

Government of Niue

# GOVERNMENT OF NIUE

DRAFT

## NATIONAL BIOSAFETY FRAMEWORK

TOKAGA MOTU

July 2006



-----  
**DISCLAIMER:**

*Information contained in this document is provided by the Government of Niue, and the views presented in the document are those of the Government of Niue. The United Nations Environment Programme (UNEP) is not responsible for the information provided in this document. UNEP does not make any warranty of any kind, either express or implied, including, but not limited to, warranties of the accuracy, reliability, completeness or content of such information in this document. Under no circumstances shall UNEP be liable for any loss, damage, liability or expense incurred or suffered which is claimed to have resulted from the use of or reliance upon the information contained in this document, including, but not limited to, any fault, error, mistake, omission or defect. Under no circumstances shall UNEP be liable for any direct, indirect, incidental, special, punitive or consequential damages.*

## MINISTER'S MESSAGE

It gives me great pleasure, on behalf of the government and people of Niue, to endorse Niue's National Biosafety Framework - Tokaga Motu ("Take Heed") for the safe transfer, handling and use of Living Modified Organisms (LMOs) and Genetically Modified Organisms (GMOs) resulting from modern biotechnology.

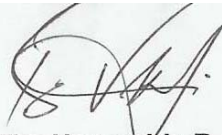
As a small island developing state, Niue faces particular vulnerabilities such as fragile ecosystems, limited biodiversity and a small land area and population. Our way of life relies on agriculture and fisheries. Organic farming and tourism have been identified as priority areas for future economic development, underlining the importance of the environment to Niue's future. Any deliberate or accidental releases of LMOs and GMOs could have an enormous impact on Niue's natural environment, human health and economic development.

Niue is one of the first Pacific island countries to finalise its National Biosafety Framework. Niue ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in July 2002. In line with these commitments, Niue has been developing its National Biosafety Framework since October 2002.

Niue's biosafety regime has been developed in the context of our broader development goals as well as our obligations under the Convention on Biological Diversity. We have made significant achievements in the environment sector since the endorsement of Niue's National Biodiversity Strategy and Action Plan in 2001. This includes passing new environment legislation and establishing the National Council for Sustainable Development, a key advisory body representing a wide range of stakeholders. Work in this area has also taken account of other government projects, such as Taoga Niue, which promotes Niuean culture and heritage.

I commend the work of the National Coordinating Committee that has overseen this project. Last but not least, my *fakaue lahi* to the former Minister for Environment, Honorable Toke Talagi, who has supported the NBF project from its initial stage to the culmination of this framework and most importantly, for his invaluable input and vision.

Finally, I would like to encourage the people of Niue to continue to participate in the implementation of this Framework so that we may all make informed decisions about the risks and benefits of modern biotechnology that we may reap the fruitful outcome of our concerted effort.



**The Honorable B. V Motufoou.**  
**Minister for Environment and Agriculture.**  
**July 2006**

---

**TABLE OF CONTENTS**

Minister's Message.....	1
Terms.....	3
Acronyms.....	3
Technical terms .....	3
Niuean terms .....	4
Acknowledgements .....	5
1. Introduction .....	7
1.1 Context for Niue's National Biosafety Framework .....	7
1.2 Key elements.....	7
2. Status of modern biotechnology in Niue .....	8
2.1 Modern biotechnology surveys .....	8
2.2 Legislation survey .....	9
3. Policies related to biosafety.....	12
3.1 Niue National Biodiversity Strategy and Action Plan .....	12
3.2 Integrated Strategic Plan 2003-2008 .....	12
3.3 National Biosafety Policy .....	13
4. Regulatory Regime .....	15
4.1 Draft Biosafety (Genetically Modified Organisms) Regulations 2006 .....	15
4.2 Draft Environment (Amendment) Bill 2006 .....	21
4.3 Other legislative reforms.....	21
5. Administrative systems.....	22
5.1 Processing requests .....	22
5.2 Monitoring and enforcement.....	25
6. Public awareness and participation.....	25
7. Annexes .....	26
- Annex 1: National Biosafety Policy for Niue.....	27
- Annex 2: Draft Biosafety (Genetically Modified Organisms) 2006 Regulations ..	53

---

## TERMS

### Acronyms

CBD	Convention on Biological Diversity
GEF	Global Environment Facility
GMO	Genetically Modified Organism
LMO	Living Modified Organism
NCSD	National Council for Sustainable Development
NBF	National Biosafety Framework
NCA	National Competent Authority
NCC	National Coordinating Committee
SPREP	South Pacific Regional Environment Programme
UNEP	United Nations Environment Programme

### Technical terms

**Biosafety** describes efforts to reduce the potential risks resulting from modern 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. Niue acceded to the Cartagena Protocol on 8 July 2002. The Protocol came into force on 11 September 2003.

