting Regulation 1999	<ul style="list-style-type: none"> To regulate access to Samoa's genetic resources and the equitable sharing of benefits derived from users 	MNRE - DEC
Biosecurity Bill 2003	<ul style="list-style-type: none"> To regulate importation of articles associated with biosecurity risk 	MAFFM - Quarantine

3. Policies related to biosafety

3.1 National Biodiversity Strategy and Action Plan

Samoa's National Biodiversity Strategy and Action Plan (NBSAP), endorsed in 2001, provides the overarching policy context for biosafety matters. The following elements of the NBSAP support, and are directly relevant to, biosafety initiatives:

THEME 1 – MAINSTREAMING BIODIVERSITY	
<p><i>Objective 3: Legislation</i></p> <p>To ensure that appropriate legislation is developed and effectively enforced to sustainably manage Samoa's biodiversity</p>	<p><i>Action 3.6</i></p> <p>Develop appropriate legislation on biosecurity to include risk management on genetically modified organisms, invasive alien species and effective border control</p>
THEME 6 – BIOSECURITY	
<p><i>Objective 1: Policy and Legislation</i></p> <p>To develop appropriate policies and legislation to ensure the effective management of biodiversity</p>	<p><i>Action 1.2</i></p> <p>Develop policy and actions for the management of biosafety issues.</p>
THEME 7 – AGROBIODIVERSITY	
<p><i>Objective 2: Research and development</i></p> <p>To conduct relevant research critical to the development of agrobiodiversity</p>	<p><i>Action 2.2</i></p> <p>Assess the impacts of new technologies (genetic expressions, living or genetically modified organisms and genetically engineered organisms) on agrobiodiversity.</p>

A number of other themes and objectives are indirectly relevant to biosafety. In particular, they address issues such as capacity building, public awareness and education. For example, Theme 1 – Mainstreaming Biodiversity emphasises the need for capacity building and Theme 4 – Community emphasises the objectives of public awareness and education.

3.2 Strategy for the Development of Samoa 2002-2004

Further context is provided by the vision of the Strategy for the Development of Samoa 2002-2004 (SDS). The SDS aims “for every Samoan to enjoy an improved quality of life premised on a competitive economy with sustained economic growth, improved education, enhanced health standards and strengthened cultural and traditional values.” The policy contains a number of strategic outcomes relevant to biosafety including: improving health standards; enhancing agricultural opportunities; and improving infrastructure and services (include the environment) to enhance Samoans' quality of life. These goals are reflected in the National Biosafety Policy for Samoa.

3.3 National Biosafety Policy for Samoa

(a) Policy development

The National Biosafety Policy for Samoa (NBPS) was developed within this overarching policy framework. It aims to ensure that Samoan people can make informed decisions in relation to modern biotechnology in a way that supports, rather than constrains, economic growth and health standards, while not diminishing cultural and traditional values.

In 2003, the National Coordinating Committee established a Drafting Team to write biosafety policy. Following consultations with stakeholder representatives via the National Coordinating Committee, the Minister of Natural Resources and Environment approved the NBPS as an annex to the NBSAP in April 2004.

The NBPS puts in place a structure to enable the development of an implementing legal regime and technical and administrative systems. It aims to ensure an adequate level of protection in the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity.

(b) Objectives

The objectives of the NBPS are:

1. To assess potential benefits and risks of modern biotechnology and its products¹ to Samoa in *achieving sustainable development*.
 2. To *build Samoa's capacity* to develop effective science based risk assessment and management that would manage and control potential risks of modern biotechnology and its products.
 3. To ensure *the safeguard of the environment* of Samoa, the health of its people and their *cultural and traditional values and knowledge* from the potential risks of modern biotechnology.
 4. To enforce *adequate safety measures* in Samoa to reduce and eliminate potential risks of modern biotechnology and its products to the environment of Samoa and the health of its people and their cultural and traditional values and knowledge.
 5. To involve all *stakeholders* in the management of GMOs.
 6. Developing a systematic management for biosafety in Samoa.
 7. Protecting genetic diversity and genetic reserves in Samoa while moving towards sustainable biotechnology.
 8. Protecting the environment and human health from probable effects of GMOs.
- Research into biological diversity.

¹ These products contain any component resulting from modern biotechnology.

- Reduction in environmental degradation through reduced use of potentially harmful chemicals.
- Capacity building for monitoring and enforcement.
- Public information and education.
- Capacity to detect GMOs unintentionally brought into Samoa.
- Develop standards, codes and guidelines relevant to management of GMOs.

Various strategies have been identified to implement these objectives. The **short term strategies**, to be completed within 1-3 years, are to:

1. Strengthen the capacity of MNRE to implement the Policy;
2. Increase public awareness and participation;
3. Develop a regulatory regime; and
4. Set up administrative systems.

The **long term strategies**, to be implemented within 3-5 years, are to:

1. Strengthen the capacity of all stakeholders to implement the Policy;
2. Improve administrative systems;
3. Strengthen institutional systems; and
4. Increase public awareness and public participation.

4. Regulatory Regime

Samoa's regulatory regime for biosafety is contained in the Draft Biological Diversity Bill ("Draft Bill") and the Draft Biosafety (Living Modified Organisms) Regulations ("Draft Regulations"). Both these instruments are currently in draft form awaiting final approval and enactment.

Together, these legislative instruments seek to give full effect to Samoa's obligations under the Cartagena Protocol. The Draft Bill is also intended to provide a mechanism to implement Samoa's obligations under the Convention on Biological Diversity. While in its current form it focuses on biosafety, regulations and future amendments may be made to the Bill to provide for the range of issues covered by the CBD.

4.1 Draft Biological Diversity Bill

The Draft Bill implements all operative provisions of the Cartagena Protocol. It provides for:

- a regulatory and administrative framework for GMOs;
- procedures relating to the importation of GMOs;
- other dealings with GMOs such as export, transit, use for food, feed and processing, contained use and unintentional and illegal releases and transboundary movements;
- criminal offences and indemnities; and
- implementation of the CBD and inter-agency cooperation.

(a) Objectives

The Draft Bill's objectives are to:

- protect Samoa's biological diversity and to give effect to the provisions of the CBD and Cartagena Protocol;
- protect Samoa's environment and the health of its people by providing an effective regulatory regime for GMOs based on timely notifications and scientific risk assessments;
- facilitate the application of the benefits of modern biotechnology in Samoa; and
- confirm the application of Samoa's laws the context of the transboundary movement of GMOs and protection of biological diversity.

(b) The Precautionary Approach

The Draft Bill enshrines the precautionary approach and compels its use in relation to GMOs and the applications of modern biotechnology. This is a fundamental principle of environmental law that has been expressed in various international declarations and case law, including Principle 15 of the Rio Declaration, adopted in 1992. The precautionary approach is also a cornerstone of the Convention on Biological Diversity and the Cartagena Protocol. Its application is critical to a small island developing state like Samoa with its vulnerabilities and capacity constraints.

The Draft Bill provides that the precautionary approach is applied if, in the event of a threat of damage to the environment or a risk to human health in Samoa, a lack of scientific certainty regarding the extent of adverse effects is not used to postpone a decision being made to minimise the potential adverse effects or risks arising in any way.

(c) National Competent Authority

The Draft Bill creates a National Competent Authority (NCA) which comprises representatives of relevant Ministries, the commercial sector and community. The NCA is chaired by either the Minister of Natural Resources and Environment or the CEO of MNRE.

The NCA has the power and responsibility to:

- oversee the implementation of the Cartagena Protocol and the advanced information agreement procedure;
- authorise the giving of any required notifications;
- determine means for undertaking scientific risk assessments;
- make decisions regarding exemptions of GMOs from notification requirements and review of decisions;
- determine policies and procedures relating to GMOs;
- ensure that policies and procedures take into account Samoan customs and traditions, as well as the environmental impact of GMOs;
- arrange for the preparation of reports in accordance with the Cartagena Protocol; and
- ensure that government is fully informed of GMO issues in Samoa, including any unintended uses.

GMOs are not permitted to be imported into Samoa unless the NCA has given approval in accordance with the procedure set out in the Draft Bill.

The NCA's activities and operations are supported by MNRE as the focal point.

(d) Focal Point

MNRE is the **designated national focal point**. As such, it will coordinate and support biosafety procedures and implementation of biosafety policy. In particular, MNRE and its CEO will have responsibility to:

- provide secretariat services and support for the NCA and any Technical Advisory Groups
- receive notifications to forward to the NCA for consideration and communicate the NCA's decisions;
- communicate with the Biosafety Clearing House;
- arrange for and facilitate risk assessments, maintenance of confidential information and reviews of decisions;
- conduct public awareness activities; and
- liaise with other Ministries and agencies, both in Samoa and overseas, in relation to the implementation and development of biosafety policy.
- appoint Technical Advisors to facilitate and advise on its works.

MNRE's designated focal point roles will be concurrent with its membership of the NCA. This includes the Minister, or in his absence the CEO's, role to chair the NCA. The roles and responsibilities of MNRE are further elaborated under the Administrative Systems section.

(e) Operation of other laws

The Draft Bill preserves the operation of other laws that interface with biosafety issues, as identified through the legislative review. It ensures that the operation of existing related laws is preserved and any other relevant permits still need to be obtained, such as quarantine permits. Any person seeking to use GMOs must still comply with requirements in other laws relating to: quarantine and the control of animal and plant diseases; environmental impact assessments, use of pesticides; export of living organisms; customs and excise; sale of medicinal drugs; establishment of businesses; and protection of consumer rights.

(f) Importation of GMOs

The Draft Bill implements the **advanced informed agreements** procedure set out in the Cartagena Protocol. Any importation of GMOs into Samoa must be notified to MNRE as the focal point. The notification is made by the exporter of the GMO or the Competent Authority of the exporting country. The advanced informed agreement procedure is subject to the timeframes prescribed by the Cartagena Protocol (see further below under Administrative Systems).

MNRE will acknowledge receipt of the notification and advise whether the NCA's approval is required or whether the NCA has determined that approvals under other laws, such as quarantine laws, are sufficient. Where the NCA's approval is required, MNRE will pass the notification to the NCA to consider.

Where the NCA's approval is required, the NCA will make a decision based on **scientific risk assessments** and taking into account the **precautionary approach**. The underlying presumption applying to risk assessments is that they will be the responsibility of the importer or notifier, and will be done at their expense. MNRE has wide powers, however, to ensure that risk assessments are done by appropriate bodies and in a scientifically sound manner. Specific allowance is made to ensure that confidential information is treated appropriately.

The representative nature of the NCA's membership ensures that all responsible authorities will be aware of the existence of GMOs in Samoa and the purposes for which they are intended to be used.

(g) Exemptions

The NCA may **exempt** imports of GMOs from the approval and risk assessment procedures. Exemptions may be given to GMOs that are:

- in transit through Samoa;
- proposed for contained use in Samoa;
- for direct use as food, feed or for processing;
- unlikely to have adverse effects on biological diversity or pose a risk to human health, as determined by the parties to the Cartagena Protocol;
- within the scope of any GMOs subject to the simplified procedures determined under the Cartagena Protocol; and
- pharmaceuticals for humans that are addressed by other relevant agreements and international organisations.

Exemptions may be granted subject to certain conditions to minimise the impact of the GMO on biological diversity or risk to human health. Exemptions for GMOs for direct use as food, feed or for processing may be first subject to a risk assessment.

All decisions of the NCA and the CEO of MNRE taken under the Act may be the subject of review on grounds consistent with those stated in the Cartagena Protocol.

(h) Other dealings in GMOs

The main focus of the Draft Bill is to regulate the importation of GMOs into Samoa. However, the Draft Bill also provides for the export, transit and contained use of GMOs. In most of these cases it is left to the applicable domestic laws to fully regulate these matters, whether in Samoa or in receiving countries.

The Draft Bill provides procedures to deal with unintentional releases and transboundary movements of GMOs. The Ministry must be notified to take the appropriate steps to give notice of the unintentional release and transboundary movement and to consult with affected or potentially affected countries. It is a criminal offence to undertake or assist with the illegal release and transboundary movement of GMOs.

Other related matters may be dealt with through regulations which may be made under the legislation.

(i) Criminal offences and indemnities

Enforcement of the regulatory regime is provided through various criminal offences. A range of activities are prohibited including importing GMOs without notifications or approvals, failing to disclose or misrepresenting information relating to an GMO and fabricating risk assessments.

Environment Officers are empowered to enforce the Draft Bill by monitoring, investigating, seizing and destroying GMOs. Environment Officers and other staff of the NCA, Technical Advisory Groups and focal point are specifically not liable for any loss or damage in relation to seized GMOs.

(j) CBD implementation and inter-agency cooperation

The Draft Bill enables regulations to be made to implement provisions of the CBD. These regulations must be consistent with other laws of Samoa. Further, measures to conserve Samoa's biological diversity should be undertaken by government and non-government stakeholders in a cooperative manner.

4.2 Draft Biosafety (Living Modified Organisms) Regulations

The Draft Biosafety (Living Modified Organisms) Regulations ("Draft Regulations") provide further detail about the administrative procedures set by the Draft Bill. They provide for basic matters such as forms and fees for notifications for transboundary movement of GMOs. The Draft Regulations also provide for independent review of the National Competent Authority's decisions.

The regulations build flexibility into the biosafety regulatory regime to take account of future scientific developments. Possible future regulations could be implemented to provide:

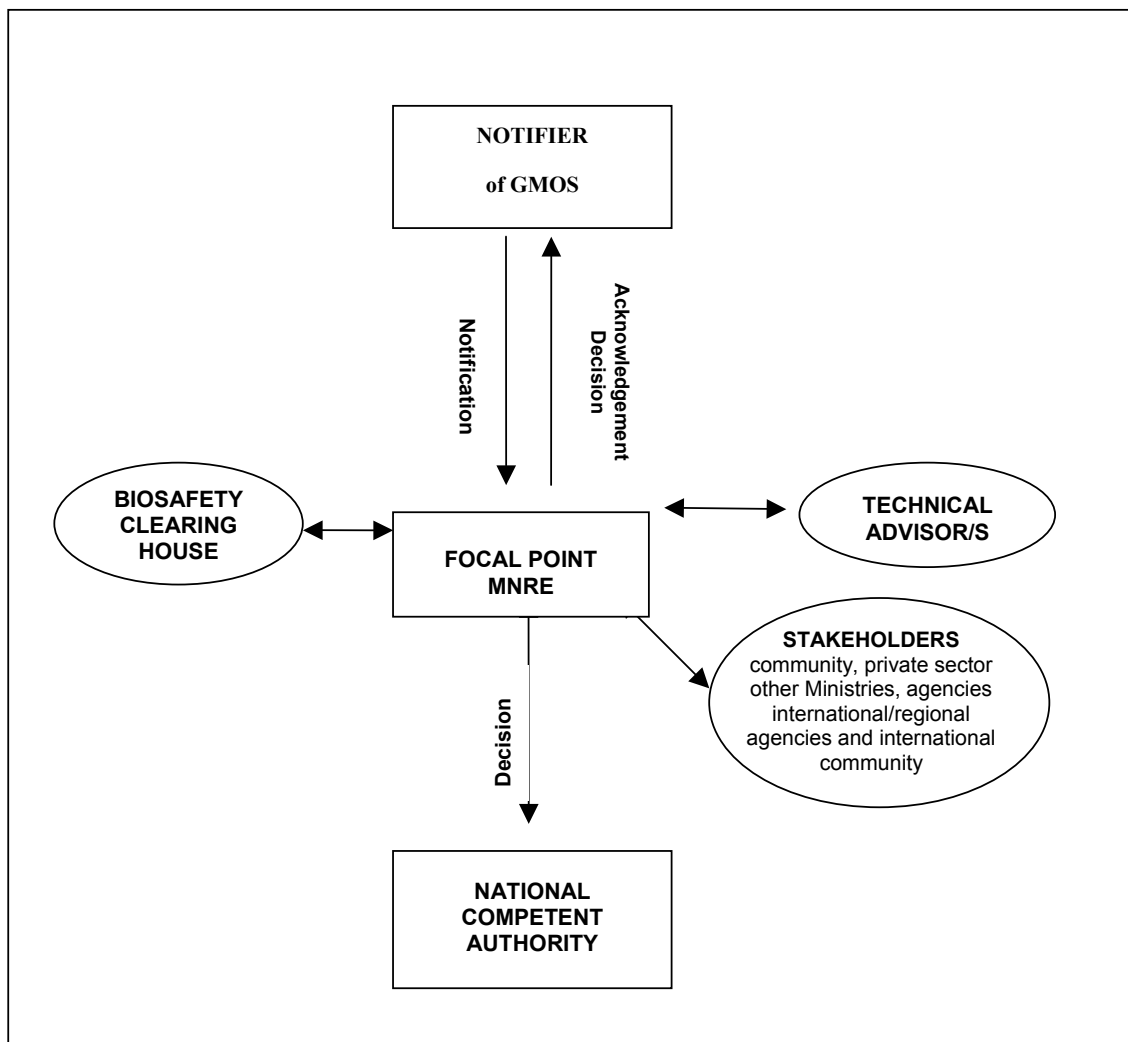
- additional concepts of "modern biotechnology";
- additional procedural aspects of the notification requirements, the review of decisions, the export of GMOs and the contained use of GMOs;
- specific requirements dealing with the transportation of GMOs by road, sea or air that take account of associated risks;
- requirements applying to planned releases of GMOs;
- requirements applying to field tests and other research procedures and techniques;
- grounds and procedures for withdrawing approvals;
- procedures for dealing with confidential information;
- other matters relating to the review of decisions; and
- matters relating to approved rules and procedures relating to liability and redress.

5. Administrative systems

5.1 Processing requests

MNRE is responsible for administering the National Biosafety Framework and overseeing its implementation. One of the objectives of the Ministry's 2003 Corporate Plan's is "to formulate and implement strategies for the sustainable management of natural resources and the environment". In order to deliver this objective, MNRE's activities, identified in the Division of Environment and Conservation's Business Plan, include completing the National Biosafety Framework.

It is important that the administrative systems established to implement the National Biosafety Framework are efficient and facilitate effective decision making. The scope and structure of the administrative system to process GMO requests is established by the Draft Bill. The process is conceptualised in the following flow chart:



(a) Step 1: Submission of Notification

First, the notifier of a GMO (or the competent authority in the country of export) must submit a notification to MNRE as the designated focal point. The notification must include information as outlined in the Draft Regulations, which incorporates Annex 1 of the Cartagena Protocol. This includes contact details, information about the GMO and intended use. The notification must also be accompanied by the prescribed fee.

MNRE will acknowledge receipt of the notification within 90 days. It will also advise whether the GMO requires approval from the NCA, or whether the NCA has previously determined that existing approvals required by other laws (such as quarantine) will be sufficient.

(b) Step 2: Processing of Notification

After MNRE has confirmed that the documentation is adequate, it will send the application to the NCA for risk assessment and consideration. The NCA's membership ensures that key stakeholders are represented.

(c) Step 3: Risk Assessment and Advice

A Technical Advisor/s will consider the notification and risk assessments and make recommendations on these matters and any issues of concern to the NCA. The NCA then makes a decision about whether to allow the importation of the GMO into Samoa. This decision must be made taking into account the risk assessment and the precautionary approach. The NCA must make its decision within 270 days of date of receiving the notification, otherwise it must notify the exporter that further time is required.

The notifier is responsible for the risk assessments and associated costs will be borne by the notifier.

(d) Step 4: Communication of Decision

The Minister's decision is communicated to the notifier via the focal point. The decision must be accompanied by reasons (unless the decision is unconditional approval to import). Approval, however, does not mean the GMO can be automatically imported. Other relevant laws must also be complied with, such as quarantine and labelling requirements.

(e) Step 5: Appeal

The notifier may seek review of a decision made by the Minister or the CEO if delegated by the Minister on specified grounds. This includes where there is a change in circumstances that may influence the risk assessment or additional scientific information is now available. Within 30 days MNRE, as the designated focal point, must respond to the request and forward it to the NCA to review. The notifier must be informed of the outcome of the review within a further 30 days.

5.2 Monitoring and enforcement

Implementation of the National Biosafety Framework will include monitoring and enforcement of decisions made by the Minister. The legislative framework empowers MNRE's Environment Officers to inspect and monitor the use of GMOs. They are also empowered to enforce the legal framework by seizing and destroying GMOs that are in breach of the law. These enforcement powers complement, and do not affect, existing powers to search and seize under quarantine, customs and excise laws.

Further monitoring and enforcement strategies will be developed during the implementation of the National Biosafety Framework. These issues will also be considered during the annual reviews and 5 year review of the National Biosafety Policy for Samoa.

6. Public Awareness and Participation

Public awareness and participation are vital elements to the success of a biosafety framework. Modern biotechnology and biosafety are complicated issues - they are new to most people and difficult to understand. It is important to work with stakeholders, including the community, to raise awareness about, and increase participation in, biosafety issues.

The Government of Samoa is committed to building community support for the National Biosafety Framework and its implementation. Stakeholders will participate in the administrative systems through membership of the National Competent Authority. Community support and understanding will be increased through public awareness activities. Local scientific and educational institutions, such as the National University of Samoa, the University of the South Pacific and Nuu Research Station, also have a vital role to play through contributing, and developing their technical expertise. Participation of stakeholders outside of Samoa – such as donor agencies, bilateral partners and regional organisations – will help support Samoa's biosafety efforts and forge links with international know-how.

6.1 Activities during development of the Framework

MNRE has undertaken a number of public awareness activities throughout the development of various elements of the National Biosafety Framework. The key message conveyed in these activities is the need for a cautious approach to consider, in a balanced way, the risks and benefits that biosafety poses to the environment, local industry and human health. The focus of the activities was to raise awareness based on the scientific information available at the time and to consider the value and implications of modern biotechnology.

During the formulation of the National Biosafety Policy for Samoa, MNRE held a number of consultation workshops that facilitated raising awareness about GMOs and discussion of the outcomes of the modern biotechnology surveys. Target groups for the workshops included government ministries, village communities and the general public across the islands of Samoa.

Other public awareness activities have included:

- a biosafety theme for the National Biodiversity Awareness Day held on 27 May 2004;
- nationally broadcast radio talk back programmes (English and Samoan language versions);
- articles in national newspapers (English and Samoan language versions);
- a ten minute television documentary on GMOs (English and Samoan language versions) shown on national television over the period of a month; and
- posters (English only) and pamphlets (English and Samoan versions) distributed during workshops and National Biodiversity Awareness Day activities.

These public awareness activities generated such community interest that the issues were discussed by a panel of community leaders on national television over three consecutive Sundays in 2004.

6.2 Future activities

The National Biosafety Policy sets a clear mandate for future public awareness activities about biosafety issues. The legislative framework empowers MNRE to undertake public awareness and consultation activities as part of the implementation of the biosafety framework.

A detailed public awareness strategy for biosafety has yet to be developed. However, target groups have been identified including: non-government organisations; women's committees; matais (chiefs); farmers; and primary and secondary school teachers. Ongoing work will include new scientific information as it comes to hand and consideration of other forms of public awareness activities.

7. Implementation Plan

A range of activities will be required to implement the National Biosafety Framework including the:

- finalisation of the Draft Biological Diversity Bill and its introduction into Parliament;
- implementation of the National Biosafety Policy for Samoa;
- establishment of the administrative system;
- delivery of public awareness and capacity building activities; and
- monitoring and enforcement of the biosafety regime.

The National Biosafety Policy for Samoa identifies a range of short and long term strategies to implement the Policy's objectives (as outlined above). The Policy will also be subject to annual reviews and an independent review after 5 years.

Effective implementation of the Framework will require sufficient financial resources and technical support. This will be critical when implementing the Policy, establishing administrative systems and ensuring effective compliance through monitoring and enforcement. Building the capacity of MNRE to undertake its functions will be crucial. The implementation process should also consider developing the capabilities of Samoa's scientific and educational institutions to

provide technical support to the regime. Encouraging community support for the biosafety regime will be a fundamental element of MNRE's public awareness activities.

8. Terms

8.1 Acronyms

CBD	Convention on Biological Diversity
CEO	Chief Executive Officer
GEF	Global Environment Facility
GMO	Genetically Modified Organism
MAFFM	Ministry of Agriculture, Forests, Fisheries and Meteorology
MNRE	Ministry of Natural Resources and Environment
DEC	Division of Environment and Conservation]
PUMA	Planning Urban Management Agency
MR-Customs	Ministry of Revenue- Custom Department
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Coordinating Committee
SPREP	South Pacific Regional Environment Programme
TCI	Trade Commerce and Industries
UNEP	United Nations Environment Programme

8.2 Technical terms

Biosafety describes efforts to reduce the potential risks resulting from biotechnology and its products.

Cartagena Protocol refers to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted at Montreal in January 2000. Samoa acceded to the Cartagena Protocol on 30 May 2002. The Protocol came into force on 11 September 2003.

Convention on Biological Diversity was adopted at Nairobi in May 1992.

DNA (deoxyribonucleic acid) is the genetic material that organisms inherit from their parents; a double stranded helical molecule.

Gene is a discrete unit of hereditary information consisting of specific sequence of DNA.

Genetic Modified Organism (GMO) means any living organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Include genetically modified human cells and tissues maintained outside the human body. Also include animal cells and tissues maintained in laboratories for research

and investigation. The term has the same meaning as living modified organism in the Cartagena Protocol.

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

Microorganism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, human, animal and plant cell in culture.

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 a GMO will cause harm to the environment if released. Risk assessments enable informed decisions to be made about GMOs before they are introduced into Samoa.

Risk management concerns how to manage any risks that have been identified in the risk assessment process.

Transboundary movement means the movement of a GMO from Samoa to another country or from another country to Samoa.

9. Annexes

Annex 1: Survey on the Extent and Impact of Release of GMOs and Commercial Products

Annex 2: Survey on the Existing National, Bilateral and Multilateral Cooperative Programmes in Capacity Building, R & D, Existing Uses and Application of Biotechnology including Review and Assessment of Existing Legislation that May Impact on the Use of Modern Biotechnology

Annex 3: Information Paper: Review of Samoan Laws, Samoa's National Biosafety Framework

Annex 4: National Biosafety Policy for Samoa

Annex 5: Draft Biological Diversity Bill

Annex 6: Draft Biosafety (Living Modified Organisms) Regulations

Annex 1

SURVEY ON THE EXTENT AND IMPACT OF RELEASE OF LMOs AND COMMERCIAL PRODUCTS

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Faculty of Science

The National University of Samoa

2003

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 1. Terms of Reference
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1. LIST OF ACRONYMS

CBD	Convention on Biological Diversity
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
GE	Genetically Engineered
GM	Genetically Modified
LMO	Living Modified Organism
LMOs-FFPs	LMOs intended for direct use as food or feed, or for processing
MAFFM	Ministry of Agriculture, Forestry, Fishery & Meteorology
MNRE	Ministry of Natural Resources & Environment
MOU	Memorandum Of Understanding
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Co-ordinating Committee
SPREP	South Pacific Regional Environment Programme
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

2. DEFINITIONS

DNA (deoxyribonucleic acid) is the genetic material that organisms inherit from their parents; a double stranded helical molecule.

Gene is a discrete unit of hereditary information consisting of specific sequence of DNA.

Genetic Modified Organism (GMO) means any organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Microorganism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cell in culture.

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.

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4. SUMMARY OF SURVEY FINDINGS

Samoa, as a Party to the Convention on Biological Diversity (CBD), ratified the Cartagena Protocol on Biosafety on 30 May 2002. The Protocol was designed to provide framework within which living modified organisms (LMOs) could be traded in a safe and responsible manner with due regard to the protection of biodiversity, also taking into consideration human health. As a step towards achieving a National Framework, a Survey on the extent and impact of release of LMOs and commercial products was carried out.

Of the Government departments, private sectors, NGOs and communities, it was identified that none could be conclusively excluded from the possibility of dealing with the use, transboundary movement, handling and release of LMOs.

Through consultations with some key stockholders, it was evident that there was no official record to implicate a release of an LMO in Samoa, prior to this survey. On the other hand, there have been commercial products that could be potentially regarded as products or derivatives of genetic modifications.

Some practical recommendations on appropriate mechanisms to monitor and regulate the extent of release and impact of LMOs and commercial products are also given.

5. BACKGROUND

Introduction

Samoa, as a Party to the Convention on Biological Diversity (CBD), ratified the Cartagena Protocol on Biosafety on 30 May 2002. The Protocol was designed to provide framework within which living modified organisms (LMOs) could be traded in a safe and responsible manner with due regard for the protection of biodiversity, also taking into consideration human health. LMOs are a result of genetic manipulations carried out by scientists.

In this Background information, a technical approach is adopted in summarising some aspects of genetic manipulations. Similarly a short review of some benefits and concerns regarding the use of genetic manipulations (or biotechnology) is presented in scientific languages – not to make it hard for the reader but to maintain some degrees of accuracy and precision for scientists who might use some of the information reported here for references as far as the National Biosafety Framework is concerned. Lastly, an overview of the Cartagena Protocol on Biosafety and its relation to the CBD, as well as its connection to genetic manipulations is described.

The Terms *Transgenic*, *Genetically Modified/Altered* Organisms & *LMOs*

There is a very fine line between **transgenic** organisms and **genetically modified** or **genetically modified** organisms. Technically, transgenic organisms carry a gene, or a transgene, which cannot be found in natural populations of that species. In genetically altered organisms, or genetically modified organisms, a native gene has been altered or parts of a chromosome have been relocated, or rearranged, with the help of chemicals or ionising radiation; the final product is again an organism carrying a gene or a chromosome that cannot be found in natural populations of that species. Thus, it becomes impossible to pinpoint where exactly genetic engineering starts as one moves from the term **transgenic organisms** to **genetically engineered organisms**. For simplicity, therefore, here, the use of the terms *transgenic* organisms, *genetically modified* organisms and *genetically engineered* organisms are interchangeable.

One could also argue that **living modified organisms** (LMOs) are actually transgenic organisms or genetically engineered/modified organisms. The distinction here is drawn from the fact that LMOs are those that are still capable of carrying out life processes (movement, respiration, sensitivity, growth, reproduction, excretion and nutrition) which characterise *living* things.

Biological Basis of Genetic Engineering

Living materials contain a master plan which determines their characteristics or features. This master plan is packed in the molecule called deoxyribonucleic acid (DNA) which is the genetic material that organisms inherit from their parents. Thus offspring resemble some parental features because the DNA has been passed along. This follows that physical feature of organisms are encoded for in the DNA molecule. The transfer of DNA from one organism to another is normally associated with the transfer of physical features.

Extracting a gene (a specific DNA sequence) from a source and inserting it into another requires very precise “cutting and pasting”. The gene of interest is cut with special chemical scissors called restriction enzyme and pasted into the DNA of another source. Because of their chemical nature the DNA molecules from the two different sources stick to one another; the pasting enzyme, ligase, also adds to the binding. The resulting molecule carrying a new combination of genes is called *recombinant* DNA.

The illustration in Figure 1 below shows how a recombinant DNA is produced and cloned. An animal DNA (which codes for a special feature) is cut and pasted into the bacterial circular DNA called *plasmid*. The recombinant plasmid is then put back into the bacterial cell for cloning (i.e making more copies of the recombinant DNA). The recombinant DNA can be inserted into a recipient using methods such as micro-injections. The recombinant DNA is injected into a germ-line cell which is then inserted into a mother (in the case of animals) and allowed to develop.

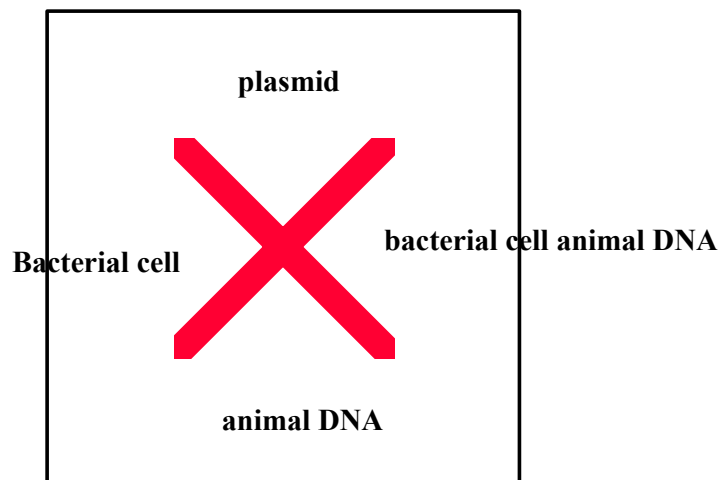


Figure 1: An illustration to show how a recombinant DNA is produced and cloned. An animal DNA is cut and pasted into the bacterial circular DNA called plasmid. The recombinant plasmid is then put back into the bacterial cell for cloning (i.e making more copies of the recombinant DNA , plasmid).

Benefits of Biotechnology

It has been claimed that biotechnology is a means of alleviating global food problems. The technology allows for more precise transfer of desirable traits, unlike the conventional breeding. This provides quality improvements such as tastier fruits and vegetables. Other improvements include resistance of crops to herbicides, pests and viral infections. Some fish species have also been engineered to provide cost effective foods. Following is a short review of some of these transgenic organisms. The review is not conclusive but it provides a glimpse of some benefits attributed to biotechnology as well as some concerns.

Herbicide Tolerance

The GM soya is an example of a crop that has been made tolerant to the herbicide glyphosate. The glyphosate is a ‘broad spectrum’ herbicide which would kill weeds and plants indiscriminately upon its application. It is therefore cannot be used on non-GM soya as it would kill the soya as well as the weeds. With the GM crop, farmers can use glyphosate to control

weeds without killing the soya. Thus it has been claimed that growing the GM soya can reduce the volume and variety of the herbicide used.

Insect (Pest) Resistance

Crops transformed with genes derived from the bacterium *Bacillus thuringiensis* (*Bt*) to express insecticidal proteins constitute one of the most common genetically engineered organisms in the environment. For example, the *Bt* maize has been engineered to make it produce this protein to ward off corn borer and crop-eating insects. As a result the transgenic maize could potentially increase in terms of yield while substituting for the chemical insecticide applications used to control the pests. Thus the environment is spared by limiting the use of insecticides or pesticides. In 1998, in the United States for example, there were at least 18 different *Bt-crops* that have been approved for field testing and three – corn, cotton, and potato – have been approved for commercial use (Andow and Hutchison 1998). The list is likely to be increasing.

Virus Resistance

It is an established fact that diseases caused by plant viruses result in significant loss of crop yields. With the knowledge of genetic engineering, opportunities therefore arise to develop virus resistance in plants.

As indicated in Table 1, a number of food crops worldwide have been successfully engineered to resist viral infections. This is achieved by a variety of ways. One way is through the insertion of viral genes into the plant genome. Most of these genes encode viral protein coats (Beachy et al. 1990), while some encode regulatory proteins such as the enzyme, replicase (Gadani et al. 1990). The mechanisms that result in plant protection are yet to be fully understood. Some (van den Boogaart et al. 1998; Waterhouse et al. 1999) have attributed the protection to a mechanism known as 'RNA-mediated resistance'. In the case the GM (Hawaiian) pawpaw, it appears that the plant cellular response is mounted upon infection, causing the virus pathogen non-functional (Gianessi et al. 2002).

Thus the benefit drawn here is the development of GM crops which can grow reasonably well in virus' infected areas.

Transgenic Fish

Transgenic fish are important commercially. Their faster growth rate and higher viability compared to the corresponding wild types have great economic implications.

The Atlantic salmon, for example, is transgenic for a number of traits. A gene which enables it to attain smolt status earlier than the wild type (Saunders et al. 1998) has been inserted and this has a potential of causing the salmon to reach sexual maturation faster which further could contribute to its increase rate of reproduction. Another gene inserted was to enable the Atlantic salmon avoid predators (Abraham and Sutterlins 1999). For the efficiency of gas diffusion, the Atlantic salmon was also given a gene for gill morphology ((Stevens and Sutterlins 1999); the implication of the latter is yet to be realised. Like the Atlantic salmon, the transgenic Coho salmon has been reported (Devlin et al. 1995a; b) to have reached sexual maturation earlier, a biological advantage that can be harvested commercially. The transgenic tilapia has been indicated to be heavier than the wild type (Rahman and Maclean 1999) giving it a possible mating advantage, as far as animal behaviour is concerned. The brown trout and rainbow trout have been made transgenic for growth hormone (GH) and thus enabling them to escape natural predators quickly

(Jonhsson et al. 1999; Johnsson and Bjornsson 1994). The list of transgenic fish is still climbing and it is most likely that their values lie in commercial interests.

Concerns Regarding Biotechnology

***Bt*-crops' weediness**

There is concern that although that *Bt*-crops now approved for commercial use appear safe, they still represent an excellent example of a trait that, should it escape (be transferred to wild plants), they would potentially increase weediness for the very same reasons it is expected to cause increased yields in crops.

***Bt*-crops' pollens**

The impact of pollens from transgenic plants on non-target crops has not been fully examined. Most commercial *Bt-corn* crops are known to express the *Bt-toxin* in pollen tissue (Fearing et al. 1997), and corn pollen is dispersed at least 60 m (Raynor et al. 1972), and possibly more than 200 m, by the wind (Louette 1995). This means that in areas where *Bt* crops are grown, large quantities of transgenic pollen with insecticidal properties will drift out of *Bt*-corn fields to wild type crops. Where cross pollination might occur, the possibility of passing the toxin along the next generation cannot be ruled out; it remains a real concern.

Furthermore, the *Bt* toxin can be transferred directly to non-targeted organisms, such as species of Lepidoptera (eg butterflies). The toxic effects on these organisms would also pose an indirect risk for other insect species.

Virus-transgenic recombination

Some potential ecological risks associated with the adoption of engineered virus resistance can fall into three major groups: (1) recombination between viral transgenes and invading viruses; (2) interactions between transgene products and invading viruses; and (3) transgene movement from transgenic crops to wild relatives.

The risks associated with virus-transgene recombination include the formation of novel viruses with modified virulence, host range, or transmission characteristics. Increased virulence could lead to greater damage to hosts of the virus, including any wild hosts in natural habitats. Increased host range could lead to more plants becoming susceptible to the onslaught of the recombinant virus. Similarly, any change in transmission characteristics of the recombinant virus could result in infections of plants that were not previously targeted by the parental virus.

Another risk of releasing crops with engineered virus resistance is the spread of viral infection through interactions between transgene products and invading viruses (Miller et al. 1997). While the long-term effect is not quite clear, it is apparent that a virus not normally transmitted by insects can acquire insect transmissibility by interactions with transgene products expressed in a

transgenic crop (Lecoq et al. 1993). This accessibility of the virus to insects as vectors to carry them around can cause more plant infections in a relatively short period of time.

Another major concern is that transgenic crops or transgenes might escape. For example they might access wild plants. The consequences of an engineered, viral resistance gene that escapes or crosses over to another crop unintentionally are currently unclear; however they do pose possible ecological risks.

Transgenic Fish

There is a concern that an escape or introduction of transgenic fish into natural communities could have an ecological impact. For example, a transgenic fish carrying an introduced gene for cold tolerance would allow the fish to invade waters in colder climates while maintaining populations in currently used habitats. This would result in the transgenic species becoming flourished at the expenses of natural species. The consequences of possible exponential growth of the transgenic species and the simultaneous, logarithm growth of the invaded species may trigger a domino effect along the marine or fresh water food chain.

The similar effect could also be observed in fish transgenic for growth hormones. The transgenic fish may reach sexual maturity sooner, spawn at different times, and escape from their normal predators. Because the transgenic fish could reproduce at a faster rate; their population may increase exponentially within a short period of time. This induced load would far exceed the 'carrying capacity' of the natural environment and possibly this would become a sufficient force to drive some native fish species to extinction. In summary, an introduction of transgenic fish into natural marine or fresh water environment might threaten the survival of wild type species.

The challenge: Regulating for Biosafety

As a result of the debate outlined above, there have been increasing discussions on how to regulate the applications of genetic modifications or biotechnology. As activities involving the technology expanded, and in particular as commercial operations increase, the scope of regulations needed to expand. Designing frameworks for GMO regulations is not easy, as the main challenge is to establish an appropriate balance between potentially important technological benefits and appropriate environmental and human health safeguards.

The biosafety cannot be achieved in isolation. This is why the Cartagena Protocol on Biosafety came into existence.

CBD and the Cartagena Protocol on Biosafety

Article 19.4 of the Convention provides for Parties to **“consider the need for and modalities of a protocol, including advance informed agreement (AIA) in particular, to ensure the safe transfer, handling and use of living modified organisms derived from modern biotechnology that may have adverse effect on biological diversity and its components”**

Therefore, the Biosafety Protocol seeks to protect biological diversity from the potential risks posed by LMOs resulting from modern biotechnology. The issues addressed include the

transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity taking into account also risks to human health (Article 4). An Advance Informed Agreement (AIA) procedure is also set out to help ensure that countries are provided with important information necessary to make informed decisions before agreeing to the import of an LMO into their territory.

The Protocol also contains other provisions such as types of information to be provided, scientifically-based risk assessment, simplified procedures, exchange of information, handling of confidential information, public awareness and participation, capacity building for developing countries.

As far as the scope of the Protocol is concerned, it appears that there are categories of LMOs or transboundary movements that are excluded. In some cases the exclusions are limited to specific provisions relating to the AIA procedure, in others they operate as general exclusions from all of the Protocol's provisions. An overview of the scope of the Protocol is summarised in the Box below.

It is also important to note that even where certain LMOs are excluded from some or all of the Protocol's provisions, they may, of course, still be subject to national regulation.

Scope of the Protocol and of the AIA procedure

LMOs subject to the provisions of the Protocol

- All LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4).

LMOs subject to AIA provisions

- LMOs intended for intentional introduction into the environment (Article 7 (1)).

LMOs excluded from the Protocol's AIA provisions

- LMOs in transit (Article 6 (1)).
- LMOs destined for contained use in the Party of import (Article 6 (2)).
- LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7 (2)).
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

LMOs excluded from the Protocol's provisions on transboundary movements

- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

Possible Implications of the Protocol for Samoa

An examination of the provisions of the Protocol suggests that there are implications for Samoa. For example, there is to be a National Biosafety Framework. The Framework should be an effective national regulatory system addressing not only imports (and exports), but also the use and release of LMOs at domestic level. With the development of academic institutions in the country, the Framework should also have provisions for future, possible genetic manipulations in laboratories. Developing such legislation certainly requires extensive consultation with a wide range of relevant departments and agencies, as well as the public, local industries and agriculture, academic and research institutions.

In relation to other Parties, the Protocol would be a means to establish transparency in the transboundary movement of LMOs and application of advance informed agreement regarding imports. It is an ideal tool for effective communications and cooperation at the international level.

With these possible benefits implied through the Protocol, some facts from the *Science* point of view still remain. Firstly, genetic engineering as a subsection of molecular biology, is a difficult and complex area. Secondly, running an experiment in molecular biology is usually very expensive. Thirdly, with years of hard training and expertise, hiring a Molecular Biologist can be also very expensive. Taken all this together, suffice to state that this is not a cheap issue.

Thus by extrapolation, the development, implementation and administration of appropriate national regulations which might also take into account other trade agreements, would require significant human, financial and technical resources. It involves a depth of co-ordination and ongoing capacity building of expertise in many specialised areas.

TERMS OF REFERENCE

This Report concentrates on the “extent and impact of release of LMOs and commercial products” and encompasses the following three important terms:

1. To identify all relevant Government departments, private sectors, NGOs and communities that deal with the use, transboundary movement, handling and release of LMOs.
2. To conduct consultations with key stockholders to verify the extent and impact of release of LMOs and commercial products in Samoa.
3. To provide practical recommendations on appropriate mechanisms to monitor and regulate the extent of release and impact of LMOs and commercial products.

6. SURVEY & RELATED TERMS OF REFERENCE

IDENTIFICATION OF ALL RELEVANT GOVERNMENT DEPARTMENTS, PRIVATE SECTORS, NGOs AND COMMUNITIES THAT DEAL WITH THE USE, TRANSBOUNDARY MOVEMENT, HANDLING AND RELEASE OF LMOs.

1. Relevant Government Departments, Private Sectors, NGOs and Communities that Deal with the Use, Transboundary Movement, Handling & Release of LMOs

In order to identify relevant Government Departments, Private Sectors, NGOs and Communities that deal with the use, transboundary movement, handling and release of LMOs, this Survey took into account some possible tasks associated with dealing with LMOs. These tasks, while not conclusive, are listed below.

Some Possible Tasks in Dealing with LMOs:

- Ownership (acceptance or not) and sustainability
- Facilitate effective implementation
- Accountability and transparency
- Capacity-building
- Improve decision-making
- Integration or mainstreaming of information
- To protect human rights, the environment and human health for present and future generations
- Strengthens ability to ensure compliance
- Ability to deal with issues at different levels
- Identification and pooling of resources and expertise
- Promote public support for any initiative for the success of the process
- For validation, to give legitimacy
- Advise Government Authority
- Build trust, change attitudes and behaviours
- Avoid revolution
- True representation on policy

At the end of series of matching, it was found that not one Government department, private sector, NGO, or Community could carry out all of the above tasks. It was apparent therefore that everyone, excluding none, is a potential dealer of LMOs.

2. Possible Handlers of LMOs

Recognising the possibility that at the public level, everyone is a potential dealer regarding LMOs, this Survey also examined some potential handlers who were asked for comments as shown.

Relevant Stakeholders	Dealing with LMOs in the Past or Present	Possibility of Dealing with LMOs in the Future	Related Comments
MAFFM – Quarantine	No	Likely	Need specialised training
MAFFM – Livestock	No	Unsure	Scary issue
MAFFM – Forests	No	Unsure	
MAFFM - Fisheries	No	Unsure	
MAFFM – Nu'u	No	Likely	
USP- Alafua	No	Likely	With proper training and plan
NUS	No	Yes	Possibility of cooperative researches with other Universities

Recommendations

- That possible 'handlers' of LMOs be consulted for their concerted efforts in handling the issues pertaining GMOs.
- A National Competent Authority (NCA) is set up. The NCA would provide substantive guidelines, assessment criteria and other specific details to guide decisions with regard to LMOs/GMOs. One of the role of NCA is to set science-based standard.

3. VERIFICATION OF THE EXTENT AND IMPACT OF RELEASE OF LMOs AND COMMERCIAL PRODUCTS IN SAMOA

Central to this Section was the verification of the extent and impact of release of living modified organisms (LMOs) and commercial products in Samoa. For LMOs, the first step was to check the types of LMOs reported to be released overseas. This would give some insights on what to look for, locally, in case some of these have entered the country.