**Convention on Biological Diversity** was adopted at Nairobi in May 1992. Niue ratified the CBD in February 1996.

**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.

**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.

**Risk assessment** measures the likelihood that an LMO or GMO will cause harm to the environment if released. Risk assessments enable informed decisions to be made about GMOs before they are introduced into Niue.

**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 Niue to another country or from another country to Niue.

## **Niuean terms**

**Taoga Niue** is the name of the Government project promoting Niuean culture and heritage.

**Tokaga Motu** means Take Heed and is the name for Niue's National Biosafety Framework.

**Halavaka Ke He Monuina** means A Prosperous Niue and is the name for Niue's Integrated Strategic Plan 2003-2008.

## ACKNOWLEDGEMENTS

The implementing agency for Niue's National Biosafety Framework - Tokaga Motu - project has been the Department of Agriculture, Forestry and Fisheries. Following completion of the Framework, responsibility for implementation of the Framework will pass to the newly created Environment Department.

We gratefully acknowledge the financial assistance provided through United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF).

The project's development has been overseen by the National Coordinating Committee, whose membership included representatives from across the government, non-government organisations, the private sector and the community.

A great number of people were involved in the development of various elements of the National Biosafety Framework. They provided invaluable guidance, assistance and input throughout the process. While it is impossible to name everyone who has provided input into the Framework, we would like to acknowledge the assistance of the following people:


Mr Sauni Tongatule	National Biosafety Framework Manager
Mr Ernest Nemaia	National Coordinating Committee Former Chairperson, Department of Agriculture, Forestry and Fisheries (DAFF)
Mrs Crispina Konelio	Quarantine, DAFF
Mr Paul Pasisi	Fisheries, DAFF
Mr Tom Misikea	National Project Coordinator, DAFF
Mr Tauehega Mautama	Non Government Organisations
Ms Tagaloa Cooper	Environment Department
Ms Judy Nemaia-Tanevesi	Biodiversity Unit
Mr Sionepokau Sionetama	HM Customs
Mr Sione Hetutu	Health Department
Mrs Christine Ioane	Office of External Affairs
Mr Birt Jessop	Trader/Importer
Mr Haden Talagi	Environment Department
Mr. Bandon Pasisi	Director of DAFF
Mrs Katie Freddie	Health Department
Ms Sinahemana Hekau	Crown Law
Mrs Sisilia Talagi	Secretary to Government

---

Mrs Trudy Culling	Trader and Importer
Dr Harry Paka	Director of Health
Ms Charlene Funaki	NBF Rapporteur, DAFF

We would also like to acknowledge the assistance provided by Dr Keneti Faulalo of the UNEP-GEF Biosafety Unit in Samoa for his assistance and guidance throughout the course of the project. A number of consultants assisted the project and we would like to thank Sonya Talagi, Grace Lino, Lofa Rex, Graham Powell, Fiona Ey, Abdul Moeed and Helen Sharpe for their tremendous input.

Finally, but not least, we would like to thank all those who participated in interviews and workshops who were so generous with their knowledge, views and time.



**Tom Misikea**  
**National Project Coordinator**

For further information, please contact:

Environment Department  
**Fonuakula**

tel: +683 4021  
fax: +683 4010  
email: tomanogi\_t@yahoo.com

# 1. INTRODUCTION

## 1.1 Context for Niue's National Biosafety Framework

Modern biotechnology and biosafety are new concepts to Niue. Low-level biotechnology has been used by farmers for centuries to crossbreed plants and animals. This has resulted in higher crop yields, bigger animals or stronger plants. Modern biotechnology can now transfer characteristics from one species to another by taking genes from one species and inserting them into the same or another species to produce new and desired characteristics. This may include resistance to disease or to pests. The products of modern biotechnology are often referred to as Living Modified Organisms (LMOs) or Genetically Modified Organisms (GMOs).

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

Biosafety is a way of reducing potential risks that result from modern biotechnology. It is a means of protecting a country's biodiversity, or its environment, ecosystems, plants, animals and micro-organisms. The key aim of biosafety protection is to safeguard human health and the environment from any possible adverse effects of LMOs or 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, which Niue ratified on 8 July 2002. Since October 2002, the Government of Niue has been developing the National Biosafety Framework - Tokaga Motu ("Take Heed") to address modern biotechnology issues through the use of biosafety methods and to implement its obligations under the Cartagena Protocol.

Niue's environment is vital to its future sustainable development, particularly given Niue's small size, fragile ecosystems and limited biodiversity. Organic farming and tourism have been identified as key export earners and a critical part of Niue's economic development. These activities are heavily dependent on the pristine nature of Niue's environment. It is vital that Niue's vulnerability is not exacerbated by the adverse effects of deliberate or accidental releases of LMOs or GMOs into the natural environment.

## 1.2 Key elements

There are five key elements to the National Biosafety Framework:

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



Each of these various elements is incorporated into Niue's National Biosafety Framework, outlined below.

## **2. STATUS OF MODERN BIOTECHNOLOGY IN NIUE**

The initial stage of the biosafety project involved gathering base-line data about the status and use of modern biotechnology in Niue, existing legislation and capacity building activities relating to biotechnology and biosafety.

### **2.1 Modern biotechnology surveys**

Three surveys were undertaken in 2003 to assess the existing status of modern biotechnology in Niue. These surveys analysed the existing:

- occurrence of modern biotechnology and LMOs and GMOs in Niue;
- organisational responsibilities, cooperative programmes and research activities relevant to biosafety such as quarantine, human health, agriculture, forestry and customs; and
- legal and institutional frameworks.

The surveys found that there had been no reported importation and use of LMOs or GMOs in Niue. However, this may have been in part due to low levels of awareness of LMOs, GMOs and biosafety issues.

The surveys further concluded that there had been no reported uses of modern biotechnology in Niue. In the 1980s, the Department of Agriculture, Forestry and Fisheries conducted low-level biotechnology work at the Vaipapahi Research Farm to strengthen the gene pool of certain species to improve plant and animal stock. This included:

- grafting plants of the same species (such as grafting different lime rootstocks to produce thornless lime trees);
- importing tissue cultures for agriculture (such as demonstration trials with different plant species); and
- artificially inseminating cattle.

These activities were later devolved to the private sector and gradually ceased by the 1990s. However, they involved low-level, and not modern, biotechnology. Modern high-level biotechnology activities require significant resources including specialised scientific skills and highly equipped laboratories. It is unlikely that any institutions in Niue will develop and use modern biotechnology in the near future.

## 2.2 Legislation survey

Legislation surveys were conducted in 2003 and 2004, the latter conducted in combination with a review of environment laws under the International Waters Programme. The surveys found that while there were a number of laws that potentially impacted on LMOs or GMOs, there was no legislation that specifically addressed the issue of modern biotechnology. Existing and proposed laws of Niue that could impact on the implementation of fundamental concepts arising from the Convention on Biological Diversity and the Cartagena Protocol are identified below.

### (a) *Environment Act 2003*

The *Environment Act 2003* is the principal environment law in Niue. It provides the legal foundation for the Environment Department and makes provision for the administration of environment related matters, the enactment of a range of environment regulations and the enforcement of environment laws in Niue. The Act provides a range of factors that must be taken into account in its application including:

- sustainable development;
- protection of indigenous flora and fauna, coastal zones and historic areas;
- preservation of culture and traditions;
- conservation and sustainable use of biological resources; and
- compliance with multilateral agreements.

The functions of the Environment Department are to:

- administer the Environment Act;
- formulate environmental management objectives, policies and laws;
- design and implement programs with line agencies relating to environmental planning and management, environmental impact assessments, waste management and pollution control, nature conservation and protection of historic areas;
- promote environmental awareness, public information programs and community involvement in environmental decision making;
- review legislation and proposals for reform;
- undertake environmental monitoring;
- provide secretariat support to the National Council for Sustainable Development;
- foster the application of traditions in environment management; and
- facilitate compliance with multilateral environment agreements.

The Act also establishes the National Council for Sustainable Development (NCSD) whose function is to advise the Minister on a range of issues including environmental planning, development and resource management and policy implementation. The NCSD also has an advisory role in relation to draft laws, rules and policies.