For commercial products, the task of identifying genetically modified products was difficult because of the lack of labeling which would show genetically modified ingredients. The commercial products are in two categories: novel-feed livestock and on-shelves products.

Thus contained here are examinations of LMOs, commercial products, and potential handlers of LMOs and recommendations.

Living Modified Organisms (LMOs)

Living Modified Organisms Reported Overseas

The list of LMOs is still increasing. Table 1 below shows an example of such list of LMOs and respective genes inserted. The rationale behind the attempt of identifying LMOs now released overseas was to provide some baseline information that can be used as references in cases where living materials accompanied by very little or no information are brought into the country.

Table 1: List of some living modified organisms reported overseas

Case Number	Name of Crop	Type
1	Papaya	Viral Resistant
2	Squash	Viral Resistant
3	Peanut	Viral Resistant
4	Peanut	Insect Resistant
5	Tomato	Viral Resistant
6	Tomato	Herbicide Tolerant
7	Lettuce	Herbicide Tolerant
8	Strawberry	Herbicide Tolerant
9	Pineapple	Nematode Resistant
10	Broccoli	Insect Resistant
11	Citrus	Viral Resistant
12	Citrus	Bacterial Resistant
13	Sweet Corn	Insect Resistant
14	Sweet Corn	Herbicide Tolerant
15	Stone Fruit	Viral Resistant
16	Raspberry	Viral Resistant
17	Potato	Insect/ Viral Resistant
18	Potato	Fungal Resistant
19	Potato	Herbicide Tolerant
20	Sugarbeet	Herbicide Tolerant
21	Grape	Bacterial Resistant
22	Apple	Bacterial Resistant
23	Sunflower	Fungal Resistant
24	Canola	Herbal Resistant
25	Soybean	Insect Resistant
26	Soybean	Herbicide Resistant
27	Rice	Herbicide Tolerant
28	Field Corn	Insect Resistant (1)
29	Field Corn	Insect Resistant (2)
30	Field Corn	Insect Resistant (3)
31	Field Corn	Herbicide Tolerant
32	Cotton	Insect Resistant
33	Cotton	Insect Resistant
34	Cotton	Herbicide Tolerant
35	Alfalfa	Herbicide Tolerant
36	Barley	Fungal Resistant
37	Wheat	Herbicide Resistant
38	Wheat	Viral Resistant
39	Eggplant	Insect Resistant
40	Sugarbeet	Herbicide Tolerant
41	Atlantic salmon	Age at smolt
42	Atlantic salmon	Gill morphology
43	Atlantic salmon	Predator avoidance
44	Cohort salmon	Age at smolt

45	Brown trout	(GH) Predator avoidance
46	Rainbow trout	(GH) Predator avoidance
47	Coho salmon	Swimming speed
48	Common carp	High feeding efficiency
49	Tilapia	More weight at sexual maturity
50	Tilapia	Less feeding competitiveness

Adapted from: Muir & Howard (2002)

Sources: National Centre for Food & Agricultural Policy (www.ncfap.org)

3.1 Live/Living Organisms Imported to Samoa

The search for imported living organisms was carried out. These were not regarded as genetically modified, however, this type of record would be useful if one sets it against the background of those listed as GM.

List of Live/Living Organisms Imported to Samoa

Organism	Year of Importation	Purpose of Importation
Birds (eg. parrots, budgies)	current	As pets
Cattles	1993, 1995, 2002	For farmers
Cattle embryos (<i>Pied montese</i>)	1994	Beef breed for farmers
Chicken (1 day old)	current	For egg layers
Eucalypts		For forestry
Fish (tilapia)		For experimentation
Fish (golden fish)	current	As pets
Fungus (<i>Metarisi</i>)		To control rhinoceros beetles
Maize (viable seeds for pop corns)	current	For commercial purpose
Pigs	1980s	For farmers
Plant (ornamental, (e.g. palms, antherium))	current	For gardeners
Potato	current	For commercial purpose
Seeds (ornamental)	current	For gardeners
Seeds (pawpaw)	current	For research at Nuu
Seeds (cucumber, tomato, cabbage)	current	For research at Nuu

Sugarbeet	current	For commercial purpose
Soil sample		For scientific investigations at USP-Alafua
Rhabdo Virus		To control rhinoceros beetle
Yeasts	current	For commercial purpose

Sources: MAFFM

The question of genetic profile accompanying any imported living thing was also raised (see Annex 2; Questionnaire 5). All the relevant departments indicated that there were no genetic profiles provided; instead there was documentation accompanying a living thing or seeds to declare the non-GM nature of the stock.

The issue of the beef cattle, *Pied montese*, was raised by someone during a radio interview, alluding to GM activities. Consequently, in the course of this Survey, some investigations were also carried out to clarify the issue. It was discovered that about 50, 7-day old embryos of *Pied montese* were brought into Samoa in 1994. These embryos were implanted into (local) cattle which acted as surrogate mothers. There were 13 new calves birthed, out of the 50 embryos used.

It was evident that there was no GM activity (according to the definition in the Protocol) involved in the process carried out in Samoa. However, some questions remained to be answered: Were the embryos brought over a result of pure breeding? Was any of the paternal or maternal genetic material subject to GM activities?

In spite of media reports in the past, there is no official record to show that Samoa has a living modified organism at present.

Recommendations

- Request donor countries or countries of origins to provide genetic profiles of livestock animals/plants for decision making before the stocks actually arrive.
- That importers or carriers of living things be required to provide certification as to the possible GM properties of the imported materials.

3.2 Commercial Products in Samoa:

For convenience, the potential GE-Commercial Products are divided into two groups: Novel feeds-Livestock & On Shelves Products

Novel feeds-Livestock

This Survey could not discover whether the frozen meats (such as pork, beef, chicken) from overseas were of novel feeds-livestock or not. The novel feeds-livestock is fed with GM crops.

The GM crop species now discovered to be used for feeding livestock include canola (rapeseed), maize (corn), soybean, cottonseed and potato. These species have been modified to express, either singly or in combination, the traits of insect resistance, herbicide tolerance, or, in the case of potatoes, resistance to virus infection.

There have been questions regarding the direct effects on livestock, as a result of consuming GM crops. In addition, there were also issues raised concerning indirect effects, such as: could the DNA of inserted or modified genes, or their protein products, be transferred to and accumulate in the food products (milk, meat, eggs) of animals fed feeds derived from GM crops; and will the consumption of animal products derived from livestock fed GM feeds lead to adverse health effects in humans?

It is beyond the scope of this Survey to examine the issues raised above, as far as addressing them is concerned. However the questions raised provided a basis for including them as part of this inventory. In the absence of relevant labelling, their inclusion would help raise an awareness.

The novel feeds-livestock is summarised in the table below. Whether this type of meat has been imported to Samoa or not is not clear as yet. It is clear however that some meats have been imported.

Novel Feeds- Livestock

<u>ANIMAL</u>	GM CROP COMPONENT
Poultry	Insect-resistant maize , Herbicide-Tolerant Soybean
Dairy Cows	Insect-resistant maize, Herbicide-Tolerant Maize
Beef Cattle	Insect-resistant maize, Herbicide-Tolerant Maize
Pigs	Insect-resistant maize

Adapted from MacKenzie & McLean (2002)

Recommendation

- That livestock or meat from overseas be declared of any novel feeds-livestock background.

3.3 Commercial Products in Samoa:

On-Shelves Products

The task of spot-checking products on shelves for potential GE ingredients had been difficult mainly due to the absence of any obvious labeling. Therefore, the '**True Food Guide**' prepared by Gene Ethics Network, Green Peace, was used to mark out products that could be potentially regarded as having GM ingredients.

The Guide marks out companies that have no policy to remove GE derived ingredients, including those from animals fed GE feed and companies that did not respond adequately to the Organisation's enquiries.

Thus the results of the surveys here do not directly show that the products indicated, contained GE ingredients; instead they may give hints that these products might contain GE ingredients.

List of Potentially GE-On-Shelves Products Available in Samoa

Baby Food

Nestle Formula
S-26 (<i>Wyeth</i>)
SMA (<i>Wyeth</i>)
Infasoy (<i>Wyeth</i>)

Baking & Cooking

Crisco Oil (<i>Goodman Fielder</i>)
Davis Gelatin (<i>Goodman Fielder</i>)
Eta Oil (<i>Goodman Fielder</i>)
Golden Canola Oil (<i>Goodman Fielder</i>)
Golden Fields Canola Oil (<i>Steric</i>)
Defiance Cake & Bread Mixes (<i>Goodman Fielders</i>)
Green Cake Mixes
Maggi Noodles (<i>Nestle</i>)
Masterfoods Herbs & Spices (<i>Effem Foods</i>)
McCormick herbs & Spices
Meadow Lea Oils (<i>Goodman Fielders</i>)
Nestle Cooking Chocolates
Tip Top Flours (<i>George Weston Foods</i>)
Vetta Oil & Pasta (<i>Goodman Fielder</i>)

Drinks

Cadbury Drinking Chocolate
Coca Cola, Sprite, Fanta, Lift, & Kirks (<i>Coca Cola Amatil</i>)

Deep Spring Soft Drinks (<i>Coca Cola Amatil</i>)
Milo (<i>Nestle</i>)
Nestle Coffee Mate & Condensed Milk
Schweppes Soft Drinks & Pepsi

Chilled & Frozen Foods

Birds Eye Frozen Foods (<i>Simplot</i>)
Bulla Ice Cream (<i>Regal cream products</i>)
Cadbury Ice Cream
Castlemaine Bacon

Source: Spot check of shelves by students. The names of shop/wholesale owners have been disclosed to MNRE for double checking purposes.

Recommendation

- That there be Requirement to label GM products as to allow for informed choices at the time of purchase.

3.4 APPROPRIATE MECHANISMS TO MONITOR AND REGULATE THE EXTENT OF RELEASE AND IMPACT OF LMOs

Ultimately, consideration of LMOs must be dealt with case by case. With this in mind, the format is recommended below for general guidance. The detailed outworking however is the sole duty of experts involved in the decision making process.

1. Introduction

This includes a brief overview of the LMO and the background of the parental organism.

2. Summary of Introduced Genetic Elements

Information includes the name of the gene, DNA sequence, type promoter, terminator and copied formed.

3. Characteristics

Information required includes the reproduction features, natural toxins and allergens

4. Donor Organism Characteristics

The scientific name of the donor, gene 'donated' and possibility of pathogenicity (ability to cause disease) are necessary to disclose.

5. Modification Method

The molecular tools (eg. plasmids) involved, processes (e.g. transformation) and the methods (e.g. regulatory sequencing) adopted are necessary information.

6. Characteristics of the Modification

(i) The Introduced DNA

A detailed description of the insert is vital. Information on Southern blot analyses is necessary.

(ii) Genetic Stability of the Introduced Trait

The stability of the insert over multiple generations must be validated as to guard against the possibility of having a 'jumping gene'.

(iii) Expressed Material

All expressed materials including unexpected proteins, chimeric sequences must be declared. Here, some information on Western blotting is required.

7. Environmental Safety Considerations.

(i) Field Testing

Field testing must be extensive to analyse reproduction characteristics, or pathogen susceptibility.

(ii) Outcrossing

Information on crossing including possible hybridisation with similar or different organism are necessary.

(iii) Weediness

These are some of important questions to ask.

In terms of plants, might the GM crop become invasive?

For animals, might the manure become fertile nutrient for invasive species?

(iv) Secondary and Non-Target Adverse Effects

The possible effect(s) on non targeted species must be considered.

(v) Impact on Biodiversity

What could be the impact of the transgenic organism in the next 20 years or so?

8. Food Safety Considerations

(i) Dietary Exposure

Data on possible exposure of any novel protein in the digestive tract must be disclosed.

(ii) Nutritional Data

Detailed compositional analyses to establish nutritional adequacy are some of relevant information needed.

(iii) Toxicity data

Data on potential toxicity of novel proteins must be understood.

(iv) Allergenicity

The potential of the novel protein to become allergenic is important to know.

Recommendation

Scientists familiar with both the molecular aspects of transgenic technology and the ecological factors must take active role in shaping regulatory rules.

3.5 APPROPRIATE MECHANISMS TO MONITOR AND REGULATE THE EXTENT OF RELEASE AND IMPACT OF COMMERCIAL PRODUCTS

The *Codex Alimentarius*

Normally commercial products that involve genetic modifications go through stringent screening before permission is granted. A number of Scientific Bodies can be consulted. Suggested here also is reference to *Codex Alimentarius*, which can be referred to for appropriate mechanisms for monitoring and regulation. It is a non-binding Code developed by the *Codex Alimentarius* Commission, a body of FAO/World Health Organisation which elaborates standards, general principles, guidelines, and recommended code of practice in relation to food safety and related issues. The *Codex* is derived from biotechnology (for example, addressing issues of potential allergenicity; possible gene transfer from LMOs; pathogenicity deriving from the organism used; nutritional considerations; risk assessment and authorisation procedures; and appropriate labelling).

7. CONCLUDING REMARKS

Here are some concluding remarks from some academic/research scientists:

1. The lack of knowledge can be dangerous. The lack of knowledge of the scientific processes involved might create unnecessary fear; the lack of knowledge of the consequences of GM products and related activities, for they are new, is also frightening.
2. There is fear of using Samoa as a dumping ground for LMOs/GE products.
3. GM has not been around long enough for the long-term consequences to be realised.
4. The incidence of cancers of all types are rising; could GM be another contributing factor to the disease?
5. The beneficial & harmful effects must be weighed out; then the decision to accept or not to accept LMOs/GMOs should not be influenced by other countries, the decision has to come from within.
6. Once 'Assessment Procedures' are in place, then the responsibility is with us to make informed decisions.
7. This is a form of warfare – there could be a permanent destruction by LMOs if they are not assessed and managed properly.
8. Even if no GM crops are grown in a developing country, the technology could have widespread impacts. National economies could suffer from the loss of export incomes from crops, like cacao, that biotech firms and farmers in developed countries are attempting to reproduce in the lab.

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Annex 1: Terms of References

SURVEY 1

- Identify all the relevant government departments, private sectors, NGOs and communities that deal with the use, transboundary movement, handling and release of LMOs.
- Conduct consultations with key stakeholders to verify the extent and impact of release of LMO's and commercial products in Samoa.
- Design and implement appropriate consultation methods for extraction of information from identified stakeholders.
- Analyse and Compile the results and findings from the consultations and submit for comments from DEC and NCC.
- Revisit the key stakeholders and present the result of the survey for further inputs and comments.
- Prepare a Survey report with practical recommendations on appropriate mechanisms to monitor and regulate the extent of release and impact of LMOs and commercial products.
- Report should be submitted within 14 days after further consultation and presentation of findings to the stakeholders.

SURVEY 2

- Identify all relevant government departments, NGOs, private sectors (including academic institutions) with national, bilateral and multilateral co-operative programmes in capacity building.
- Identify any existing Research and Development programmes dealing with LMOs at the National, Bilateral and Multilateral level.
- Identify any existing uses and application or possibilities of dealing with importation of LMOs.
- Conduct consultations with key stakeholders to identify existing national legislation(s) and impact on the use and application of modern biotechnology.
- .Analyse and Compile the results and findings from the consultations and submit for comments from the DEC and NCC

- Assess and review the adequacy of existing legislations on safe use arrangements that may impact on the use of modern biotechnology.
- Revisit the key stakeholders and present the result of the survey for further inputs and comments.
- Prepare a Survey Report with practical recommendations on appropriate mechanisms to promote, strengthen and / or develop co-operative programmes on capacity building, and any existing legal mechanisms for safeuse and application of modern biotechnology.
- Report should be submitted within 14 days after further consultation and presentation of findings to the stakeholders.

Annex 2: Samples of Questionnaires

Questionnaire 1

Identification of Existing Uses and/or Application or Possibilities of Dealing with Importation of Living Modified Organisms (LMOs)

Past

1. Were there existing use(s) and/or application(s) of LMOs in your Organisation?
(Please circle your answer.) *Yes* *No*
2. If you answered *Yes* to 1, please state the use(s) and/or application(s) of the LMOs.

Present

3. Are there existing uses and/or applications of LMOs in your Organisation?
(Please circle your answer.)
4. If you answered *Yes* to 3, please state the use(s) and/or application(s) of the LMOs.

Future

5. Are there likely to be use(s) and/or application(s) of LMOs in your Organisation?
(Please circle your answer.) *Yes* *No*
6. Is your Organisation likely to deal with importation of LMOs in the future? (Please circle your answer.)

Yes

No

7. If you answered *Yes* to 6, how far ahead is the future (Please circle).
1 year 5 years 10 years 20 years 50 years or more

Name of the Person who filled this form:

Signature:

Date:

Department/Company/Sector:

Questionnaire 2

Inventory of Potential GM Products in Samoa

Baby Food

Product	Available (tick)	Where	Date
Nestle Formula			
S-26 (Wyeth)			
SMA (Wyeth)			
Infasoy (Wyeth)			

Baking & Cooking

Product	Available (tick)	Where	Date
Barilla Pastas			
Cake Mate King (Mc Cormick Foods)			
Crisco Oil (Goodman Fielder)			
Davis Gelatin (Goodman Fielder)			
Eta Oil (Goodman Fielder)	Yes		
Golden Canola Oil (Goodman Fielder)			
Golden Fields Canola Oil (Steric)			
Defiance Cake & Bread Mixes (Goodman Fielders)			
Krummies (George Weston Foods)			
Green Cake Mixes			
Maggi Noodles (Nestle)			
Masterfoods Herbs & Spices (Effem Foods)			
McCormick herbs & Spices			
Meadow Lea Oils (Goodman Fielders)			
Mon Folla Oil (Abel Lemon Distribution)			
Nestle Cooking Chocolates			
Tip Top Flours (George Weston Foods)			
Vetta Oil & Pasta (Goodman Fielder)			

Drinks

Product	Available (tick)	Where	Date
Cadbury Drinking Chocolate			
Coca Cola, Sprite, Fanta, Lift, & Kirks (Coca Cola Amatil)			
Cottees (Cadbury Schweppes)			
Deep Spring Soft Drinks (Coca Cola Amatil)			
Lucozade (Smith Kline Beecham)			
Milo (Nestle)			
Move & Oak (Dairy Farmers)			
Nestle Coffee Mate & Condensed			

Milk			
Schweppes Soft Drinks & Pepsi			

Chilled & Frozen Foods

Product	Available (tick)	Where	Date
Birds Eye Frozen Foods (<i>Simplot</i>)			
Bulla Ice Cream (<i>Regal cream products</i>)			
Cadbury Ice Cream			
Castlemaine Bacon			

Questionnaire 3

BIOSAFETY SURVEY

This Survey examines the use, transboundary movement, handling and release of LMOs. It also provides initial steps in re-examining the living organisms already released in Samoa as far as their genetic profiles are concerned.

Definitions

The following use of terms was adopted from the Cartagena Protocol on Biosafety.

Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Modern biotechnology means the application of:

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

A. Inventory of Live/Living organisms Imported to Samoa

1. Using the Table below, please indicate:
 - (i) if any of the following have been imported to Samoa;
 - (ii) the year(s) of importation;
 - (iii) place(s) of release into Samoan environment.

Organism	Already Imported to Samoa? <i>Yes or No</i>	Year(s) of Importation	Place(s) of Release into Samoan Environment
Birds			
Cattles			
Carrots			
Chicken			
Escherichia coli			
Eucalypts			
Fish			
Fly			
Maize			
Mice			
Microorganisms			
Nematodes			
Pigs			
Plants			
Potato			
Seeds			
Sheep			
Sugarbeet			
Soil sample			
Viruses/Viroids			

Yeast			
-------	--	--	--

2. Was there any other living organism not stated above imported to Samoa? Please specify and provide details as needed above.

B. Genetic Profiles of Imported Live Cattle, Pigs and Chicken, Plant (of any type) and Seed (of any type)

Please indicate if your Agency has in possession, any report regarding the genetic profiles of organisms stated in the Table below.

Name of Organism	Genetic Profile Available <i>Yes or No</i>	Name of Country Originated from	Any Related Comments
Cattle			
Chicken			
Pig			
Plant (of any type)			
Seed of any type)			

LMOs released in Samoa

1. Has there been any LMO released in Samoa? (Please circle)
Yes *No*

2. If *Yes*, how many types of LMOs that were released in Samoa already?

3. Please list the names of LMOs released already in Samoa.

1. _____

2. _____

3. _____

.....

Possibility of Importation of LMOs

1. Has your Agency received any application for importing LMOs to Samoa? (Please circle your answer.) *Yes* *No*

2. In case of importation of LMOs to Samoa, please state the name of the Legislation/Act/Law that your Agency would use in assessing whether permission is granted or not.

3. Please outline the Procedure your Agency would take on line with the relevant Legislation/Act/Law in assessing whether permission is granted or not.

Name of the Person who filled this form: _____

Signature: _____

Date: _____

Department/Company/Agency: _____

Annex 2

SURVEY ON THE EXISTING NATIONAL, BILATERAL AND MULTILATERAL CO-OPERATIVE PROGRAMMES INCAPACITY BUILDING, R & D, EXISTING USES, AND APPLICATION OF BIOTECHNOLOGY INCLUDING REVIEW AND ASSESSMENT OF EXISTING LEGISLATION THAT MAY IMPACT ON THE USE OF MODERN BIOTECHNOLOGY

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The National University of Samoa

2003

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1. LIST OF ACRONYMS

CBD	Convention on Biological Diversity
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
GE	Genetically Engineered
GM	Genetically Modified
LMO	Living Modified Organism
LMOs-FFPs	LMOs intended for direct use as food or feed, or for processing
MAFFM	Ministry of Agriculture, Forestry, Fishery & Meteorology
MNRE	Ministry of Natural Resources & Environment
MOU	Memorandum Of Understanding
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Co-ordinating Committee
SPREP	South Pacific Regional Environment Programme
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

2. DEFINITIONS

DNA (deoxyribonucleic acid) is the genetic material that organisms inherit from their parents; a double stranded helical molecule.

Gene is a discrete unit of hereditary information consisting of specific sequence of DNA.

Genetic Modified Organism (GMO) means any organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Microorganism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cell in culture.

Modern biotechnology means the application of:

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

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4. SUMMARY OF SURVEY FINDINGS

Co-operative programmes in capacity building with regard to modern biotechnology is relatively new to Samoa. At present, there is no existing research on LMOs at the national level. The development programme that directly addresses LMOs is now being administered by the MNRE.

So far any existing use or application of LMOs in Samoa has not been officially made know. However it remains a real possibility that LMOs may be imported into the country.

The relevant legal framework is also developing and expertise is required such that national legislation can be formulated as to directly impact on the use and application of modern biotechnology.

Some recommendations are also given.

5. BACKGROUND

Introduction

Samoa, as a Party to the Convention on Biological Diversity (CBD), ratified the Cartagena Protocol on Biosafety on 30 May 2002. The Protocol was designed to provide framework within which living modified organisms (LMOs) could be traded in a safe and responsible manner with due regard for the protection of biodiversity, also taking into consideration human health. LMOs are a result of genetic manipulations carried out by scientists.

In this Background information, a technical approach is adopted in summarising some aspects of genetic manipulations. Similarly a short review of some benefits and concerns regarding the use of genetic manipulations (or biotechnology) is presented in scientific languages – not to make it hard for the reader but to maintain some degrees of accuracy and precision for scientists who might use some of the information reported here for references as far as the National Biosafety Framework is concerned. Lastly, an overview of the Cartagena Protocol on Biosafety and its relation to the CBD, as well as its connection to genetic manipulations is described.

The Terms '*Transgenic, Genetically Modified/Altered Organisms & LMOs*'

There is a very fine line between **transgenic** organisms and **genetically modified** or **genetically modified** organisms. Technically, transgenic organisms carry a gene, or a transgene, which cannot be found in natural populations of that species. In genetically altered organisms, or genetically modified organisms, a native gene has been altered or parts of a chromosome have been relocated, or rearranged, with the help of chemicals or ionising radiation; the final product is again an organism carrying a gene or a chromosome that cannot be found in natural populations of that species. Thus, it becomes impossible to pinpoint where exactly genetic engineering starts as one moves from the term **transgenic organisms** to **genetically engineered organisms**. For simplicity, therefore, here, the use of the terms *transgenic* organisms, *genetically modified* organisms and *genetically engineered* organisms are interchangeable.

One could also argue that **living modified organisms** (LMOs) are actually transgenic organisms or genetically engineered/modified organisms. The distinction here is drawn from the fact that LMOs are those that are still capable of carrying out life processes (movement, respiration, sensitivity, growth, reproduction, excretion and nutrition) which characterise *living* things.

Benefits of Biotechnology

It has been claimed that biotechnology is a means of alleviating global food problems. The technology allows for more precise transfer of desirable traits, unlike the conventional breeding. This provides quality improvements such as tastier fruits and vegetables. Other improvements include resistance of crops to herbicides, pests and viral infections. Some fish species have also been engineered to provide cost effective foods. Following is a short review of some of these transgenic organisms. The review is not conclusive but it provides a glimpse of some benefits attributed to biotechnology as well as some concerns.

Herbicide Tolerance

The GM soya is an example of a crop that has been made tolerant to the herbicide glyphosate. The glyphosate is a 'broad spectrum' herbicide which would kill weeds and plants

indiscriminately upon its application. It is therefore cannot be used on non-GM soya as it would kill the soya as well as the weeds. With the GM crop, farmers can use glyphosate to control weeds without killing the soya. Thus it has been claimed that growing the GM soya can reduce the volume and variety of the herbicide used.

Insect (Pest) Resistance

Crops transformed with genes derived from the bacterium *Bacillus thuringiensis* (*Bt*) to express insecticidal proteins constitute one of the most common genetically engineered organisms in the environment. For example, the *Bt* maize has been engineered to make it produce this protein to ward off corn borer and crop-eating insects. As a result the transgenic maize could potentially increase in terms of yield while substituting for the chemical insecticide applications used to control the pests. Thus the environment is spared by limiting the use of insecticides or pesticides. In 1998, in the United States for example, there were at least 18 different *Bt-crops* that have been approved for field testing and three – corn, cotton, and potato – have been approved for commercial use (Andow and Hutchison 1998). The list is likely to be increasing.

Virus Resistance

It is an established fact that diseases caused by plant viruses result in significant loss of crop yields. With the knowledge of genetic engineering, opportunities therefore arise to develop virus resistance in plants.

As indicated in Table 1, a number of food crops worldwide have been successfully engineered to resist viral infections. This is achieved by a variety of ways. One way is through the insertion of viral genes into the plant genome. Most of these genes encode viral protein coats (Beachy et al. 1990), while some encode regulatory proteins such as the enzyme, replicase (Gadani et al. 1990). The mechanisms that result in plant protection are yet to be fully understood. Some (van den Boogaart et al. 1998; Waterhouse et al. 1999) have attributed the protection to a mechanism known as 'RNA-mediated resistance'. In the case the GM (Hawaiian) pawpaw, it appears that the plant cellular response is mounted upon infection, causing the virus pathogen non-functional (Gianessi et al. 2002).

Thus the benefit drawn here is the development of GM crops which can grow reasonably well in virus' infected areas.

Transgenic Fish

Transgenic fish are important commercially. Their faster growth rate and higher viability compared to the corresponding wild types have great economic implications.

The Atlantic salmon, for example, is transgenic for a number of traits. A gene which enables it to attain smolt status earlier than the wild type (Saunders et al. 1998) has been inserted and this has a potential of causing the salmon to reach sexual maturation faster which further could contribute to its increase rate of reproduction. Another gene inserted was to enable the Atlantic salmon avoid predators (Abraham and Sutterlins 1999). For the efficiency of gas diffusion, the Atlantic salmon was also given a gene for gill morphology ((Stevens and Sutterlins 1999); the implication of the latter is yet to be realised. Like the Atlantic salmon, the transgenic Coho salmon has been reported (Devlin et al. 1995a; b) to have reached sexual maturation earlier, a biological advantage that can be harvested commercially. The transgenic tilapia has been indicated to be heavier than the wild type (Rahman and Maclean 1999) giving it a possible mating advantage, as

far as animal behaviour is concerned. The brown trout and rainbow trout have been made transgenic for growth hormone (GH) and thus enabling them to escape natural predators quickly (Jonhsson et al. 1999; Johnsson and Bjornsson 1994). The list of transgenic fish is still climbing and it is most likely that their values lie in commercial interests.

Concerns Regarding Biotechnology

Bt-crops' weediness

There is concern that although that *Bt*-crops now approved for commercial use appear safe, they still represent an excellent example of a trait that, should it escape (be transferred to wild plants), they would potentially increases weediness for the very same reasons it is expected to cause increased yields in crops.

Bt-crops' pollens

The impact of pollens from transgenic plants on non-target crops has not been fully examined. Most commercial *Bt-corn* crops are known to express the *Bt-toxin* in pollen tissue (Fearing et al. 1997), and corn pollen is dispersed at least 60 m (Raynor et al. 1972), and possibly more than 200 m, by the wind (Louette 1995). This means that in areas where *Bt* crops are grown, large quantities of transgenic pollen with insecticidal properties will drift out of *Bt*-corn fields to wild type crops. Where cross pollination might occur, the possibility of passing the toxin along the next generation cannot be ruled out; it remains a real concern.

Furthermore, the *Bt* toxin can be transferred directly to non-targeted organisms, such as species of Lepidoptera (eg butterflies). The toxic effects on these organisms would also pose an indirect risk for other insect species.

Virus-transgenic recombination

Some potential ecological risks associated with the adoption of engineered virus resistance can fall into three major groups: (1) recombination between viral transgenes and invading viruses; (2) interactions between transgene products and invading viruses; and (3) transgene movement from transgenic crops to wild relatives.

The risks associated with virus-transgene recombination include the formation of novel viruses with modified virulence, host range, or transmission characteristics. Increased virulence could lead to greater damage to hosts of the virus, including any wild hosts in natural habitats. Increased host range could lead to more plants becoming susceptible to the onslaught of the recombinant virus. Similarly, any change in transmission characteristics of the recombinant virus could result in infections of plants that were not previously targeted by the parental virus.

Another risk of releasing crops with engineered virus resistance is the spread of viral infection through interactions between transgene products and invading viruses (Miller at al. 1997). While the long-term effect is not quite clear, it is apparent that a virus not normally transmitted by insects can acquire insect transmissibility by interactions with transgene products expressed in a

transgenic crop (Lecoq et al. 1993). This accessibility of the virus to insects as vectors to carry them around can cause more plant infections in a relatively short period of time.

Another major concern is that transgenic crops or transgenes might escape. For example they might access wild plants. The consequences of an engineered, viral resistance gene that escapes or crosses over to another crop unintentionally are currently unclear; however they do pose possible ecological risks.

Transgenic Fish

There is a concern that an escape or introduction of transgenic fish into natural communities could have an ecological impact. For example, a transgenic fish carrying an introduced gene for cold tolerance would allow the fish to invade waters in colder climates while maintaining populations in currently used habitats. This would result in the transgenic species becoming flourished at the expenses of natural species. The consequences of possible exponential growth of the transgenic species and the simultaneous, logarithm growth of the invaded species may trigger a domino effect along the marine or fresh water food chain.

The similar effect could also be observed in fish transgenic for growth hormones. The transgenic fish may reach sexual maturity sooner, spawn at different times, and escape from their normal predators. Because the transgenic fish could reproduce at a faster rate; their population may increase exponentially within a short period of time. This induced load would far exceed the 'carrying capacity' of the natural environment and possibly this would become a sufficient force to drive some native fish species to extinction. In summary, an introduction of transgenic fish into natural marine or fresh water environment might threaten the survival of wild type species.

The challenge: Regulating for Biosafety

As a result of the debate outlined above, there have been increasing discussions on how to regulate the applications of genetic modifications or biotechnology. As activities involving the technology expanded, and in particular as commercial operations increase, the scope of regulations needed to expand. Designing frameworks for GMO regulations is not easy, as the main challenge is to establish an appropriate balance between potentially important technological benefits and appropriate environmental and human health safeguards.

The biosafety cannot be achieved in isolation. This is why the Cartagena Protocol on Biosafety came into existence.

CBD and the Cartagena Protocol on Biosafety

Article 19.4 of the Convention provides for Parties to "consider the need for and modalities of a protocol, including advance informed agreement (AIA) in particular, to ensure the safe transfer, handling and use of living modified organisms derived from modern biotechnology that may have adverse effect on biological diversity and its components"

Therefore, the Biosafety Protocol seeks to protect biological diversity from the potential risks posed by LMOs resulting from modern biotechnology. The issues addressed include the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on

the conservation and sustainable use of biological diversity taking into account also risks to human health (Article 4). An Advance Informed Agreement (AIA) procedure is also set out to help ensure that countries are provided with important information necessary to make informed decisions before agreeing to the import of an LMO into their territory.

The Protocol also contains other provisions such as types of information to be provided, scientifically-based risk assessment, simplified procedures, exchange of information, handling of confidential information, public awareness and participation, capacity building for developing countries.

As far as the scope of the Protocol is concerned, it appears that there are categories of LMOs or transboundary movements that are excluded. In some cases the exclusions are limited to specific provisions relating to the AIA procedure, in others they operate as general exclusions from all of the Protocol's provisions. An overview of the scope of the Protocol is summarised in the Box below.

It is also important to note that even where certain LMOs are excluded from some or all of the Protocol's provisions, they may, of course, still be subject to national regulation.

Scope of the Protocol and of the AIA procedure

LMOs subject to the provisions of the Protocol

- All LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4).

LMOs subject to AIA provisions

- LMOs intended for intentional introduction into the environment (Article 7 (1)).

LMOs excluded from the Protocol's AIA provisions

- LMOs in transit (Article 6 (1)).
- LMOs destined for contained use in the Party of import (Article 6 (2)).
- LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7 (2)).
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

LMOs excluded from the Protocol's provisions on transboundary movements

- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

Possible Implications of the Protocol for Samoa

An examination of the provisions of the Protocol suggests that there are implications for Samoa. For example, there is to be a National Biosafety Framework. The Framework should be an

effective national regulatory system addressing not only imports (and exports), but also the use and release of LMOs at domestic level. With the development of academic institutions in the country, the Framework should also have provisions for future, possible genetic manipulations in laboratories. Developing such legislation certainly requires extensive consultation with a wide range of relevant departments and agencies, as well as the public, local industry and agriculture, academic and research institutions.

In relation to other Parties, the Protocol would be a means to establish transparency in the transboundary movement of LMOs and application of advance informed agreement regarding imports. It is an ideal tool for effective communications and cooperations at the international level.

With these possible benefits implied through the Protocol, some facts from the Science point of view still remain. Firstly, genetic engineering as a subsection of molecular biology, is a difficult and complex type of biochemistry. Secondly, running an experiment in molecular biology is usually very expensive. Thirdly, with years of hard training and expertise, hiring a Molecular Biologist can be also very expensive. Taken all this together, suffice to state that this is not a cheap issue.

Thus by extrapolation, the development, implementation and administration of appropriate national regulations which might also take into account other trade agreements, would require significant human, financial and technical resources. It involves a depth of co-ordination and ongoing capacity building of expertise in many specialised areas.

6. TERMS OF REFERENCE

This Report concentrates on the existing National, Bilateral and Multilateral co-operative programmes in capacity building, R & D, Existing uses, and application of Biotechnology including review and assessment of Existing Legislation that may impact on the use of Modern Biotechnology. The tasks involved include the following:

1. To identify all relevant government departments, NGOs, private sectors (including academic institutions) with national, bilateral and multilateral co-operative programmes in capacity building.
2. To identify any existing Research and Development programmes dealing with LMOs at the National, Bilateral and Multilateral level.
3. To identify any existing uses and application or possibilities of dealing with importation of LMOs.
4. To conduct consultations with key stakeholders to identify existing national legislation(s) and impact on the use and application of modern biotechnology.
5. To assess and review the adequacy of existing legislations on safe use arrangements that may impact on the use of modern biotechnology.

6. To provide practical recommendations on appropriate mechanisms to promote, strengthen and / or develop co-operative programmes on capacity building, and any existing legal mechanisms for safe use and application of modern biotechnology.

7. SURVEY & RELATED TERMS OF REFERENCE

1. To identify all relevant government departments, NGOs, private sectors (including academic institutions) with national, bilateral and multilateral co-operative programmes in capacity building.

Despite references made in the Biosafety Protocol, to cooperation in capacity-building, there are no specific commitments from developed countries with regard to capacity-building. The Global Environment Facility (GEF) is the financial mechanism established under the CBD for assistance. There is no specific guidance given in the Protocol as to the level of financial resources that may be needed for implementation of the Protocol.

This Survey attempted to gain some information as to the status in Samoa. The Table below summarises some of the information gained.

Existing Research and Development programmes dealing with LMOs at the National, Bilateral and Multilateral level.

Relevant Stakeholders	Capacity Building Programme	Duration of Programme	Implementing Agency	Objective of programme
• UNDP	Yes		UNDP	To carry out Capacity Need Assessment in Samoa
• FAO	Yes	ongoing	FAO	To advice on standard of food according to <i>Codex Alimentarius</i>
Government				
• Attorney General's Office	No			
• MAFFM – Quarantine	Yes	2002 - 2004	Samoa & Australia	To further training of staff and upgrade facilities
• MAFFM – Livestock	No			
• MAFFM – Forests				
• MAFFM – Fisheries				
• MAFFM – Nu'u	No			
• MNRE	Yes	ongoing	UNEP/GEF	To implement and administer the National Biosafety Frameworks

• MR - Custom	No			
Non Government Organisation				
• Siosiomaga Society	No			
Academic Institution				
• USP- Alafua	No			
• NUS	No			

UNDP already approved a grant for Samoa to carry out Capacity Needs. Because of the urgent need to regulate the transboundary movement, handling, and release of LMOs, it is crucial that the National Biosafety Framework be seriously considered in terms of fund allocation.

While FAO does not appear to advise against or for the use of LMOs or food with GE ingredients, the Organisation still contributes by giving out publications of consultations and workshops on issues such as Safety assessment of foods derived from GM microorganisms (FAO/WHO 2001). Recently, at the fifth meeting of the FAO South West Pacific Ministers for Agriculture, one of the recommendations was to encourage FAO to assist countries build capacity in risk analysis of transborder movement of LMOs in the region particularly in training and raising awareness about GMOs and LMOs (Communique 2003)

Academic Institutions

While the University leaders of USP-Alafua have indicated that they have no capacity programme currently geared to handle research or work related to genetic engineering or biotechnology, it is however crucial to point out that on campus there exist these specialities: Plant Physiology, Plant Pathology, Meat Hygiene, Genetics, Entomology and Agricultural Systems. All these specialities are very important for decision-making process as far as biotechnology is concerned. What is currently missing is a laboratory specifically designed and facilitated for Molecular Biology that would directly address issues on GMOs/LMOs.

Similarly, NUS is modest in responding to capacity programme. At present the University does not have capacity building as such. There are no facilities for basic research, no laboratory to handle biotechnology.

But the current scenario at the country's National University should also be assessed in terms of possibility. There might be potential for future work related to the current issue. For example, within the Faculty of Science, there are staff members whose strengths lie in fields such as Biochemistry, Microbiology, Chemistry, Environmental Engineering and Mathematics, all of which could be consulted for decision-making processes. In addition, the extraction of DNA at NUS had been reported early in 2002. (This skill has now being disseminated into schools.) With this initial step to DNA manipulation and possible drive of the local scientists to make do with what they have, one can perhaps speculate that it is only a matter of time that restriction enzymes become a tool in the laboratories. Secondly, NUS has a number of relational Universities through Memorandum of Understandings (MOU). Might some of these Universities engage NUS into areas such as bio-prospecting (at the molecular level) or field testing (LMOs), then the compound effect of capacity buildings from without could become immeasurable. It is interesting to note that a study of DNA sequence of the spacer region between the *ATP-synthetase-Beta-subunit* gene and the *ribulose-1,5-biphosphate carboxylase subunit* gene of the

chloroplast genome in the plant family, *Gesneriaceae*, (Samuel et al. 1997) was also made possible as a result of a collecting permit granted by the Samoan Government.

NUS' Relational Universities through MOU

Country	University
Australia	• Australian National University
	• Queensland University of Technology
	• New Castle University
Japan	• Wasida University
	• Asia Pacific Reitsumeikan University
New Zealand	• Auckland University
	• Christchurch College of Education
	• Otago University
	• Waikato University
U.S. A.	• Brigham Young University, Hawaii
	• University of Hawaii
	• University of Wisconsin

Courtesy of the NUS Registrar

Recommendation

- There is a need for development of National capacity for scientific risk assessment & management.
- At present, the development of competencies for risk assessment & management require expert advisory committees, or a combination of internal and external scientific expertise.
- For sustainability, the continual training of locals is encouraged.

2. To identify any existing Research and Development programmes dealing with LMOs at the National, Bilateral and Multilateral level.

At present, there is no existing research on LMOs at the national level. The development programme that directly addresses LMOs is now being administered by the MNRE.

3. To identify any existing uses and application or possibilities of dealing with importation of LMOs.

So far any existing use or application of LMOs in Samoa has not been officially made know. However it remains a real possibility that LMOs may be imported into the country.

4. Identification of Existing National Legislation & Impact On the Use & Application of Modern Biotechnology

An assessment of the adequacy of existing legislation on safe use and arrangement that may impact on the use of bio-technology was also carried out.

A questionnaire designed especially to probe the existence of legislation that might directly address the issue of bio-technology was given to the office of Attorney General. This was in addition to the consultant's research carried out in legal libraries and through interviews.

Areas Covered By Existing National Legislation/Law/Regulation/Guidelines

The table below indicates this search.

Areas	Administrative Agency
Agriculture	MFFM
Animal Use	MFFM
Antibiotic Resistance Genes in GMOs	
Biodiversity	MNRE
Biosafety	MNRE
Biotechnology	
Consumer Packaging & Labelling	TCI
DNA Fingerprinting	
Endangered Species	MNRE
Environment	MNRE
Feed	MFFM
Fish Inspection	MFFM
Food & Drugs	Health
GM Products	
Gene Splicing	
Gene Therapy	
Health & Safety	Health
Human Cloning	
Industry	TCI
Import of Controlled Substances	MFFM
Import/Export of Living Organisms	MAFFM
Intellectual Property	Justice
Introduction of New Species	
Invasive Species	
In vitro fertilisation	
Laboratory Biosafety Resources	
Livestock Animals & Fish Derived from Biotechnology	
Livestock Plants Derived from Biotechnology	
LMOs	

LMOs for Contained Use	
LMOs for Intentional Introduction into the Environment	
LMOs for Food, Feed, or Processing	
Meat Inspection	Health
Microorganisms	
Pesticide & Chemical Used in Agriculture	MFFM
Pesticide & Chemical Used in Industry	TCI
Plant Breeding	MFFM
Plant Protection	MFFM; MNRE
Plant Seeds	MFFM
Quarantine	MFFM
Trade	TCI
Traditional Medicine Property Right	
Transport of Biological Substances	
Transport of Goods	Custom
Transgenic Organisms	
World Trade Organisation & Related Agreements	TCI

Source: Office of the Attorney General

What is obvious from the search above is that there are gaps in the regulatory system, there are issues now confronting society that must be directly addressed.

Recommendation

- That a regulatory framework that directly addresses biotechnology be in place.

5. Assessment & Review of Existing Legislation that may Impact On the Use of Modern Biotechnology and Biosafety.

A survey on existing National legislation that might impact on the implementation of the Biosafety Frameworks was carried out. The Legislation identified include those cited in the Table below.

Legislation	Relevant Scope of Act	Responsible Agencies
Agriculture, Forests and Fisheries Ordinance 1959 and Regulations	<ul style="list-style-type: none"> • To strengthen the capabilities of agricultural inspection and quarantine services 	MAFFM
Animal Ordinances 1960 and Regulations	<ul style="list-style-type: none"> • To develop control measures to protect and conserve biodiversity • To control and/or prevent the introduction of inappropriate foreign plants and animals 	MAFFM
Noxious Weeds Ordinance 1961	<ul style="list-style-type: none"> • To control the propagation of harmful plants 	MAFFM
Forest Act 1967	<ul style="list-style-type: none"> • To develop control measures to protect and conserve biodiversity 	MAFFM - Forestry

Development Bank Act 1974	<ul style="list-style-type: none"> To encourage new cash crops To encourage local entrepreneurial activities 	Development Bank
National Parks & Reserves Act 1974	<ul style="list-style-type: none"> To preserve native species 	MAFFM
Customs Act 1977	<ul style="list-style-type: none"> To control and/or prevent the introduction of inappropriate foreign plants and animals 	MR - Customs
Plants Act 1984 and Regulations	<ul style="list-style-type: none"> To prevent the introduction of inappropriate foreign plants 	MAFFM MR-Customs
Lands, Survey and Environment Act 1989	<ul style="list-style-type: none"> To ensure and promote the conservation and protection of the natural resources and environment of Samoa 	MNRE
Trade, Commerce & Industry Act 1990	<ul style="list-style-type: none"> To encourage new cash crops To develop resource-based industries To encourage local entrepreneurial activities To attract foreign investment To negotiate trade agreements 	TCI
Enterprise Incentives & Export Promotion Act 1992	<ul style="list-style-type: none"> To encourage new cash crops To encourage local entrepreneurial activities 	TCI
Protection and Conservation of Wild Animals Amendment Regulations 1993	<ul style="list-style-type: none"> To develop planning controls to protect and conserve biodiversity 	MNRE
	PROPOSED	
Environment Impact Assessment Regulation 1998	<ul style="list-style-type: none"> To regulate and guide impact assessments in Samoa for both private and public development proposals 	MNRE - PUMA
Environment Bio-Propecting Regulation 1999	<ul style="list-style-type: none"> To regulate access to Samoa's genetic resources and the equitable sharing of benefits derived from users 	MNRE - DEC
Biosecurity Bill 2003	<ul style="list-style-type: none"> To regulate importation of articles associated with biosecurity risk 	MAFFM Quarantine

As far as records are concerned there is no legislation which directly addresses bio-technology. The closest at present is the Biosecurity Bill 2003. However the Bill itself does not seem to have enough scope to address issues pertaining genetic engineering and Biosafety.

Recommendations

- That a regulatory framework be in place addressing the following issues:
 - LMOs destined for contained use (eg. research in laboratories)
 - LMOs destined for intentional introduction into the environment
 - LMOs intended for direct use as food or feed, or for processing (LMOs-FFPs)
 - LMOs destined for export and/or import
- As part of the framework, LMO Importers/exporters be licensed, apart from the expenses incurred for a specific application for an LMO.