Comprehensive provision is made for a range of environmental offences. A general power is given to Cabinet to make regulations in relation to a wide range of environmental issues.

**(b) *Agriculture Quarantine Act 1984***

The *Agriculture Quarantine Act 1984* and its Regulations make provision for the protection of plants and animals through import, export and disease controls. The Act applies to genetically modified forms of organisms (through its definitions). Wide enforcement powers are given to quarantine officers.

**(c) *Draft Biosecurity Bill***

The Draft Biosecurity Bill aims to protect the health, environment and agriculture of Niue and to facilitate trade in its animal and plant products. This Bill is part of a regional project undertaken by the Secretariat of the Pacific Community that seeks to harmonise biosecurity laws in the Pacific. Its purposes are to:

- control the introduction and spread of new pests and diseases affecting plants and animals;
- control those pests and diseases affecting plants and animals that are already present in Niue;
- provide for the safe import and export of animals, plants and their products; and
- facilitate cooperation in the prevention of the international movement of pests and diseases affecting plants and animals.

The Draft Bill creates a comprehensive regime to control the import and export of plants and animals, as well as internal control of pests. Articles, pests and diseases that are an unacceptable biosecurity risk to Niue may be declared prohibited. Some exemptions apply, including for goods in transit. Duties are placed on importers and exporters to declare goods and make them available for inspection. Masters and captains must also permit inspections and file documents. The Draft Bill restricts the disposal of garbage and ballast at sea.

The Minister of Agriculture may approve the release of beneficial organisms or biocontrol agents to control or eradicate particular pests or diseases in Niue. This may only be done after receipt of appropriate scientific advice and with the authorisation of Cabinet.

The biosecurity regime would be administered by the National Biosecurity Service. Biosecurity officers are given powers to enforce the regime. A range of public officials, including environment officers, must cooperate in the implementation of the legislation. The regime also facilitates international cooperation in biosecurity matters.

**(d) Customs Act 1966**

The *Customs Act 1966* consolidates a range of laws relating to customs, excise and border control. It regulates the import and export of goods, including prohibiting certain imports and exports. Goods may not be landed without a customs entry being made and written permission given. Customs officers are given extensive enforcement powers.

**(e) Carriage By Air Act 1967**

The *Carriage By Air Act 1967* gives effect to the Warsaw Convention and regulates domestic carriage by air. This could have potential impact for the transportation of LMOs.

**(f) Niue Public Health Ordinance 1965**

The *Niue Public Health Ordinance 1965* consolidates the laws relating to public health. It vests various powers and functions in the Chief Medical Officer. Other relevant provisions relate to sanitation of buildings, dwellings and water supplies.

**(g) Niue Village Councils Ordinance 1967**

This Ordinance provides for the establishment of Village Councils to undertake a local government role. Village Councils have broad powers, including conducting business enterprises, improving housing standards, promoting agricultural and fisheries enterprises and cooperating with the Government to provide social services. To deliver these functions, Councils are empowered to make by-laws and to levy taxes. These provisions are relevant to the recognition of traditions, culture and traditional authority in the biosafety sphere.

**(h) Niue Cultural Council Act 1986**

This Act establishes the Niue Cultural Council to promote Niue's natural history and material culture. The Council's functions are to: promote all aspects of Niuean culture; encourage the study of oral traditions, language and creative arts; encourage archaeology and conservation; and regulate the use and development of historic sites.

### 3. POLICIES RELATED TO BIOSAFETY

#### 3.1 Niue National Biodiversity Strategy and Action Plan

The Niue National Biodiversity Strategy and Action Plan (NBSAP), endorsed in 2001, sets the policy framework for the conservation and sustainable management of Niue's biological resources. The NBSAP is a comprehensive strategy for the implementation of the provisions of the CBD in Niue. The following elements of the NBSAP support, and are directly relevant to, biosafety initiatives:

<b>Theme 4 Governance</b>	<i>Objective 1</i>	<i>Action 1.6</i>
	Enact necessary legislation for the conservation and sustainable use of biodiversity	Ensure that Niue becomes a party to the Cartagena Protocol (biosafety protocol).
	<i>Objective 3</i>	<i>Action 3.2</i>
	Develop appropriate institutional mechanisms and capacity for the implementation of this strategy.	Build capacity in the Environment Unit, Department of Community Affairs, as the key implementing agency to ensure the full realisation of this strategy.

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.