A Model Framework

SPREP has published an outline of framework or law that can be adopted in part, by Samoa:

- Define the objective of the regulation
- Define the scope of the regulation – what activities and organisms are covered
- Place responsibility for implementation of the regulations on a Minister or Ministers and on particular government department (or departments) or agency
- Establish or designate advisory body (ies) to advise on technical aspects of regulatory decisions
- Establish a general prohibition on activities involving LMOs unless an authorisation / licence has been obtained in accordance with regulations
- Establish a system of permits or authorisations for activities involving LMOs
- Allow for exemptions or fast-track or simplified procedures for certain LMOs with which there is extensive experience under the regulations, or which have been deemed to be low-risk
- Provide for public information and consultation on permit applications and/or on policy issues
- Set out information required in an application for a permit (information required may vary according to the type of LMO and /or the intended activity)
- Address the protection of commercial confidential information
- Establish a risk assessment procedure, whereby risks associated with the release or other activity are identified, in accordance with risk assessment criteria
- Allow for risk management conditions to be attached to permits, including any applicable labelling or marking requirements
- Set out procedures for monitoring and review of activities subject to permit, including compliance with conditions
- Set out penalties and sanctions for non-compliance
- Make provisions for liability for any damage arising out of activities involving LMOs
- Address unintentional releases and emergency measures
- Make certain transitional arrangements in respect of pre-existing activities or applications

Adapted from SPREP: Convention on Biological Diversity

6. CONCLUDING REMARKS

Co-operative programmes in capacity building with regard to modern biotechnology is relatively new to Samoa. At present, there is no existing research on LMOs at the national level. The development programme that directly addresses LMOs is now being administered by the MNRE with the help of GEF. It is imperative to concentrate on capacity building for scientific and legal aspects.

So far any existing use or application of LMOs in Samoa has not been officially made known. However it remains a real possibility that LMOs may be imported into the country.

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Annex 1. Terms of References

Survey 2

- Identify all relevant government departments, NGOs, private sectors (including academic institutions) with national, bilateral and multilateral co-operative programmes in capacity building.
- Identify any existing Research and Development programmes dealing with LMOs at the National, Bilateral and Multilateral level.
- Identify any existing uses and application or possibilities of dealing with importation of LMOs.
- 3. Conduct consultations with key stakeholders to identify existing national legislation(s) and impact on the use and application of modern biotechnology.
 - .Analyse and Compile the results and findings from the consultations and submit for comments from the DEC and NCC
- 4. Assess and review the adequacy of existing legislations on safe use arrangements that may impact on the use of modern biotechnology.
 - Revisit the key stakeholders and present the result of the survey for further inputs and comments.
- 5. Prepare a Survey Report with practical recommendations on appropriate mechanisms to promote, strengthen and / or develop co-operative programmes on capacity building, and any existing legal mechanisms for safe use and application of modern biotechnology.
 - Report should be submitted within 14 days after further consultation and presentation of findings to the stakeholders.

Annex 2: Questionares

Questionnaire 1

Identification of Existing National Legislation That May Impact on the Use & Application of Modern Biotechnology

The aim of this questionnaire is to identify existing legal mechanisms related to Biosafety, even in a peripheral manner. In addition it provides an initial step in examining if existing legal mechanisms could be used to impact the use and application of modern biotechnology.

Definitions:

The following use of terms was adopted from the Cartagena Protocol on Biosafety.

Genetic Modified Organism (GMO) means any organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Microorganism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cell in culture.

Modern biotechnology means the application of:

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

1. What is the legal system operating in Samoa? (Please tick the appropriate box)

Common Law

Civil Law

Mixed System

Other (Please specify): _____

2. Are there existing National Legislation/Law/Regulation/Guidelines on any of the following areas? (Please tick Yes or No.)

Areas	Yes	No	Administrative Agency
Agriculture			
Animal Use			
Antibiotic Resistance Genes in GMOs			
Biodiversity			
Biosafety			
Biotechnology			
Consumer Packaging & Labelling			
DNA Fingerprinting			
Endangered Species			
Environment			
Feed			
Fish Inspection			
Food & Drugs			
GM Products			
Gene Splicing			
Gene Therapy			
Health & Safety			

Human Clothing			
Industry			
Import of Controlled Substances			
Import/Export of Living Organisms			
Intellectual Property			
Introduction of New Species			
Invasive Species			
In vitro fertilisation			
Laboratory Biosafety Resources			
Livestock Animals & Fish Derived from Biotechnology			
Livestock Plants Derived from Biotechnology			
LMOs			
LMOs for Contained Use			
LMOs for Intentional Introduction into the Environment			
LMOs for Food, Feed, or Processing			
Meat Inspection			
Microorganisms			
Pesticide & Chemical Used in Agriculture			
Pesticide & Chemical Used in Industry			
Plant Breeding			
Plant Protection			
Plant Seeds			
Quarantine			
Trade			
Traditional Medicine Property Right			
Transport of Biological Substances			
Transport of Goods			
Transgenic Organisms			
World Trade Organisation & Related Agreements			

3. With the **Areas** answered *Yes*, in Question 2, please indicate the Administrative Agency responsible by filling in the relevant column in the Table above. (Where “Administrative Overlaps” might occur, please indicate all the Agencies involved.)

4. Is there likely to be a specific legislation in the future which impacts the use of LMOs and modern biotechnology in Samoa according to the Cartagena Protocol?

5. Please provide comments on some specific areas to be covered in a relevant legislation in the future.

Name of the Person who filled this form:

Signature:

Date:

Department/Company/Sector:

6. Other Collaborating Agencies

(Please list all the collaborating agencies, i.e international/regional organisations, local institutions.)

- 1. _____
- 2. _____
- 3. _____
- 4. _____
- 5. _____

7. Main Target Group(s)/Beneficiaries:

Please specify the main target group(s)/audience(s) and beneficiaries of the project.

8. Contact Details:

Please provide the name and details of a contact person who is responsible for updating information about the project and responding to requests from the database users.

Name _____

Title (Miss, Ms, Mrs, Mr or Dr) _____

Organisation _____

Designation _____

Address _____

Phone _____

Fax _____

E-mail _____

Web site _____

9. Type of Funding:

Please indicate the type of funding.

Government Budget

Bilateral

Multilateral

NGO

Private Sector

Foundation

Individual Donor

10. Name of Funding Agency and Contribution

Please provide the name of the agency/donor and if possible, indicate the total project funding and amount from each funding source.

	Funding Agency	Amount Donated in US \$
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____

11. Goal:

Please state the overall goal of the project.

12. Objectives:

Please outline the main objectives of the project.

1. _____
2. _____
3. _____
4. _____
5. _____

13. Main Capacity Building Areas:

Please indicate the main Biosafety capacity building area(s) addressed in the project.

- Human resources Development
- Public Awareness
- Education & Participation
- Identification of LMOs and/or LMO-FFPs
- Risk Assessment

- Information Exchange & Data Management
- Risk Management
- Institutional Strengthening
- Scientific, Technical & Institutional Collaboration
- National Regulatory Frameworks
- Technology Transfer
- Other(s) (Please specify): _____

14. **Country:** _____

15. **Submitter**

I confirm that the above information is correct and I agree to its inclusion in the Biosafety Projects database of the Convention on Biological Diversity Secretariat and I have no objection to this information being made publicly available.

**Names of the Person (Please print):
who filled this form**

Matai Name(s): _____

First Name: _____

Family Name: _____

Signature: _____

Date: _____

Department/Company/Sector: _____

Annex 3

INFORMATION PAPER

REVIEW OF SAMOAN LAW

AUGUST 2004

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- 1.1 The National Biosafety Framework Project
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 3. *Notification of LMO-FFP's*
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 6. *Provision of information to the Bio-safety Clearing House*
 7. *Capacity Building*

PART 3 SAMOA'S LEGISLATION

- 3.1 Current and proposed legislation
- 3.2 Assessing the relevance of laws to this Review
- 3.3 A "COMPETENT AUTHORITY" FOR SAMOA
 - Lands, Surveys and Environment Act 1989*
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 - Ministry of Primary Industries Development Bill 2003*
 - Health Ordinance 1959*
- 3.4 REGULATION, MANAGEMENT AND CONTROL
 - Quarantine (Biosecurity) Bill 2003
 - Plants Act 1984
 - Business Licences Act 1998
 - Consumer Information Act 1988
 - Fair Trading Act 1998
- 3.5 RISK ASSESSMENTS BASED UPON SOUND SCIENTIFIC ANALYSIS
 - National University of Samoa Act 1997
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- 3.6 EFFECTS ON THE ENVIRONMENT AND ON THE BIOLOGICAL DIVERSITY
 - Fisheries Act 1988
 - Forests Act 1967
- 3.7 RISKS TO HUMAN HEALTH
 - Food and Drugs Act 1967
 - Poisons Act 1968
- 3.8 TRANSBOUNDARY MOVEMENTS
 - Customs Act 1977
 - Maritime Zones Act 1999
 - Carriage by Air Act 1964
- 3.9 PUBLIC AWARENESS AND PARTICIPATION (INCLUDING THE INVOLVEMENT OF THE PRIVATE SECTOR)
 - Internal Affairs Act 1995
- 3.10 PRESERVATION OF CULTURAL AND TRADITIONAL VALUES
 - The Constitution of Samoa
 - Village Fono Act 1990
- 3.11 REGIONAL AND INTERNATIONAL COOPERATION AND HARMONISATION OF ARRANGEMENTS
 - Foreign Affairs Act 1976

PART 1 – BACKGROUND AND OBJECTIVES

1.1 The National Biosafety Framework Project

With assistance from the United Nations Environment Programme, Samoa has embarked upon the task of formulating a National Biosafety Framework. This project is being implemented by the Ministry of Natural Resources and Environment.

1.2 Fundamental Objectives

The following are fundamental objectives in the context of developing National Biosafety Frameworks –

- (a) Much emphasis is placed on the concepts of regulation, management and control;
- (b) A key focus is on the “risks” associated with the use and release of living modified organisms (LMO’s);
- (c) The potential for adverse affects on human health and on the environment generally are acknowledged;
- (d) These adverse impacts may affect the conservation and sustainable use of biological diversity;
- (e) Capacity building is crucial, and access to financial resources and to transfers of technology are noted in this regard;
- (f) Regard must be had to the “different situation, capabilities and requirements of each Party”;
- (g) The need for arrangements to facilitate the sharing of knowledge and information is an important aspect;
- (h) A clear focus is placed on transboundary movement;
- (i) The raising of public awareness is an important feature, and reference is made to facilitating private sector involvement; and
- (j) Harmonisation of arrangements at sub-regional, regional and global levels is called for.

1.3 Placing this Legislative Review in context

A review of relevant legislation is a single 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 LMO’s and systems aimed at assessing and managing risks.

With such matters in mind UNEP has identified four main elements of a National Biosafety Framework –

1. A regulatory system to address safety in the field of modern biotechnology.
2. An administrative system to handle requests for permits authorising certain activities such as releases of LMO’s.

3. A decision making system that includes risk assessment and management for the release of LMO's.
4. Mechanisms for public participation and information.

The review of legislation must assist in applying a proper focus on these elements. In this way the implementation of the National Biosafety Framework can be facilitated by the clear conceptualisation of practical and achievable administrative arrangements in Samoa applying under its laws.

PART 2 – SAMOA'S INTERNATIONAL OBLIGATIONS

2.1 The Cartagena Protocol

Note: The provisions of the *Cartagena Protocol* are technical and complex, and a full understanding of their substance and application can only be achieved by knowing the background, and their context *vis-à-vis* other international conventions and arrangements. It is not proposed to offer such explanations here. The purpose of this Review is to identify the obligations that Samoa has assumed under this Protocol. For a more thorough explanation and analysis of the nature and extent of the provisions of the *Cartagena Protocol* it is suggested that reference be made to the IUCN publication *An Explanatory Guide to 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”.

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)*

Samoa 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)*

Samoa's obligations relate to the following matters –

- (a) Notification must be given of any transboundary movement of a LMO from Samoa. 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 Samoa receiving a notification of the transboundary movement of a LMO to Samoa, receipt of the notification must be acknowledged.
- (c) Within 270 days of receiving the notification of the transboundary movement of a LMO to Samoa, 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) Samoa'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 in to 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 Samoa of any confidential information provided in this way.
- (f) Given its circumstances it may be said that Samoa 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 Samoa to undertake the necessary risk assessments.

Some LMO's are excluded from the AIA arrangements

The LMO's that are excluded from the AIA arrangements include –

- 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 Samoa'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 Samoa 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.

Samoa 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, Samoa must –

- comply with the Protocols notification and consultation requirements; and
- 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 Samoa to prevent and penalise transboundary movements of LMO's that occur in contravention of Samoa'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 Samoa is obliged to provide to the Bio-safety Clearing House –

- Decisions on import or release of LMO's, including those made under the AIA arrangements;
- 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;
- Any determination that a decision will be made on the first import of a particular LMO-FFP in accordance with a risk assessment;
- Summaries of risk assessments or environment reviews of LMO's generated by Samoa's regulatory process;
- Bilateral, regional and multilateral arrangements under Article 14; and
- Any illegal movements of LMO's.

7. *Capacity Building*

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

PART 3 – A REVIEW OF SAMOA’S RELEVANT LEGISLATION

3.1 Current and proposed legislation

For ease of reference, this Review of Samoa’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”.

3.2 Assessing the relevance of laws to this Review

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 Samoa
- 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

The laws (and proposed laws) of Samoa are therefore reviewed under the above headings.

3.3 A “COMPETENT AUTHORITY” FOR SAMOA

LANDS, SURVEYS AND ENVIRONMENT ACT 1989

Year passed – 1989

Effective from – 5th March 1990

Amended in 1992/1993

Repealed the Land Ordinance 1959, the Land Amendment Act 1964 and the Land Amendment Act 1976.

Administered by the Ministry of Natural Resources and Environment

Main objects

To establish the Department of Lands, Surveys and Environment and to make comprehensive provision in relation to land and the management of the environment.

Relevance to this Review

This is the principal law relating to the management and protection of the environment currently in force in Samoa.

Substance of relevant provisions

Part VIII Makes detailed provision concerning conservation and protection of the environment, including: –

- The appointment of a Principal Environment Officer as a deputy to the Director of Lands (section 93);
- The Department is given broad ranging functions and powers in relation to conservation and environment protection. (sections 95 and 96);
- An Environment Board is established and its membership and functions provided for (sections 97 - 103);
- The Minister is given broad powers in relation to the management of the environment, including assessments, monitoring and the approval of guidelines (section 104). The Minister may authorise special investigations (section 105);
- Provision is made for the appointment of conservation officers and for their duties and powers (sections 106 – 115);
- The Director may prepare draft Management Plans in relation to a range of aspects of the environment. These must be considered by the Board and can be approved by the Minister (sections 116 – 118);
- Provision is made for the protection of foreshores and coastal waters (sections 119 – 122);
- Pollution of Samoa's waters is controlled (section 123);
- An Environment fund is established (section 124); and
- Provision is made in respect of the control of litter (section 125 – 134);

Section 146 A very broad range of matters over which Regulations may be made is provided for.

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENT BILL 2003

Year drafted – 2003

Current status – Under review by the Office of Attorney General

To be administered by the Ministry of Natural Resources and Environment

Main Object

To establish the Ministry of Natural Resources and Environment, and to define its functions.

Relevance to this Review

MNRE will have a range of relevant functions under this Bill, and responsibility for the administration of relevant laws.

Substance of the relevant provisions

- Section 13* The Minister may appoint advisory bodies.
- Section 20* Powers to monitor, investigate and enforce are given to authorised officers. (This includes the taking of samples, the production of documents and the seizure of items).
- Section 25* Technical evidence may be given by certificate.
- Schedule 2* A wide range of responsibilities are vested in the Ministry, including –
- Environment and conservation functions
 - The implementation of Samoa's obligations under environment related Conventions
 - Responsibilities relating to Samoa's other natural resources

AGRICULTURE, FORESTS AND FISHERIES ORDINANCE 1959

Year passed – 1959

Effective from – 24 August 1959

Amended – 1989 and 1992/1993

Administered by the Ministry of Agriculture, Forests and Fisheries and Meteorology

Main object

To establish the Department (now Ministry) of Agriculture, Forests and Fisheries

Relevance to this Review

MAFFM is charged with responsibility for many important functions relating to conservation and the management of the environment and quarantine matters.

Substance of relevant provisions

- Section 4(b)* MAFFM is required “to promote in conjunction with Lands, Surveys and Environment the conservation, production and development of the natural resources of Samoa, especially soil, water and forest”. Particular obligations concerning the forest resource are stated.
- Section 4(c)* MAFFM is required to “regulate fishing” and promote the “conservation of fish”.
- Section 4(d)* MAFFM is required to “regulate, control and supervise” the storage and use of pesticides.

MINISTRY OF PRIMARY INDUSTRIES DEVELOPMENT BILL 2003

Year drafted – 2003

Current status – Under review by the Office of Attorney General

To be administered by the Ministry of Primary Industries Development

Main Object

To establish the Ministry of Primary Industries Development, and to define its functions.

Relevance to this Review

MPID will have a range of relevant functions under this Bill, and responsibility for the administration of relevant laws.

Substance of the relevant provisions

Section 13 The Minister may appoint advisory bodies.

Section 20 Powers to monitor, investigate and enforce are given to authorised officers. (This includes the taking of samples, the production of documents and the seizure of items).

Section 21 Technical evidence may be given by certificate.

Schedule 2 A wide range of responsibilities are vested in the Ministry, including –

- Crops and horticulture
- Animal production and health
- Responsibilities relating to Samoa's other natural resources including forest and fisheries
- Quarantine
- Policy and planning

HEALTH ORDINANCE 1959

Year passed – 1959

Effective from – 28th September 1959

Amended – 1969 and 1981

Administered by the Ministry of Health

Main object

To make provision for the Department of Health and for matters relating to public health.

Relevance to this Review

The Department of Health has the primary responsibility for public health in Samoa.

Substance of relevant provisions

Section 7 The functions of the Department of Health include –

- To advise any statutory corporation in matters relating to public health in so far as that corporation is charged with the care of the public health
- To promote and carry out researches and investigations in relation to matters concerning the public health...
- To publish reports, information and advice concerning the public health

Section 10 It is a function of the Board of Health established under section 9 to consider, advise and make recommendations to the Minister in relation to any matter which may in any way affect the health of the people of Samoa.

Section 29 Very broad powers are given to the Director-General of Health to act in relation to infectious diseases, including the power to require persons, places, buildings, premises, animals and things to be isolated, quarantined or disinfected. Persons, ships, aircraft, animals or things may be prevented from coming into Samoa.

GAPS IDENTIFIED IN SAMOA'S LAWS – DESIGNATION OF A COMPETENT AUTHORITY

There is no clear gap in the context of identifying a “competent authority” for Samoa under the Cartagena Protocol. If the proposed MNRE Bill is passed and if it retains the principal functions related to the implementation of Samoa's international obligations in the environment field, then there will be a clear legal mandate for MNRE to play this role. MNRE will be required by law to cooperate and consult with the other agencies identified in this section.

3.4 REGULATION, MANAGEMENT AND CONTROL

QUARANTINE (BIOSECURITY) BILL 2003

Year drafted 2003

Status – Currently under review

This Bill proposes to repeal the Plants Act, the Animals Ordinance, the Bunchytop Act, the Cocoa Diseases Act, the Noxious Weeds Ordinance and the Rhinoceros Beetle Ordinance

Main object

To make comprehensive provision relating to regulated imports and associated biosecurity risks, and for the control of pests and diseases in animals, plants and the wider environment.

Relevance to this review

This Bill will replace the provisions of the Plants Act as the primary basis for quarantine restrictions in Samoa.

Substance of the relevant provisions

Section 2 Defines “biosecurity risk” to mean the likelihood of diseases or pests being introduced into Samoa and the resulting damage from the introduction.

“Regulated articles” includes animals and plants, if their movement may have potential to introduce or spread a pest or disease to or within Samoa.

- Section 14* No person may import any living culture or organism unless authorised by the CEO.
- Section 15* The CEO may declare goods to be regulated articles if he or she is of the opinion that there is an unacceptably high level of biosecurity risk, and if scientific advice to this effect has been received.
- Section 16* The CEO must be notified of the intended import of any regulated article.
- Section 18* The inspection and examination of regulated goods upon arrival is provided for.
- Section 21* Approval may be given for the importation of any regulated article for the purpose of scientific research or experiment to improve the quality of plants, animals or the wider environment, or for any other purpose approved by the CEO.
- Section 24* Immigration officers, customs officers and postal officers are obliged to assist with the enforcement of this law.
- Section 41* The Minister may make arrangements with other Ministries and agencies to effectively coordinate national biosecurity matters.

PLANTS ACT 1984

Year passed – 1984

Effective date – 20 December 1984

Never amended

Repealed the Plants and Soils Importation (Disease Control) Ordinance 1950

Administered by the Ministry of Agriculture, Forests, Fisheries and Meteorology

Main object

To make comprehensive provision in relation to plants and plant diseases.

Relevance to this review

Many features of this Act relate to the importation and exportation of plants, and to quarantine-related issues.

Substance of relevant provisions

- Section 4* Land may be set aside for the quarantine of plants.
- Section 5* Ports may be designated as the lawful points of import and export, and buildings may be designated for the grading and treatment of imported plants.
- Section 6* Emergency restrictions may be imposed on the import of any plant to prevent the introduction of diseases or pests.
- Section 7* Exemptions may be given to permit the import of prohibited plants for purposes of scientific research, and conditions may be imposed.
- Section 8* Illegally introduced plants may be seized.

Section 9 Post officers and customs officers are obliged to assist in the enforcement of this Act.

Section 10 Regulations may be made in relation to a wide range of matters, including –

- Prohibiting or restricting the importation of any plant or plant material, either generally or from a particular place, which may introduce disease or a pest, or which may be of a weak, inferior or undesirable strain
- Prescribing conditions for introducing plant material
- Providing for the masters of vessels and aircraft to provide prescribed information
- Providing for the production of plant health certificates granted or issued overseas
- Providing for the inspection, observation, disinfection, treatment, destruction, reshipment or disposal of any introduced plant

Part IV Controls can be placed on the export of plants, and regulations can make extensive provision in this regard.

Part V Officers and inspectors may be appointed, and they are given rights of entry.

BUSINESS LICENCES ACT 1998

Year passed – 1998

Effective from – 24 December 1998

Never Amended

Administered by the Commissioner of Inland Revenue

Main objects

To make comprehensive provision in relation to the licensing of businesses in Samoa.

Relevance to this Review

Under this Act certain business activities can be prohibited in Samoa

Substance of the relevant provisions

Section 4 No person may commence or carry on any business or economic activity which involves, at any time, any of the activities referred to in the Schedule.

Schedule The current prohibited activities under this Act include –

- Nuclear and toxic waste disposal
- Export of products that are prohibited under any law
- Processing and export of endangered species

(Note: The *Foreign Investment Act 2000* confirms the prohibitions provided for under section 4 of the *Business Licences Act 1998* and the Schedule, and applies them in the context of approvals for foreign investment).

CONSUMER INFORMATION ACT 1988

Year passed – 1989

Effective date – 20 September 1989

Never amended

Administered by the Ministry of Commerce, Industry and Labour

Main object

To make provision for informative labeling and marking of goods and for the prevention of misleading and deceptive packaging, labeling and advertising of goods.

Relevance to this review

This Act may be used to require the disclosure of the use of LMO's in packaged food products.

Substance of the relevant provisions

Section 2 “Food” has the same meaning as in the *Food and Drugs Act 1967*.

Section 5 Regulations may specify any ingredient in a food product about which information must be provided in any labeling and packaging of the product.

Section 6 Prescribes requirements in relation to the type of labeling to be used.

Section 7 No comment or explanation may be given in any labeling which contradicts or is inconsistent with any required labeling. Misleading labeling may not be used.

Section 12 The Minister may appoint advisory committees.

Section 19 Prior notice must be given in relation to any alleged breach of this Act, and the views of the alleged offender may be given and taken into account.

Section 22 Upon conviction for any offence under this Act the court may order the withdrawal of the product from sale.

FAIR TRADING ACT 1998

Year passed – 1998

Effective date – 19 June 1998

Never amended

Repealed the Commerce Act and amended the Consumer Information Act

Administered by the Ministry of Commerce, Industry and Labour

Main object

To make comprehensive provision in relation to consumer protection.

Relevance to this review

Standards may be applied to goods offered for sale, and other arrangements made for the protection of the rights of consumers.

Substance of the relevant provisions

- Section 7* The Minister may by Regulation apply product safety or quality standards for any specified goods. The standards must be aimed at preventing or reducing risk or injury to persons. The requirements may relate to methods of manufacture, testing of goods and labelling.
- Section 8* Goods must not be supplied unless they conform to an approved standard.
- Section 9* The CEO may conduct inquiries into any matter involving the sale of goods to which approved standards apply.
- Section 11* The Minister may order the recall of any goods which do not comply with an approved standard.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Agriculture, Forests and Fisheries Ordinance (3.3) – MAFFM is required to regulate, control and supervise the storage and use of pesticides.

The University of the South Pacific School of Agriculture Act (3.5) – The USP Campus retains the function of providing and extending pest-control, animal health and related services for the people of Samoa.

Food and Drugs Act (3.7) – Regulations may be made under this Act for the licensing and control of the manufacture, importation, sale, distribution or use of sera, vaccines, antigens, toxins, antitoxins or other biological preparations.

Poisons Act (3.7) – Regulations may declare any substance to be a “prohibited substance”.

GAPS IDENTIFIED IN SAMOA’S LAWS – REGULATION, MANAGEMENT AND CONTROL

Samoa’s current laws appear to make adequate provision in relation to controlling the movement of LMO’s into and out of Samoa. Use could be made of existing laws to require notification to be given of the existence of LMO’s in any product sold within Samoa.

It is however noted, that none of these provisions are predicated on the basis of the precautionary approach. This is particularly so in relation to the draft *Quarantine (Biosecurity) Bill*. It in no way applies the precautionary approach. In fact the deeming of “regulated articles” under this proposed law is made dependant upon the existence of scientific advice to this effect. And it should be noted that the useful references in the current *Plants Act* to regulating weak, inferior or undesirable strains of plants are not restated in the new Bill. In many respects the existing 1984 *Plants Act* is preferable to the more recent proposed law.

3.5 RISK ASSESSMENTS BASED UPON SOUND SCIENTIFIC ANALYSIS

NATIONAL UNIVERSITY OF SAMOA ACT 1997

Year passed – 1997

Effective from – 14 March 1997

Amended – 1998

Repealed the National University of Samoa Act 1984

Administered in the Ministry of Education

Main object

To provide for the administration of the National University of Samoa.

Relevance to this Review

The National University of Samoa is one of two tertiary academic institutions established under Samoan law and providing teaching and research at tertiary level.

Substance of the relevant provisions

- Section 5* The functions of the University include –
- The acquisition and transmission of knowledge by teaching, consultancy and research
 - The encouragement of intellectual independence
 - The promotion of the economic and social development of Samoa
- Section 6* The concepts of academic freedom are further enshrined in this section.
- Section 22* The duties of the Council include –
- To take steps necessary to ensure that the University's standards in education, training and research are accepted by the international academic community
 - To ensure that the principles of academic freedom are achieved
 - To seek to participate on the economic and social development of Samoa
- Section 39* The funds of the University include monies received by way of fees or otherwise in respect of the performance and exercise of any of its functions.

THE UNIVERSITY OF THE SOUTH PACIFIC SCHOOL OF AGRICULTURE ACT 1977

Year passed – 1977

Effective from – 25 August 1977

Never amended

Administered in the Ministry of Agriculture, Forests, Fisheries and Meteorology

Main object

To establish the USP School of Agriculture in Samoa, and to endow lands for its purposes.

Relevance to this review

This is another tertiary academic institution within Samoa, and operates specifically in the fields of agriculture.

Substance of the relevant provisions

Section 4 The functions of the University Campus include –

- To advance knowledge of agriculture and agricultural science and to disseminate and maintain the same by teaching and research
- To initiate, plan and implement agricultural research calculated to promote the well-being, needs and interests of the communities of the South Pacific
- To collect and disseminate scientific information relating to agriculture including the publication of scientific reports and journals
- To continue to provide and to extend pest-control, animal health and related services for the people of Samoa
- To advise the Government on agricultural matters
- To undertake research and advisory services for Government, and other authorities, institutions, associations, companies and other persons

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Plants Act (3.4) – Exemptions on plants prohibitions may be granted for the purposes of scientific research.

Advisory Committees may be established under the *Ministry of Natural Resources and Environment Bill*, the *Ministry of Primary Industry Development Bill*, the *Consumer Information Act (3.4)* and the *Poisons Act (3.7)*.

Food and Drugs Act (3.7) – This Act permits the appointment of analysts.

GAPS IDENTIFIED IN SAMOA'S LAWS – RISK ASSESSMENTS

It is likely that this is an area in which gaps must inevitably exist in relation to Samoa's capacity to undertake risk assessments based on scientific analysis done within Samoa. There is no government Ministry responsible for science and technology and no government agency dedicated to scientific research.

On the other hand there are two tertiary education institutions established under statute. These laws do permit, and may in fact require, these University's to assist government in the conduct of research and its application within Samoa.

3.6 EFFECTS ON THE ENVIRONMENT AND ON THE BIOLOGICAL DIVERSITY*FISHERIES ACT 1988*

Year passed – 1988

Effective from – 18 July 1988

Amended – 1999

Administered by the Ministry of Agriculture, Forests and Fisheries and Meteorology

Main objects

To provide for the conservation, management and development of Samoa's fisheries, and for the licensing of foreign fishing vessels.

Relevance to this Review

- The Act aims to promote the conservation, management and development of Samoa's fisheries and the protection and preservation of the marine environment.
- Marine scientific research and exploration of the living marine resources may be regulated.

Substance of relevant provisions

Section 3(1) States the purposes of the Act in relation to the conservation of Samoa's fisheries and the protection of the marine environment.

Section 3(3) Empowers the Director to: –

- Collect and analyse statistical information;
- Monitor activities for their effect on the fisheries; and
- Consult with industry and village representatives to make by-laws aimed at the conservation and management of the fisheries.

Section 10 The Minister may authorise marine scientific research and impose conditions.

Section 25 Regulations may be made in relation to the following: –

- Measures for the conservation and management of fisheries, including closed seasons and areas, prohibited methods and gear, and the species and sizes of fish not allowed to be taken;
- The provision of statistical information; and
- Prevention of marine pollution.

The 1998 amendments made specific provision for the licensing of –

- Commercial and experimental aquaculture operations.
- The export or import of certain fish or fish products.
- Fish processing establishments.

FORESTS ACT 1967

Year passed – 1967

Effective from – 12 December 1967

Never amended

Repealed the Forestry Regulations 1963

Administered by the Ministry of Agriculture, Forests and Fisheries

Main object

To make provision for the conservation, protection and development of the soil, water and forests of Samoa.

Relevance to this Review

- The Act includes some regulatory provision dealing with quarantine issues.

Substance of the relevant provisions

Section 70 Certificates are required in relation to the import of any tree, tree seed, timber or timber product to certify that it does not contain any injurious insect, fungus, bacterium or virus.

Section 71 Regulations may be made aimed at controlling and eradicating any disease affecting trees.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Lands, Surveys and Environment Act (3.3) – Extensive provision is made in Part IV relation to the protection of the environment. And wide ranging regulations may be made.

Agriculture, Forests and Fisheries Ordinance (3.3) – MAFFM is required to promote the conservation and development of Samoa's natural resources in conjunction with MNRE.

GAPS IDENTIFIED IN SAMOA'S LAWS – EFFECTS OF THE ENVIRONMENT AND THE BIOLOGICAL DIVERSITY

A principle gap appears in this context. There is no formal procedure requiring or prescribing the assessment of environmental impacts. In this way there is no clearly defined role for the public to participate in such assessments and to thereby be advised of potential impacts on their environment.

3.7 RISKS TO HUMAN HEALTH

FOOD AND DRUGS ACT 1967

Year passed – 1967

Effective date – 24 July 1967

Never amended

Repealed the Food and Drugs Act 1947(NZ) and four New Zealand Regulations

Administered by the Ministry of Health

Main object

To make comprehensive provision in relation to the sale of food.

Relevance to this review

This Act deals with matters concerning adulteration of food and the analysis of foods.

Substance of the relevant provisions

- Section 2* The definition of “substance” includes any natural or artificial substance, and any manufactured article or any article which has been subjected to any artificial treatment or process.
- Section 5* “Adulteration” is defined in some detail and includes the addition of any substance which affects its nutritive or other beneficial properties as compared to the food in its pure state.
- Section 6* Provision is made for the appointment of analysts.
- Section 8* It is an offence to sell any food which does not meet a standard prescribed by Regulation, or which contains any substance prescribed by Regulation.
- Section 11* It is an offence to advertise food that contravenes any regulation requiring the labelling or packaging of food or which may likely deceive a purchaser as to the properties of any food.
- Section 15* Powers of entry, inspection, seizure and destruction are given to officers.
- Section 21* The CEO-Health may require the provision of further information in relation to the manufacture or sale of any food that may be in breach of this Act or the Regulations.
- Section 24* Provision is made for taking samples for analysis.
- Section 26* Certificates from an analyst are to be in the prescribed form, and under section 28, these are to be prima facie evidence of the facts stated therein.
- Section 28* Regulations may make provision for a wide range of matters, including –
- Standards of strength, weight, quality, purity, quantity or composition of any food, or any ingredient or component of any food
 - Prohibiting or restricting the addition of any specified thing
 - Prohibiting the modes of any manufacture, preparation or preservation of any food
 - Licensing or controlling the manufacture, importation, sale, distribution or use of sera, vaccines, antigens, toxins, antitoxins or other biological preparations
 - Securing the freedom of contamination of any food during the course of its manufacture, preparation, storage, packing, carriage or delivery
 - Prescribing the mode of labelling of packages of foods, ingredients or containers
 - Prescribing the matters to be contained or omitted from any packaging
 - Prescribing the notation any food as being imported into Samoa
 - Prescribing the method of analysis

Year passed – 1968

Effective date – 29 July 1968

Amended 1988

Administered by the Ministry of Health

Main object

To regulate the importation, carriage, custody and sale of poisons and prohibited substances.

Relevance to this review

Whilst LMO's cannot be described as "poisons", this Act regulates anything that is declared to be a "prohibited substance".

Substance of the relevant provisions

Section 5 Regulations may declare any substance to be a "prohibited substance".

Section 6 Advisory committees may be appointed by the Minister for Health.

Section 27 No person may sell any prohibited substance unless approved by the Minister.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Health Ordinance (3.3) – The Ministry for Health has wide-ranging responsibilities in relation to public health, including providing advice to government, research and investigations and the provision of information and advice. Powers to order quarantine restrictions are also provided for.

Fair Trading Act (3.4) – Regulations may impose standards relating to product safety or quality aimed at reducing the risk of injury to persons.

GAPS IDENTIFIED IN SAMOA'S LAWS – RISKS TO HUMAN HEALTH

There do not appear to be substantive gaps in the laws applying in this context.

3.8 TRANSBOUNDARY MOVEMENTS

CUSTOMS ACT 1977

Year passed – 1977

Effective date – 20 December 1977

Amended 1983, 1984, 1990

Numerous ordinances and New Zealand laws and Orders are repealed Administered by the Ministry of Revenue

Main object

To make comprehensive provision in relation to the collection of duties and for the importation and exportation of goods.

Relevance to this review

Wide powers are given to control the import and export of goods.

Substance of the relevant provisions

Section 49 Specified goods or classes of goods can be declared to be prohibited imports on grounds including the public interest. This may have general application or be limited to the importation of goods from any specified person or place. Conditions on imports may be imposed.

Section 73 Prohibition Orders may be made in relation to the export of goods on grounds of the public interest or if the goods have not been prepared or manufactured in accordance with law, or if they do not conform to conditions as to purity and soundness.

MARITIME ZONES ACT 1999

Year passed – 1999

Effective from – upon assent of Head of State (1999)

Laws repealed – Territorial Sea Act 1971 and Exclusive Economic Zone Act 1977

Never amended

Administered by the Ministry of Foreign Affairs

Main objects

To make provision in relation to the sovereignty of Samoa, including its internal waters, the contiguous zone, the exclusive economic zone and the continental shelf.

Relevance to this Review

- It makes comprehensive provision in relation to the sovereignty of Samoa and the areas of its waters over which it asserts rights in accordance with international law.
- Certain acts within the territorial sea by foreign vessels that may harm the environment or affect its resources are deemed to be “prohibited passage”.
- Prior approval must be given for vessels carrying hazardous substances or substances harmful to the environment in the territorial sea.

Substance of relevant provisions

Delineation of Samoa's jurisdiction

Section 3 Describes the internal waters of Samoa.

- Section 4* Extends the territorial sea of Samoa to 12 nautical miles from the baselines on Samoa's coast.
- Section 9* Deems the seabed and subsoil of the territorial sea to be public land.
- Section 18* Extends the contiguous zone to 24 nautical miles from the baselines on Samoa's coast.
- Section 19* Extends the exclusive economic zone to 200 nautical miles from the baselines on Samoa's coast.
- Section 24* Describes the continental shelf of Samoa.

Samoa's jurisdiction concerning natural resources and the protection of the environment.

- Section 12* Deems passage through the territorial sea by a foreign vessel as being prejudicial to the peace, good order and security of Samoa if it –
- does any act of willful and serious pollution to the marine environment.
 - carries out any fishing activities without a licence.
 - carries out any scientific research or hydrographic research activities.
- Section 14(2)* Requires all vessels carrying radioactive or other inherently dangerous, noxious or hazardous wastes, or substances harmful to the environment, through the territorial sea to have prior authorisation.
- Section 18* The government may exercise any powers and take any measures in relation to the contiguous zone to enforce any laws relating, inter alia, to environment protection.
- Section 20(2)* The government has jurisdiction in the exclusive economic zone in relation to the following –
- the establishment and use of artificial islands, installations and structures.
 - marine scientific research; and
 - the protection and preservation of the marine environment.
- Section 22* Deems any offence in relation to the matters listed in section 20 within the EEZ to have been done within Samoa.
- Section 27* Regulations may be made in relation to –
- the conduct of scientific research within the EEZ;
 - regulating the exploration and exploitation of the EEZ for the production of energy from waters, currents and winds, and for other economic purposes,
 - regulating the construction, use and operation of artificial islands, installations and structures within the EEZ,
 - prescribe measures for the protection and preservation of the marine environment.

CARRIAGE BY AIR ACT 1964

Year passed – 1964

Effective date – 30 December 1964

Amended 1978

Certain New Zealand laws are repealed

Administered by the Ministry of Transport and Infrastructure

Main object

To apply the Warsaw Convention to international air carriage to and from Samoa.

Relevance to this review

The Convention requires that the consignor provides necessary information and documentation to enable clearance of the goods to the consignee.

Substance of the relevant provisions

Article 16 The consignor must furnish such information and attach to the air waybill such documents as are necessary to meet the formalities of customs, octroi or police before the cargo can be delivered to the consignee

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Plants Act (3.4) – Regulations made under this Act may impose controls on the export of any plant, and may require the masters of ships and aircraft to provide prescribed information.

Business Licences Act (3.4) – No business may be licensed in Samoa whose business activities relate to the export of any product that is prohibited by any law.

GAPS IDENTIFIED IN SAMOA'S LAWS – TRANSBOUNDARY MOVEMENTS

There do not appear to be substantive gaps in Samoa's laws applying in this context.

3.9 PUBLIC AWARENESS AND PARTICIPATION (INCLUDING THE INVOLVEMENT OF THE PRIVATE SECTOR)

INTERNAL AFFAIRS ACT 1995

Year passed – 1995

Effective from – 10th July 1995

Repealed the Pulenuu and Sui-ole-Malo Act 1978

Never amended

Administered by the Ministry of Internal Affairs

Main object

To establish the Ministry of Internal Affairs and to make provision for the recognition and organisation of village authority.

Relevance to this Review

- The Act makes basic but comprehensive provision with respect to village authority, which is to stand as a system of local government throughout Samoa.

Substance of relevant provisions

Functions of the Ministry

Section 5(1) The functions of the Ministry include: –

- To formulate policies in relation to the recognition and organisation of village authority based upon Samoan custom (a);
- To advance local government through the development of village authority (b) – (d), (g), (i);
- To prepare by-laws for recommendation to the Minister as proposed by the village authorities (f);
- To receive, assess and approve requests from village authorities for development assistance (k); and
- To assist village authorities with social and economic projects and village development (n) and (o).

Creation of committees and offices

Section 10 Creates an Executive Committee for Upolu, Manono and Apolima, and another for Savaii.

Section 11 Executives Committees are to consult with village authorities concerning the implementation of government policies and projects, and to assist village authorities.

Section 14 Villages are to nominate a Pulenuu to be appointed by Cabinet on the advice of the Minister. Government representatives known as Sui-ole-Malo may also be appointed under this section.

Section 15 Pulenuu and Sui-ole-Malo are given extensive functions relating to the maintenance of good order in villages (and areas under their authority) and liaison with government. Some interesting obligations are: –

- To encourage health and sanitation activities;
- To report to the police the use by any person of dynamite or chemicals for fishing;
- To inform of new pests and disease present in a village;
- To assist government with the implementation of its projects; and
- To do any duty imposed upon them by Regulation.

Section 18 By-laws may be made and enforced in villages by Regulation made under this Act.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Health Ordinance 1959 (3.3) – The Ministry's functions include the publication of reports, information and advice concerning public health.

Food and Drugs Act (3.7) – Regulations made under this Act may require the labelling of packages of food, and any ingredients.

Consumer Information Act (3.4) – Requirements may be imposed relating to the labelling of goods and packaging to inform the public of the nature and ingredients of a product.

Fair Trading Act (3.4) – Product safety and quality standards may be applied to any goods aimed at preventing or reducing risks to persons, and appropriate labelling may be required.

The University of the South Pacific School of Agriculture Act 1977 (3.5) – The USP campus has a function of collecting and disseminating scientific information, including the publication of scientific reports and journals.

GAPS IDENTIFIED IN SAMOA'S LAWS – PUBLIC PARTICIPATION AND AWARENESS

As noted above the absence of formal procedures requiring the assessment of environmental impacts, and the participation of the public on these processes, remains a significant gap in Samoa's laws.

There is no formal recognition under Samoa's laws of representative bodies drawn from the private sector or the general community.

3.10 PRESERVATION OF CULTURAL AND TRADITIONAL VALUES

THE CONSTITUTION OF SAMOA

Year passed – 1960

Effective date – 1 January 1962

Amended 1991 (3 Acts) and 1997 (2 Acts)

The Constitution is the underlying law and no individual, body or Ministry has specific administrative responsibility for it.

Main object

To make provision for the constitutional framework of Samoa.

Relevance to this review

Recognition is given under the Constitution to the institutions of traditional governance, status and land ownership of Samoa

Substance of the relevant provisions

Section 100 Matai titles are recognised in accordance with Samoan custom and usage, and with any law making provision in this regard.

Section 101 The status of customary land is recognised.

VILLAGE FONO ACT 1990

Year passed – 1990

Effective from – 30 July 1990

Never amended

Administered by the Parliament

Main object

To empower the exercise within a village by the Village Fono of authority in accordance with Samoan custom and tradition.

Relevance to this Review

- A Village Fono may exercise authority over any person ordinarily resident in a village. This includes the exercise of any power as provided in any other law.

Substance of relevant provisions

Section 3 Recognises the existence and authority of Village Fonos. It empowers them to exercise authority in accordance with Samoan custom and as provided for in any law.

Section 4(2) Village Fonos have the specific power to

- To make rules for the maintenance of hygiene in the village.
- To make rules governing the development and use of village land for the economic betterment of the village.
- To require persons to perform work in relation to the above two matters.

Section 6 The authority to impose punishments includes the power to –

- To impose a fine in money, fine mats, animals of food.
- To order an offender to undertake work on village land.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

National University of Samoa Act (3.5) – A primary function of the NUS is as a “centre of excellence in the study of Samoa, the Samoan language and Samoan culture”.

GAPS IDENTIFIED IN SAMOA'S LAWS – RECOGNITION OF SAMOAN CUSTOM

Whilst there may be no clear gaps in this context, there is a very clear challenge to

effectively apply these laws so as to secure the objective of recognising and applying Samoan cultural and traditional values.

3.11 REGIONAL AND INTERNATIONAL COOPERATION AND HARMONISATION OF ARRANGEMENTS

FOREIGN AFFAIRS ACT 1976

Year passed – 1976

Effective from – 23 August 1976

Never amended

Administered by the Prime Ministers Department

Main object

To make provision for the administration of foreign affairs for the Government of Samoa.

Relevance to this review

Key features of the obligations under the Cartagena Protocol involve the sharing of knowledge and information with other Governments, and the creation of regional and international cooperation arrangements to deal with the technical aspects of the Protocol's requirements.

Substance of the relevant provisions

There are in fact no substantive provisions under this Act which prescribe the means by which Samoa is to fulfil its international obligations, or by which it might form international alliances and partnerships to pursue these ends.

RELEVANT PROVISIONS OF OTHER LAWS REVIEWED IN THIS REPORT

Ministry of Natural Resources and Environment Bill (3.3) – MNRE is to be given a clear mandate in relation to the implementation of Samoa's international obligations, including liaising with regional and international bodies.

GAPS IDENTIFIED IN SAMOA'S LAWS – INTERNATIONAL COOPERATION AND HARMONISATION

The continuing absence of laws dealing with the mechanics of observing Samoa's international obligations is a gap in Samoa's laws of some significance. The vesting of these responsibilities in MRNE as proposed in the MRNE Bill would go a long way to providing a remedy for this situation.

Annex 4

MINISTRY OF NATURAL RESOURCES & ENVIRONMENT Policy Submission to the Cabinet Development Committee

National Policy on the Conservation of Biological Diversity

Purpose of policy

This policy provides the framework for the conservation and sustainable use of Samoa's terrestrial and marine resources. It also provides specific objectives for the protection of Samoa's native species from destructive land management practices and invasive species. This policy also recognises the importance of biological diversity not only for local health and well being but also for evolution and for maintaining life sustaining systems on earth.