The NBSAP identifies the Department of Community Affairs, Department of Agriculture, Forestry and Fisheries (DAFF) and the Department of Justice, Lands and Survey as the key implementing agencies. DAFF has taken the lead role in developing the National Biosafety Framework. Since the formulation of the NBSAP, the *Environment Act 2003* has established the Environment Department which has key responsibilities in this area. Following finalisation of the National Biosafety Framework, the Environment Department will be responsible for its implementation.

#### 3.2 Integrated Strategic Plan 2003-2008

Biosafety issues also need to be considered in the context of Niue's Integrated Strategic Plan 2003-2008 (Halavaka Ke He Monuina – A Prosperous Niue). The Integrated Strategic Plan sets strategic objectives and guiding principles for the Niue Government. In particular, it addresses activities that develop policy, legal and institutional structures.

The Integrated Strategic Plan sets strategic objectives in five main sectors. The following objectives are of key relevance to the National Biosafety Framework:

<b>ENVIRONMENT: Sustainable management of Niue's natural resources for future generations.</b>	
<b>Strategies</b>	<b>Actions</b>
Global responsibilities	Participate in international environment programmes to assist Niue in meeting its global environmental responsibilities.
Global responsibilities	Seek international assistance in implementing sound environmental policy.
<b>SOCIAL: Enjoy a lifestyle of a thriving, educated and healthy community that has access to a wide range of quality social infrastructure, services and development opportunities.</b>	
Health	Provide quality health services to all residents and promote a healthy lifestyle.
Language and Cultural Heritage	Ensure the survival of Niue's sovereign and ethnic identity through its language, customs and traditions, arts and crafts and history.
<b>ECONOMIC DEVELOPMENT: Maximise benefits from Niue's resources in a sustainable manner</b>	
Agriculture	Facilitate agricultural development of products with proven commercial merits, particularly vanilla, through research and product and market development.
Fisheries	Increase the returns from the fisheries resource in a sustainable and responsible manner.

### 3.3 National Biosafety Policy

#### (a) Policy development

The National Biosafety Policy (Annex 1) was developed within this overarching policy framework. It aims to ensure that Niuean people can make informed decisions in relation to modern biotechnology. This should be done in a way that supports sustainable development for the environment, economic growth and health standards, while not diminishing cultural and traditional values.

Prior to the policy being developed, several public consultation workshops were held in April - July 2004. These consultations aimed to raise awareness about biosafety and to seek community views about the priorities, objectives and community involvement in the development of a biosafety framework. After the policy was drafted in June 2004, further consultation workshops were held to seek community views. The final policy was approved by Cabinet in July 2004.

The National Biosafety Policy 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 LMOs resulting from modern biotechnology that may have adverse effects on sustainable use of biological diversity.

## **(b) Objectives**

The objectives of Niue's National Biosafety Policy are:

- To implement procedures to **control the importation**, and **require labelling**, of GMOs, GMO products and their derivatives into Niue.
- To protect Niue's fragile **environment and biodiversity**, including genetic resources, through biosafety controls.
- To protect the **health** of Niue's residents, taking into account the need for safe medicines as well as the advantages and disadvantages of modern biotechnology.
- To protect **niche markets** for the national economy including eco-tourism, organic agriculture and fisheries, by using biosafety mechanisms.
- To protect Niue's unique **cultural values and customary heritage** that includes our traditional knowledge and genetic resources.
- To enable **consultation** and active participation by all stakeholders in the biosafety framework, including policy development, decision making processes, implementation and monitoring.
- To undertake ongoing **public awareness** activities on biosafety issues with all stakeholders, including government, villages, schools and private organisations.

## **(c) Guiding Principles**

The National Biosafety Policy includes principles to guide its implementation. These are:

- thorough scientific analysis, assessment and evaluation to ensure that the benefits of introduction of any GMOs, GMO products and derivatives, outweigh the costs to Niue's sustainable development including human health, environment, culture, customary heritage, society and economy;
- the precautionary principle, so that 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;

- a culture of information sharing, collaboration and consultation between stakeholders;
- strong, effective and realistic procedures for monitoring and enforcement; and
- revision of the National Biosafety Policy as new technologies and approaches are developed.

The National Biosafety Policy has been incorporated into the regulatory regime, outlined below.