Previous references

International concerns over the issue of unsustainable use of biodiversity were formally recognised in the 1971 Ramsar Convention on Wetlands of International Importance, Especially as Waterfowl Habitat, the 1972 Convention for the Protection of the World Cultural and Natural Heritage and the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora. Other references include the 1979 Bonn Convention on the Conservation of Migratory Species of Wild Animals, the 1992 Convention on Biological Diversity, and the 1995 Washington Declaration on the Protection of the Marine Environment from Land-based Activities and the 2000 Cartagena Protocol on Biosafety.

At the local level, the conservation of biological diversity is one of the target environment components identified in the National Environment and Development Management Strategies approved by Cabinet in 1993. Other studies and reports on Samoa's biodiversity include: 1993 State of Environment Report the 1991 Lowland Ecological Survey, the 1996-97 Upland Ecological Survey and the 2001 National Biodiversity Strategy and Action Plan. Licensing procedures for bio prospecting and research have also been developed (see Annex 1). The future direction for the sustainable management of national biodiversity is contained in the Strategies for the Development of Samoa 2000-2001 and 2002-2004.

Requesting Agency

Ministry of Natural Resources & Environment (MNRE)

Implementing Agency

MNRE

Other stakeholders relevant to policy implementation

Ministry of Agriculture

Ministry of Women, Community & Social Development

Ministry of Foreign Affairs & Trade

Ministry of Education, Sports & Culture

Ministry of Labour, Commerce & Industry
Office of the Attorney General
Samoa Tourism Authority
Samoa Water Authority
The National University of Samoa
Samoa Umbrella for Non Governmental Organisation
Marine Protected Areas Committees

Background to the formulation of the policy

A range of international agreements have been developed to promote the conservation of biological diversity. The 1992 Convention on Biological Diversity emphasised the management of biological resources as critical for the conservation of biological diversity sustainable use. The 2000 Cartagena Protocol on Biosafety sought to ensure an adequate level of protection in the field of safe transfer of living modified organisms (the results of modern biotechnology) that may have adverse effects on the conservation and sustainable use of biologically diverse environments. Samoa's ratification of the Biosafety Protocol in 2002 has further highlighted the need to protect Samoa's biological and genetic resources from harmful invasive species.

Priority concerns in biodiversity conservation at the national level include: the loss of biodiversity due to deforestation and logging and the over-harvesting of marine and terrestrial resources. Other concerns include the introduction of alien invasive species that threaten biodiversity of the local environment and the use of destructive methods of fishing and land clearance. The 1993 National Environment Development and Management Strategies and State of Environment Report identified the conservation of biological diversity as a key national environmental priority. These documents recognise the importance of traditional methods and knowledge in sustainable management of biodiversity. Another priority area included in National Environment Development and Management Strategies is increasing public awareness and understanding of the importance of conserving biodiversity in Samoa's environment.

The unsustainable use of resources is often a direct outcome of conditions where access to knowledge, money, and technological expertise is limited. Consequently this policy recognises that in order to improve the management of Samoa's biodiversity it is necessary to improve the economic welfare of the people. As most of Samoa's biodiversity exists within customary land there is also need for constant consultative exchanges between government and private stakeholders, ensuring that the biological diversity of Samoa's natural resources is conserved.

Detailed statement of the policy

Goal

The conservation of Samoa's biological diversity for present and future generations and the sustainable development of its genetic resources for the benefit of all.

Objectives

In order to achieve the above goal, the following objectives have been identified

Objectives	Comments
1. Improve public awareness and understanding of the nature of Samoa's biodiversity and the threats facing the long-term integrity of its biodiversity	<ul style="list-style-type: none"> ● Develop stakeholder understanding and public awareness through educational and promotional programmes such as seminars, workshops and training courses ● Stress community participation in these programmes ● Launch media campaign through television, websites, radio ● Strengthen awareness events such as the Biodiversity Awareness Day ● Provide educational Awareness tools and materials and integrate into school curricula ● Target groups such as local communities, young people and students
2. Strengthen the management of information on inventories of biodiversity resources	<ul style="list-style-type: none"> ● Profiling Local knowledge / traditional knowledge on biodiversity use, which covers medicinal use etc ● Compile inventories of marine and terrestrial resources ● Develop databases for storing information used for the purposes of planning and public awareness ● Disseminate information amongst stakeholders including individuals, government agencies, public and private institutions and communities ● Update the State of Environment Report ● Engage qualified personnel to analyse information and conduct studies and research on biodiversity concerns
3 Build capacity for the management of biodiversity	<ul style="list-style-type: none"> ● Assess current capacity to identify urgent needs and priorities ● Training programmes for community participation in sustainable use of biodiversity and genetic resources ● Carry out pilot projects to acquire necessary expertise ● Establish close consultative links between the Environment & Conservation Division of MNRE and communities groups in developing sustainable use of resources ● Secure government funds for biodiversity and genetic resources programmes ● Institute training programme for all sectors on the control of invasive species
4. Conserve national biodiversity and genetic resources	<ul style="list-style-type: none"> ● Expand the size and number of conservation areas in order to conserve ecosystems ● Rehabilitate degraded ecosystems ● Promote community participation and support for sanctuaries and reserves

	<ul style="list-style-type: none"> ●Review existing legislations relevant to the conservation of biodiversity ●Enforce compliance with mechanisms put in place for conservation of biodiversity and genetic resources ●Develop monitoring systems ●Enhance beneficial traditional knowledge in the conservation of biodiversity and genetic resources ●Forge agreements between government and community over the protection of biodiversity and genetic resources
5. Promote the sustainable use of national biodiversity and genetic resources	<ul style="list-style-type: none"> ●Community participation on all biodiversity programmes regarding benefit issues and access to resources ●Identify mechanisms to promote small scale income generating activities for areas under conservation in a sustainable use manner; such as Handicrafts, eco-tourism, timber, food, medicinal use and aesthetic values of biodiversity and genetic resources ●Market investments are identified and put in place ●Establish mechanisms for equitable access to resources are ●Strengthen and establish new national parks and conservation areas
6. Incorporate biodiversity concerns into environment planning and assessment	<ul style="list-style-type: none"> ●Use data as the basis for management plans, decision-making and policy, ensuring a rapid and effective response to immediate concerns ●Assessment of the effects of development on biodiversity and genetic resources ●Adopt suitable standards aimed at mitigating potential threats to biodiversity ●Develop management plans ●Conduct environmental impact assessments for future development ●Implement an economic valuation of biodiversity and genetic resources
7. Control and eradicate harmful invasive species, which impede on the restoration of endangered species and the sustainability of Samoa's biodiversity.	<ul style="list-style-type: none"> ●Biosecurity of Samoa's native Biodiversity: with potential impacts on native biodiversity from alien species, rigorous programmes along with appropriate well equipped facilities and trained staff to be put in place ●Bio-security system in place to protect endemic species and native resources ●Quarantine services to impose penalties on the illegal importation of any type of introduced species in order to protect our endemic species ●Assessment of the impact of invasive species is required to determine their adverse consequences on native or endemic species ●Implement legislation to control and monitor the introduction of alien pests ●Agreements at the international and regional level are identified and integrated at the national level on access

	<p>and benefit sharing</p> <ul style="list-style-type: none"> ● Work in collaboration with border control services to control the introduction of alien invasive species through Quarantine
<p>8. Promote global partnerships to support the management of biological diversity</p>	<ul style="list-style-type: none"> ● Develop international networks so that Samoa may benefit through transfer of knowledge and technology ● Strengthen the implementation of the Convention on Biological Diversity and the Cartagena Protocol ● Explore linkages to other international conventions and protocols namely: <ul style="list-style-type: none"> - Ramsar Convention on Wetlands of International Importance, Especially as Waterfowl Habitat, the --- Bonn Convention on the Conservation of Migratory Species of Wild Animals - Convention on International Trade in Endangered Species of Wild Fauna and Flora - Convention for the Protection of the World Cultural and Natural Heritage - United Nations - Framework on Climate Change - Vienna Convention for the protection of the Protection of the Ozone Layer ● Develop linkages with regional conventions such as: <ul style="list-style-type: none"> - Apia Convention on Conservation of Nature in the South Pacific Region, the Convention for the --Protection of the Natural Resources and Environment of the South Pacific Region and related protocols, and - Waigani Convention to Ban the Importation into Foreign Island Countries of Hazardous and Radioactive Waste and to Control the Transboundary movement and management of hazardous waste within the South Pacific Region ● Secure donor funding for project implementation

Strategies

To achieve the above-stated objectives, the following strategies have been identified:

Strategies	Activities
<p><u>Short-term (3-5 years)</u> Strengthen the capacity of the Environment & Conservation Division to implement the policy.</p>	<ul style="list-style-type: none"> ● Incorporate policy implementation into the current work of the Environment & Conservation Division ● Complete work on the National Biodiversity Strategy and Action Plan – Add-on enabling activities ● Complete the preparation of the Biosafety National Management Plan ● Complete preparation of the Savaii Lowland and Upland Forests Conservation project ● Complete preparation of the Marine Biodiversity Conservation Management Plan ● Complete work on the National Invasive Species Strategy & Action Plan ● Complete preparation of Management Plans for the Aleipata and Safata Marine Protected Areas

	<ul style="list-style-type: none"> ● Expand inventories of terrestrial and marine biodiversity resources ● Set up database system to store and facilitate the dissemination of biodiversity and genetic resources information ● Improve the capabilities of border control services to prevent the entry of harmful species ● Strengthen the management of the Convention on Biological Diversity and the Cartagena Protocol as well as other related agreements
<p><u>Medium- to long-term</u> Strengthen national capacity through MNRE to implement the policy and promote the sustainable management of national biological diversity</p>	<ul style="list-style-type: none"> ● Establish a new section for Policy Implementation & Monitoring in the Environment & Conservation Division, supported under the MNRE annual budget ● Implement the National Biodiversity Strategy and Action Plan ● Implement the Biosafety National Management Plan ● Implement the Marine Biodiversity Management Plan ● Implement the National Invasive Species Strategies & Action Plan ● Expand existing Marine Protected Areas and create new reserves ● Create new national parks and reserves to conserve biodiversity ● Review current legislation to highlight the importance of biodiversity conservation, protection and sustainable use ● Formalise the inclusion of the Convention on Biological Diversity and other agreements into Samoan law ● Assess the impacts of development projects and human activities and monitor their effects on biodiversity ● Conduct an economic evaluation to assess the costs and benefits of national biodiversity ● Document and develop patents for traditional knowledge and methods on the value of native plants and animals ● Establish scientific research programmes to expand knowledge of local biodiversity and genetic resources.

Expected benefits from the policy initiative

Overall the policy will contribute to the achievement of sustainable development in regards to the following areas:

- Increased awareness on the value of biodiversity and genetic resources,
- Strengthened stakeholder capacity for sustainable management,
- Improved quality of data for planning and decision making,
- Income generating activities access to and benefit sharing fro biodiversity and genetic resources, and
- Protection of national biodiversity for the benefit of future generations.

Relationship to Strategies for the Development of Samoa

The national development strategies will continue to set the future direction of sustainable development in all sectors including the environment. The policy requires that the management of biodiversity and genetic resources is integrated into socio-economic planning and ensures the monitoring of development impacts that may adversely affect biodiversity resources

Human resources implications

In the short-term there are no human resources requirements for policy implementation as such will be carried out by the Terrestrial and Marine Biodiversity sections. However in the long-term there is a need to strengthen MNRE's capacity in policy management by establishing a new section for Policy Implementation & Monitoring within the Environment & Conservation Division, headed by a Principle Policy Officer with a senior and at least one officer. This new section will also be responsible for the implementation of other policies under Environment & Conservation Division including Deforestation and Heritage Conservation.

Financial implications

Initial funding for policy implementation is not required as this work is incorporated into the work of the current Terrestrial and Marine Biodiversity sections of the Environment & Conservation Division. In the long-term funding is required under MNRE's annual budget to support the proposed Policy Implementation & Monitoring section, charged with the management of the policy.

Legislative implications

There is a need to develop strong enabling legislation to deal with the conservation and protection of biodiversity and genetic resources. While the proposed MNRE Bill 2003 clearly sets out the functions and responsibilities dealing with resource conservation, an urgent review of the existing Lands, Surveys and Environment Act 1989 is required to articulate provisions on the security of, access to and benefit sharing from Samoa's biodiversity and genetic resources.

Relations with other agencies

There will be close consultation between MNRE and the other relevant agencies on policy implementation in order to lend support and avoid duplication. In particular cordial cooperation with the non-governmental organisations and traditional institutions will enhance good public relations facilitating the successful implementation of the policy.

Proposed implementation schedule

The National Policy on the Conservation of Biological Diversity will come into effect once approved by Cabinet and the MNRE will be responsible for its implementation. It will be reviewed annually with full independent evaluation to be carried out every five years.

Recommendation

That the Cabinet Development Committee endorse this policy for Cabinet approval.

Responsible officer

Tu'u'u Dr. Ieti Taule'alo
Chief Executive Officer
MNRE

Date of submission: 12 March 2004

Annex 1: PROCEDURES FOR A LICENSING TO INVESTIGATE AND/OR STUDY THE BIOLOGICAL DIVERSITY RESOURCES OF SAMOA

The following procedures shall be followed by all individual, groups or businesses who wish to undertake investigation and/or research studies on the biodiversity resources of Samoa. Application forms are available from the Ministry of Natural Resources & Environment (MNRE), Environment & Conservation Division, Governm`ent House No. 7, Beach Road Vaiala.

Application

- Proponent to lodge application for licence with the Chief Executive Officer of MNRE through the Assistant Chief Executive Officer, Environment & Conservation Division
- Licensing fee of \$500 to be paid with application
- Processing time for application up to 10 working days, and
- Licence valid for 12 months from date of approval.
- Renewal of license will depend on compliance with conditions of previous license

Sampling

- Sampling fee for collection is \$200 plus VAGST per sample
- Collection of sample prohibited in National Parks and Reserves
- Consent from private landowners to be facilitated by the MNRE
- Environment & Conservation Division staff to monitor sampling process and verify collection details. All incurred costs plus VAGST to be met by the proponent
- Only dried samples can be exported, and
- Size of samples to be 100 grams for plant material or 1 gram for extract

Reporting

- Register of all samples to be kept at the Environment & Conservation Division, the proponent to provide all necessary information to complete records;
- Proponent to submit report on status and/or analysis of samples every six months, and
- Ownership of samples to remain with the Government of Samoa;

Benefit sharing

- Subject to mutually agreed terms
- Relevant traditional knowledge and practice to be acknowledged and considered in any subsequent benefit sharing; and
- Minimum royalty to be 10%

Annex 5

BIOLOGICAL DIVERSITY PROTECTION BILL 2004

SAMOA

Arrangement of Provisions

PART I

PRELIMINARY

1. Short title and commencement
2. Interpretation
3. Objectives and the precautionary approach
4. Acts binds the State

PART II

REGULATORY FRAMEWORK FOR LIVING MODIFIED ORGANISMS

5. National Competent Authority
6. Responsibilities and Powers of the National Competent Authority
8. Role of the Ministry
9. Powers of the Chief Executive Officer
10. Other statutory powers not affected

PART III

PROCEDURES RELATING TO THE IMPORTATION OF LIVING MODIFIED ORGANISMS

11. Notifications of transboundary movements
12. Approvals for imports
13. Scientific risk assessments
14. Confidential information
15. Exemptions from the procedure
16. Review of decisions

PART IV

OTHER REGULATORY REQUIREMENTS RELATING TO LIVING MODIFIED ORGANISMS

17. Exportation of Living Modified Organisms
18. Transit of Living Modified Organisms
19. Use for food, feed and for processing
20. Contained use
21. Unintentional releases and transboundary movements
22. Illegal releases and transboundary movements

PART V

OTHER PROVISIONS CONCERNING LIVING MODIFIED ORGANISMS

23. Offences
24. Dealing with organisms contravening this Act
25. Regulations concerning living modified organisms
27. Indemnities

PART VI

OTHER MATTERS RELATING TO THE PROTECTION OF BIODIVERSITY

27. Implementation of the Convention
28. Inter-agency cooperation

2004 No.

A BILL INTITLED

AN ACT to protect Samoa's biological diversity and to regulate the development, use, handling, and transboundary movement of genetically modified organisms and the applications of modern biotechnology consistent with Samoa's obligations and rights under the *Convention on Biological Diversity* and the *Cartagena Protocol*, and for related purposes.

BE IT ENACTED by the Legislative Assembly of Samoa in Parliament assembled as follows:

PART I PRELIMINARY

- 1. Short title and commencement** – (1) This Act may be cited as the Biological Diversity Protection Act 2004.

(2) This Act shall come into effect on the date it is assented to by the Head of State.

- 2. Interpretation** – (1) In this Act, 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;

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

“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;

“Chief Executive Officer” means the Chief Executive Officer of the Ministry of Natural Resources and Environment;

“Contained use” means any operation, 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;

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

“Develop” means genetic modification of a living organism, field testing, and fermentation of genetically modified organism;

“Environment Officer” has the same meaning as in any Act administered by the Ministry, and includes the Chief Executive Officer and any officer of the Ministry, *or other public servant*, designated as an Environment Officer by the Chief Executive Officer;

“Export” and “exportation” mean intentional transboundary movement from Samoa to another Party or from another Party to Samoa, 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 to other Parties;

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

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

“Genetically modified organism” means any living organism with the exception of human beings that possesses a novel combination of genetic material obtained through the use of modern biotechnology. Include genetically modified human cells and tissues maintained outside the human body. Also include animal cells and tissues maintained in laboratories for research and investigation. The term has the same meaning as living modified organism in the *Cartagena Protocol*;

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

“Microorganism” means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, human, and animal and plant cell in culture.

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

“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;
- (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; or
- (c) any other process or technique prescribed by Regulations made under this Act;

“National Competent Authority” and “Authority” mean the National Competent Authority appointed under section 6;

“Notifier” means any person giving notification of an intended transboundary movement of a genetically modified organism under section 12;

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

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

(2) Words used in this Act, 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 – (1) The Objectives of this Act are to -

manage importation, development, field testing, fermentation, release, or export of genetically modified organisms;

protect Samoa's biodiversity, environment, and people from any adverse effects resulting from genetically modified organisms;

manage importation and release of organisms that are not genetically modified organisms and are not found at large and in the wild in Samoa;

(a) make provision for the protection of Samoa's biological diversity and to give effect to the provisions of the *Convention on Biological Diversity* and the *Cartagena Protocol*;

(b) protect the environment of Samoa and the health of its people by providing an effective regulatory regime applying to genetically modified organisms and the application of modern biotechnology based upon timely notifications being given of transboundary movements, and proper scientific risk assessments being undertaken;

(c) facilitate the application of the benefits of modern biotechnology in Samoa by the implementation of an appropriate regulatory regime; and

(d) confirm the application of Samoa's laws applying in the context of the transboundary movement of genetically modified organisms and the protection of Samoa's biological diversity.

4. Precautionary approach – (1) All persons and agencies having responsibilities under this Act, or whose functions and powers may relate to any matter or thing involving the development, use, handling and transboundary movement of genetically modified organisms and the applications of modern biotechnology within Samoa, shall apply the precautionary approach when discharging their responsibilities and functions, or exercising their powers.

(2) For the purposes of this section, the precautionary approach is applied if, in the event of a threat of damage to the environment or a risk to human health in Samoa, a lack of scientific certainty regarding the extent of adverse effects is not used to postpone a decision being made to minimise the potential adverse effects or risks arising in any way from a matter or thing regulated under this Act.

5. Act binds the State – The provisions of this Act shall bind the State.

PART II
REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS

- 6. National Competent Authority** – (1) The Cabinet shall appoint members, from time to time, to form a National Competent Authority, which shall include the Chief Executive Officer and such other members nominated by the Minister taking into account -:
- (a) the need to ensure adequate representation of relevant Ministries and agencies;
 - (b) the required technical competence of government representatives on the Authority;
 - (c) any approved policy relating to biodiversity and the applications of modern biotechnology; and
 - (d) the need to facilitate adequate participation by appropriate representatives of the community and of commercial and industry interests.
- (2) Appointments made under sub-section (1) may specify a position in a Ministry or agency, and the member from time to time shall be deemed to be the person holding that position on a permanent or temporary basis.
- (3) The Minister shall be the Chairperson of the National Competent Authority, and in the absence of the Minister the Chief Executive Officer shall be Chairperson.
- (4) The Chief Executive Officer may make arrangements for the attendance at any meeting of the National Competent Authority of representatives of any Ministry, agency or institution if the Chief Executive Officer is of the opinion that their attendance shall assist the deliberations of the Authority.
- (5) Meetings of the National Competent Authority shall be called by the Chief Executive Officer at such times and intervals as are necessary for the Authority to discharge its functions under this Act, and for the decisions of the Authority to be made in accordance with the requirements of this Act and the *Cartagena Protocol*.
- (6) The National Competent Authority may determine its own procedures, and decisions may be made or endorsed by circular resolution or in any other approved manner without the need for a meeting of the Authority to be called.
- (7) Members (including coopted members under sub-section (4)) shall be entitled to receive allowances in accordance with a current determination relating to the payment of allowances to committees of the Government.
- (8) The National Competent Authority may authorise the Chief Executive Officer to exercise a power related to any of its functions in a manner which is consistent with any procedures approved by the Authority.

7. **Responsibilities and Powers of the National Competent Authority** – The National Competent Authority established under section 6 shall have the power and responsibility to –
- (a) oversee the implementation within Samoa of all aspects of the *Cartagena Protocol*, including the Advanced Informed Agreement Procedure;
 - (b) authorise the giving of any notification required by this Act and the *Cartagena Protocol* to be given by or on behalf of Samoa;
 - (c) determine and endorse appropriate and cost effective means by which risk assessments are to be undertaken in a scientifically sound manner as required by the *Cartagena Protocol*;
 - (d) make or endorse decisions consistent with the provisions of the *Cartagena Protocol*, including –
 - (i) the exemption of certain genetically modified organisms from the requirements of Part III of this Act by the appropriate application of Article 13 of the *Cartagena Protocol*; and
 - (ii) the review of decisions in accordance with Article 12 of the *Cartagena Protocol*;
 - (e) determine and endorse policies and procedures in relation to -
 - (i) the monitoring of the development, use, handling and transboundary movement of genetically modified organisms within Samoa, and all matters related to the application of modern biotechnology;
 - (ii) risk assessment and risk management applying to any aspect of the development, use, handling and transboundary movement of genetically modified organisms within Samoa, and all matters related to the application of modern biotechnology;
 - (iii) the identification and evaluation of risks and hazards associated with genetical engineering and the introduction of genetically modified organisms into Samoa;
 - (iv) responding to unintentional and unlawful transboundary movements;
 - (v) the dissemination of information to relevant Ministries and agencies to facilitate and support their performance of any related responsibility; and
 - (vi) the keeping of certain information confidential as required by the *Cartagena Protocol*;
 - (f) ensure that all policies and procedures determined and approved under this Act take account of the particular impacts of genetically modified organisms on living communities and areas within Samoa;

- (g) ensure that the customs and traditions of Samoa are taken into account when the development and use of genetically modified organisms and the application of modern biotechnology are under consideration;
 - (h) arrange for the preparation of reports, and authorise the provision of information in accordance with this Act and the *Cartagena Protocol*;
 - (i) ensure that Cabinet, and all Ministries and agencies, are fully informed of any unintended release of genetically modified organisms within Samoa, and of any other matter associated with genetically modified organisms which may affect the well-being of the nation or the health of its people;
 - (j) manage notifications for importation, development, field testing, fermentation, or release of genetically modified organisms in Samoa; and
 - (k) manage importation and release of organisms that are not genetically modified organisms and are not found at large and in the wild in Samoa;
 - (l) develop forms and guides to be used for notification to the NCA concerning genetically modified and other organisms as appropriate;
 - (m) develop containment standards for the containment of genetically modified and other organisms as appropriate;
 - (n) make arrangement for keeping of certain information confidential in accordance with the provision of the Act and the *Cartagena Protocol*.
- 8. Role of the Ministry** – For matters relating to the *Cartagena Protocol* the Ministry shall be the designated national focal point, and shall also be responsible for –
- (a) providing secretariat and support services to the National Competent Authority and the Technical Advisory Group;
 - (b) communicating notifications, information and reports to the Biosafety Clearing House, and as otherwise required by the *Cartagena Protocol*;
 - (c) 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;
 - (d) arranging for and facilitating the review of risk assessments undertaken in accordance with this Act and the *Cartagena Protocol*;
 - (e) arranging for certain information to be treated as confidential in accordance with this Act and the *Cartagena Protocol*;
 - (f) 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 this Act and envisaged by the *Cartagena Protocol* in relation to their use and development within Samoa;

- (g) liaising with other Ministries 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 genetically modified organisms and the application of modern biotechnology within Samoa;
 - (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 Samoa, or proposed to be imported into Samoa, 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 Samoa in the field of biosafety; and
- (h) appointing suitably qualified persons to advise on issues relating to GMOs and applications of modern biotechnology with or affecting Samoa.
- (i) setting fees and charges for the services it would provide and (ii) to empowering to recover costs if it is so decides.
- (j) facilitating 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*.

9. Powers of the Chief Executive Officer – (1) For the purposes of implementing this Act, and to meet the obligations and to exercise the rights of Samoa under the *Cartagena Protocol*, the Chief Executive Officer shall have the power to –

- (a) call meetings of the National Competent Authority and Technical Advisory Groups;
- (b) approve assistance and support to the National Competent Authority.
- (c) specify the means by which scientifically based risk assessments are to be carried out and reported upon, including –

- (i) the appropriate bodies to undertake the risk assessments;
 - (ii) the scope of the risk assessments and the methodologies to be applied; and
 - (iii) payment of the cost of risk assessments, and reimbursement to the Government of any costs associated with undertaking the risk assessments;
- (d) require additional risk assessments to be undertaken when decisions are to be reviewed in accordance with Article 12;
- (e) 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 Samoa under the *Cartagena Protocol*;
- (f) make arrangements for the keeping of certain information confidential in accordance with the provisions of this Act and the *Cartagena Protocol*;
- (g) communicate decisions made under this Act and in accordance with the *Cartagena Protocol*, and provide information and reports to the appropriate body [note that it is in the majority of cases would be the CBD BCH as well as the regional BCH] as required by it;
- (h) arrange for the monitoring and reporting of the effects to the biodiversity, environment and people arising from genetically modified organisms and the application of modern biotechnology within Samoa;
- (i) approve any appropriate program of public information and education concerning genetically modified organisms and the implementation of the requirements under the *Cartagena Protocol* and this Act; and
- (j) do any other act or thing necessary to –
- (i) manage the risks associated with genetically modified organisms and the application of modern biotechnology within Samoa;
 - (ii) ensure that the Ministry fulfils its role as focal point under Article 19; and
 - (iii) effectively liaise with the Biosafety Clearing-House and the CBD Secretariat and Conference of the Parties to the *Convention on Biological Diversity* as well as with Meetings of the Parties (MOP) to the *Cartagena Protocol* –

which are consistent with this Act and the provisions of the *Cartagena Protocol*.

(2) Where the National Competent Authority has exercised a power under section 7 which concerns a matter specified in sub-section (1), the Chief Executive Officer shall exercise the power specified in sub-section (1) in a manner which is consistent with the decision or determination of the National Competent Authority.

10. 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 this law, and all approvals, permits and licences required to be obtained in relation to the importation, exportation, development, use, storage, handling or movement of any genetically modified organism must be obtained under any applicable Act, notwithstanding that additional provision is made under this Act.

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

- (a) microorganisms, plant and animal quarantine and disease control;
- (b) the assessment of impacts on the environment;
- (c) the use of pesticides;
- (d) the importation and exportation of fish and the development of aquaculture;
- (e) the carriage of goods by air or sea;
- (f) the development and use of medicinal drugs for human use; and.
- (g) the development and use of animal remedies.

(3) Nothing in this Act shall affect or derogate from the exercise of any power under any Act, or the obligation to comply with any Act relating to –

- (a) the importation, exportation and transportation of genetically organisms;
- (b) the assessment of impacts of activities on the environment;
- (c) the protection of human health;
- (d) the development, sale and use of therapeutic goods;
- (e) the establishment and undertaking of business activities; and
- (f) consumer protection and the provision of product information to consumers.

PART III PROCEDURES RELATING TO THE IMPORTATION OF GENETICALLY MODIFIED ORGANISMS

11. Notifications of transboundary movements – (1) No genetically modified organism may be imported into Samoa unless notification of the intended transboundary movement has been given to the Ministry by the exporter or the Competent Authority of the country from where the genetically modified organism is to be exported.

(2) A notification given under sub-section (1) shall –

- (a) be in the prescribed form and if no form is prescribed it shall contain all information specified in Annex 1 to the *Cartagena Protocol*; and
 - (b) be accompanied by the prescribed fee; and
 - (c) be delivered to the Chief Executive Officer.
- (3) The Chief Executive Officer shall acknowledge the receipt of the notification within 90 days of its receipt, and the acknowledgement shall state
- (a) the date of receipt of the notification;
 - (b) whether the notification appears to be in compliance with sub-section (2)(a); and
 - (c) whether an approval is required from the National Competent Authority under section 13, or that the National Competent Authority has determined that the approvals required by other applicable laws in Samoa shall be sufficient authorisation for the intended transboundary movement.
- (4) Any failure to acknowledge receipt in accordance with sub-section (3) may not be deemed to be consent to the importation of the genetically modified organism.

12 Approvals for imports – (1) Subject to section 16, this section shall apply to all imports of genetically modified organisms notified under section 12, unless the Chief Executive Officer has given notice under section 12(3)(c) that the National Competent Authority has determined that other applicable laws shall constitute sufficient authorisation.

(2) Subject to sub-section (1), no genetically modified organism may be imported into Samoa unless approval for the transboundary movement has been given by the National Competent Authority under this section.

(3) After consideration of the intended transboundary movement of any Or only those subject to the AIA procedure. genetically modified organism consistent with section 14, the National Competent Authority shall within 270 days of the receipt of the notification relating to it –

- (a) approve the import, with or without conditions;
- (b) prohibit the import;
- (c) request additional information from the notifier;
- (d) advise the notifier 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.

(4) Reasons for any decision shall be provided to the notifier, unless the decision is an unconditional approval for the import, but a failure to give reasons shall not affect the validity of the decision.

(5) Any failure to communicate a decision in accordance with sub-section (3) may not be deemed to be consent to the importation of the genetically modified organism.

13. Scientific risk assessments – (1) Subject to the precautionary approach stated in section 3(2), decisions made under section 13(3) shall be based upon risk assessments which shall –

- (a) comply with any general requirements imposed by the National Competent Authority under section 7(c);
- (b) be in accordance with any requirements imposed by the Chief Executive Officer under section 10(1)(c);
- (c) be undertaken in a scientifically sound manner taking into account internationally recognised risk assessment methodologies and techniques;
- (d) be based upon the information supplied in the notification given under section 12(2) and other available scientific evidence to identify and evaluate possible adverse effects on biological diversity and risks to human health and the environment; and
- (e) be reviewed and assessed by the National Competent Authority.

(2) In accordance with a determination made by the Chief Executive Officer under section 10(1)(c), all risk assessments shall be the responsibility of the notifier and the costs associated with them shall be borne by the notifier.

(3) Nothing in this Act prevents a risk assessment being undertaken in conjunction with any assessment required under any other Act applying to the importation of a genetically modified organism.

14. Confidential information – (1) When giving notification under section 12 or providing any additional information that is required, the notifier 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 Chief Executive Officer 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 or a Technical Advisor, persons undertaking the relevant risk assessment and Environment Officers.

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

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

- (a) the notifier shall be advised of the Chief Executive Officer's decision;
- (b) reasons for the decision shall be provided if requested by the notifier;
- (c) the Chief Executive Officer shall consult with the notifier if requested;
- (d) the decision may be reviewed under section 17; and
- (e) If no agreement can be reached the notifier may withdraw the notification with all the information provided by the notifier.

15. Exemptions from the procedure – (1) The National Competent Authority may exempt the importation of a genetically modified organism from the need to comply with sections 13 and 14 if the notification given under section 12 indicates that the genetically modified organism is –

- (a) to be in transit through Samoa;
- (b) to be the subject of contained use within Samoa;
- (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 and the environment;
- (e) of a type that the National Competent Authority considers 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 Samoa; and
- (f) a pharmaceutical for human consumption that is addressed by other relevant legislation or agreements and subject to the control of other international organisations.

(2) In granting an exemption under sub-section (1), 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 and the environment.

(3) In 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 days after notification has been given –

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

- 16. Review of Decisions** – (1) A notifier or person who has given notification under section 12 may request the Ministry for the review of any decision made under this Act by the National Competent Authority or the Chief Executive Officer, 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; and
 - (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-section (1), the Ministry 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;
 - (c) refer the matter, together with all relevant information that has been provided in support of the request, to the National Competent Authority; and
 - (d) otherwise deal with the review of the decision in the manner prescribed by Regulation
- (3) The National Competent Authority may review and change any decision made under this Act on the grounds stated in sub-section (1) on its own motion, and in that event the notifier shall be informed of the change of decision within 30 days.
- (4) No change of decision made under this section shall avoid the requirement to give notifications under section 12 for subsequent imports of the genetically modified organism to which the change of decision relates, or prevent the Chief Executive Officer from requiring that risk assessments be undertaken in relation to the subsequent imports.

PART IV OTHER REGULATORY REQUIREMENTS RELATING TO GENETICALLY MODIFIED ORGANISMS

- 17. Exportation of Genetically Modified Organisms** – (1) A person who exports any genetically modified organism from Samoa to a Party or a non-Party shall, prior to the export of the organism, give written notification to –
- (a) the Ministry;
 - (b) the Competent Authority in the country where the organism is being exported to; and
 - (c) to any other Ministry or agency as required by law or by this Act.
- (2) A notification given under sub-section (1) shall –

- (a) contain the information specified in Annex 1 to the *Cartagena Protocol*;
- (b) contain any further information required by the Ministry or the relevant Competent Authority in the Part of import.
- (c) otherwise be in compliance with any Regulation prescribing matters relevant to the export of genetically modified organisms from Samoa.

(3) No export of a genetically modified organism may be made from Samoa to any Party unless –

- (a) it is approved by the Competent Authority of the Party in the Part of import
- (b) it is in accordance with any conditions imposed by the relevant Competent Authority in the Party of import; and
- (c) it has any other approval required under any law applying in Samoa.

(4) No genetically modified organism may be exported to a non-Party without the approval of the National Competent Authority, which shall take into account the requirements of this Act and any other relevant law, and the objectives of the *Cartagena Protocol*.

Article 8(2) of the *Cartagena Protocol* requires that the Party of export shall ensure that there is a legal requirement for the accuracy of information. There is a need to provide for measures to address this requirement in the Bill and possibly under this section. Provision of such a requirement has flow on effect on the information that a notifier provides and therefore to ensure that the information provided in a notification is verified as being correct it would be appropriate to require a statutory declaration to this effect.

18. Transit of Genetically Modified Organisms – No genetically modified organisms may be brought into Samoa in transit to any other country unless –

- (a) notification has been given under section 12;
- (b) any condition imposed under section 16(2) is complied with; and
- (c) the requirements of any law relating to customs and excise, quarantine and any other relevant matter are complied with.

19. Use for food, feed and for processing – (1) No person may import any genetically modified organism for use as food, feed or for processing in Samoa unless –

- (a) section 16(3) has been complied with, if it is being imported into Samoa for the first time; and
- (b) all relevant laws regulating its use are complied with, in every case.

(2) Where approval is given for the importation of a genetically modified organism to be used as food, feed or for processing under any relevant law, and the genetically modified organism may be subject to transboundary movement from Samoa, the Ministry shall –

- (a) notify the Biosafety Clearing-House in accordance with Annex II of the *Cartagena Protocol*, within 15 days of an approval for export being given; and

- (b) give other notifications and information in accordance with Article 11(1) and (3) of the *Cartagena Protocol*.
- 20. Contained use** – Any contained use (development, field testing, fermentation, processing) of a genetically modified organism within Samoa shall be in accordance with any condition, requirement or restriction –
- (a) imposed under any relevant law; and
 - (b) prescribed by Regulation, which shall not be inconsistent with the procedures and requirements imposed under any relevant law.
- 21. Unintentional releases and transboundary movements** – (1) Any person who permits or becomes aware of an unintentional release of a genetically modified organism into the environment within Samoa, or an unintentional transboundary movement of a genetically modified organism from Samoa, shall immediately notify the Ministry and provide such information as the Chief Executive Officer may require.
- (2) An unintentional release or transboundary movement of a genetically modified organism for the purposes of this section, is one which –
- (a) has no required approval under this Act; or
 - (b) arises from the breach of a condition of any approval given under this Act – but which has not been intentionally released or moved by any person having control of it.
- (3) Upon receiving a notification under sub-section (1), the Ministry shall immediately give notice of the unintentional release or transboundary movement to –
- (a) the members of the National Competent Authority;
 - (b) the Biosafety Clearing-House;
 - (c) any affected or potentially affected Party or non-Party; and
 - (d) any other international organisation which the Chief Executive Officer determines –
- and shall consult with any affected or potentially affected country to enable them to determine appropriate responses, including the taking of emergency measures.
- (4) A notification given under sub-section (3) shall comply with Article 17(3) of the *Cartagena Protocol*.
- 22. Illegal releases and transboundary movements** – (1) No person may permit, arrange, assist with, counsel, procure, aid or abet a release of a genetically modified organism within Samoa if the release –
- (a) has no required approval under this Act; or
 - (b) arises from the breach of a condition of any approval given under this Act.

(2) No person may permit, arrange, assist with, counsel, procure, aid or abet a transboundary movement of a genetically modified organism from Samoa if the transboundary movement –

- (a) has no required approval consistent with the *Cartagena Protocol*; or
- (b) arises from the breach of a condition of any approval given in relation to it.

(3) In addition to any other penalty imposed for a breach of this section, the person responsible for the breach may be ordered to pay the costs associated with the disposal of the genetically modified organism, including all costs associated with its repatriation from or destruction in any country to which it has been permitted to move.

PART V OTHER PROVISIONS CONCERNING GENETICALLY MODIFIED ORGANISMS

23. Offences – (1) Any person who –

- (a) imports a genetically modified organism into Samoa in respect of which no notification has been given as required by section 12;
- (b) fails to give any notification required by section 12;
- (c) fails to fully disclose all information known to be relevant to the genetically modified organism in a notification relating to it;
- (d) imports a genetically modified organism into Samoa without having an approval required under section 13 or section 16(3);
- (e) fails to comply with any condition or requirement imposed under section 16(2);
- (f) fabricates any risk assessment, or misrepresents any matter associated with a risk assessment undertaken in accordance with section 14 or section 16(3);
- (g) fabricates or misrepresents any scientific or technical information relied upon for the purposes of requesting a review of any decision under section 17;
- (h) exports a genetically modified organism from Samoa in respect of which no notification has been given as required by section 18;
- (i) exports a genetically modified organism from Samoa without having an approval required under section 18(3) and (4);
- (j) breaches section 22(1) in relation to an unintentional release or transboundary movement of a genetically modified organism;
- (k) breaches section 23 in relation to an illegal release or transboundary movement of a genetically modified organism; or

(1) fails to comply with any other obligation or requirement imposed under this Act - commits an offence and shall be liable upon conviction to a fine not exceeding 1000 penalty units or to imprisonment for a term not exceeding 10 years, or to both.

(2) Any person who provides false information in or for any notification given under this Act or when required under this Act to provide any information, commits an offence and shall be liable upon conviction to a fine not exceeding 50 penalty units.

(3) Any person who divulges or deals with confidential information contrary to section 14 (2) or (3) commits an offence and shall be liable upon conviction to a fine not exceeding 50 penalty units.

24. Dealing with organisms contravening this Act – (1) For the purposes of enforcing the provisions of this Act, 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 other Act.

(2) In relation to any genetically modified organism which has been imported into Samoa in contravention of this Act, or which is or remains in Samoa in breach of this Act or any condition imposed under it, an Environment Officer may –

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

(3) Nothing in this Act 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.

25. Regulations concerning genetically modified organisms – (1) The Head of State, acting on the advice of Cabinet, may make Regulations for the purposes of implementing the provisions of this Act and the *Cartagena Protocol*.

(2) Without limiting the generality of sub-section (1), the Regulations may make provision in relation to -

- (a) any forms or fees relating to any notification, approval or other procedure under this Act;
- (b) the keeping of information confidential as provided by this Act;
- (c) any requirements, consistent with laws regulating the carriage of goods by land, air or sea, relating to the transportation of genetically modified organisms; to cover effective containment within Samoa.]
- (d) requirements applying to planned releases of genetically modified organisms;

- (e) requirements applying to field tests of genetically modified organisms and other aspects of research into them;
- (f) the grounds and procedures for the withdrawal of any approval given under this Act, and the implications of a withdrawal of approval;
- (g) emergency responses to any unintentional or unlawful release of a genetically modified organism, or any other which release which has, or may have, an adverse impact on biological diversity or which poses a risk to human health and the environment; and to use GMOs as an emergency response for bioremediation or treatment of outbreaks and it would be advisable to cover that aspect in the legislation.]
- (h) the application of agreed rules and procedures relating to liability and redress for damage resulting from transboundary movements of genetically modified organisms.

(2) Regulations made under sub-section (1) may prescribe offences and impose penalties of fines not exceeding 50 penalty units.

- 26. Indemnities** – The Government, the Minister, the Chief Executive Officer, Environment Officers and members of the National Competent Authority and Technical Advisory Groups established under this Act shall not be liable for any loss or damage, or subject to any criminal prosecution, in relation to any exercise of any power in relation to a genetically modified organism taken in accordance the provisions of this Act.

PART VI

OTHER MATTERS RELATING TO THE PROTECTION OF BIODIVERSITY

- 27. Implementation of the Convention** - (1) The Head of State, acting on the advice of Cabinet, may make Regulations for the purposes of implementing the *Convention on Biological Diversity*.

(2) Without limiting the generality of sub-section (1), Regulations may make provision in relation to –

- (a) the regulation and management of Samoa's biological resources;
- (b) the regulation of any activity which may be detrimental to Samoa's biological diversity;
- (c) the control and eradication of invasive species; to cover organisms that are not GMOs and are not found in Samoa.
- (d) the recognition, protection and application of traditional knowledge, innovations and practices in relation to the management, protection and utilisation of Samoa's biological diversity;

- (e) measures and facilities for in-situ and ex-situ conservation of Samoa's biological diversity;
- (f) the declaration and management of protected areas, and the implementation of special measures to conserve Samoa's biological diversity;
- (g) access to genetic resources within Samoa, and the equitable sharing of benefits arising from the development and exploitation of such resources;
- (h) access to and transfer of technologies relevant to Samoa's biological diversity;
- (i) plans, strategies and measures for the rehabilitation and restoration of degraded eco-systems;
- (j) systems for the monitoring of and reporting on issues and matters relevant to or affecting Samoa's biological diversity; and
- (k) any other appropriate measure to promote the conservation and sustainable use of Samoa's biological diversity.

(3) Regulations made under this section may prescribe offences and impose penalties of fines not exceeding 500 penalty units.

28. Inter-agency cooperation – (1) All regulations made under section 287 shall be consistent with any other law applying in Samoa and which is the administrative responsibility of another Ministry.

(2) Appropriate steps shall be taken, as directed by Cabinet, to ensure that measures relating to the conservation of Samoa's biological diversity are taken by Ministries, government agencies and non-government organisations in a cooperative manner.

Annex 6

BIOSAFETY (GENETICALLY MODIFIED ORGANISMS) REGULATIONS 2004

SAMOA

Arrangements of Provisions

1. Short title and commencement
2. Interpretation
3. Form of Notifications
4. Fees for Notifications
5. Review of Decisions

PURSUANT to section 27 of the *Biological Diversity Protection Act 2004*, **I, MALIETOA TANUMAFILI II**, Head of State, acting on the advice of Cabinet **HEREBY MAKE** the following Regulations:

DATED at Apia this day of 2004

REGULATIONS

1. **Short title and commencement** – (1) These Regulations may be cited as the Biosafety (Genetically Modified Organisms) Regulations.

(2) These Regulations shall come into effect on the date they are signed by the head of State.
2. **Interpretation** – In these Regulations, unless the context otherwise requires –

“the Act” means the *Biological Diversity Protection Act 2004*.
3. **Form of Notifications** – All applications for the notification of transboundary movements of genetically modified organisms into the Samoa required by section 12 of the Act shall be in the form specified in the Schedule.
4. **Fees for Notifications** – The fee to accompany every notification under section 12 of the Act shall be ST\$500.00.
5. **Review of Decisions** – (1) The National Competent Authority may require that a requested review of any decision made under section 17 the Act shall be referred to an independent agency or body acceptable to the Authority and the person seeking the review, which shall report back to the Authority and make recommendations concerning the review.

(2) Any costs associated with a referral under sub-regulation (1) shall be born by the person seeking the review of the decision, but the person may decline to meet the costs and withdraw the request any time prior to being notified of the body determined to undertake the review.

(3) In addition to meeting any costs incurred under sub-regulation (2), all requests for a review of any decision made under section 17 of the Act shall be accompanied by a fee of ST\$250.00

SCHEDULE

NOTIFICATION OF TRANBOUNDARY MOVEMENT OF A GENETICALLY MODIFIED ORGANISM TO SAMOA

Annex 1 of Cartagena Protocol

1. Name, address, telephone and facsimile numbers and email address of -
 - (a) notifier

If not in Samoa then contact details of a contact person in Samoa is also to be provided.

state the nature of the relationship between the Samoan contact person and the notifier.
2. Name and identity of the GMO (GMO) –
 - (a) Domestic classification
 - (b) Biosafety Level of GMO in the state of export
3. Purpose of the transboundary movement to Samoa –
 - (a) import for release
 - (b) import for contained use
 - (c) transit through the Samoa (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 (including field testing, fermentation, or processing), 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 GMO?

In addition, it is important to require information on genetic modification(s) carried out and to include information of genetic constructs, host/vector systems, promoters, markers, donors etc.

- 8. Give full details of the intended use of the GMO.
- 9. Give full details of the quantity and volume of GMO to be transferred.
- 10. Has your organisation undertaken a risk assessment of the GMO to be transferred? (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

There is a need to include field testing, fermentation, and cells and tissues as proposed in the Bill.

- 12. Regulatory status of GMO within the country of export – (State any reason for any previous rejection of approval or ban of the GMO, 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