## **4. REGULATORY REGIME**

Niue's regulatory regime for biosafety is contained in the Draft Biosafety (Genetically Modified Organisms) Regulations 2006 (Annex 2). These Regulations would be made under the *Environment Act 2003*. Consequential amendments are also required to the *Environment Act* as provided by the Draft Environment (Amendment) Bill 2006. Both these instruments are currently in draft form awaiting final approval and enactment.

### **4.1 Draft Biosafety (Genetically Modified Organisms) Regulations 2006**

The Draft Biosafety (Genetically Modified Organisms) Regulations 2006 are proposed to be made under the *Environment Act 2003*. This Act formed the National Council for Sustainable Development (NCSA) which is ideally placed to take on the responsibilities of the National Competent Authority. The NCSA is central to environmental management and protection in Niue and represents government, private sector and community interests. While the NCSA is the key decision-making body in relation to biosafety, all its decisions must be endorsed by Cabinet. This accountability mechanism reflects the importance that Niue places on the balancing of risks and benefits of biosafety.

The Draft Regulations implement all operative provisions of the Cartagena Protocol. They provide for:

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



## **(a) Objectives**

The Draft Regulations' objectives are to:

- manage the importation, development, field testing, fermentation, release or export of LMOs and GMOs;
- protect Niue's biodiversity, people, and environment from adverse effects resulting from LMOs and GMOs;
- manage the importation and release of organisms that are not genetically modified and are not found at large and in the wild in Niue;
- regulate GMOs and modern biotechnology applications in Niue so as to manage adverse effects on the environment and to protect human health;
- facilitate Niue's economic development by ensuring that beneficial uses of LMOs, GMOs and modern biotechnology may be applied after appropriate scientific assessments have been undertaken;
- protect Niue's cultural values and heritage that may be affected by modern biotechnology; and
- ensure that Niue's community is made aware of matters relating to LMOs, GMOs and modern biotechnology and can participate meaningfully in the biosafety regulatory process.

## **(b) The Precautionary Principle**

The Draft Regulations enshrine the precautionary principle and compel 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 principle 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 Niue with its associated vulnerabilities and capacity constraints.

The Draft Regulations provide that the precautionary principle is applied if, in the event of a threat of damage to the environment or a risk to human health in Niue, 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. The precautionary principle applies to a broad range of activities involving GMOs, including development, field testing, fermentation, release, processing, use, handling and transboundary movement of GMOs and the applications of modern biotechnology in Niue.

## **(c) National Competent Authority**

The Draft Regulations establish that the National Council for Sustainable Development (NCSD) will be Niue's National Competent Authority for all purposes associated with the Cartagena Protocol. The NCSD comprises representatives of relevant Ministries, the commercial sector and community. It is chaired by the Minister of Environment or, in his

absence, the Director of Environment. The NCSD reports to the Minister for Environment through the Director of Environment.

The NCSD has the power and responsibility to:

- oversee the implementation of the Cartagena Protocol and the advanced information agreement procedure;
- authorise any required notifications to be given by Niue (such as to the Biosafety Clearing House) through the Office of External Affairs;
- determine means, scope, methodologies and the cost basis for undertaking scientific risk assessments;
- make decisions to exempt GMOs from notification requirements and to review decisions which shall be endorsed by Cabinet;
- arrange for the preparation of reports and provision of information regarding GMOs in accordance with the Cartagena Protocol;
- determine and apply policies, procedures and standards relating to GMOs;
- ensure that policies and procedures take into account the impact of GMOs on communities and areas in Niue as well as Niuean customs and traditions; and
- ensure that government is fully informed of GMO issues in Niue, including any unintended uses and other relevant matters that may affect the well being of Niue or the health of Niueans.

GMOs are not permitted to be imported into Niue unless the NCSD has given approval in accordance with the procedure set out in the Draft Regulations.

The NCSD's activities and operations are supported by the Environment Department as the focal point.

#### **(d) Technical Advisory Groups**

One or more **Technical Advisory Groups** may be appointed to assist the NCSD in the discharge of its functions. Technical Advisory Groups are appointed by the Minister, on the NCSD's recommendation. Technical Advisory Groups may have responsibility to:

- report on any applications relating to GMOs including their use, storage, handling, transboundary movement, development, field testing, fermentation or release;
- report on applications for review of a decision by the NCA;
- report on any matters relating to GMOs and the implementation of the Cartagena Protocol in Niue; and
- recommend changes to policies relating to GMOs and modern biotechnology.

The activities and operations of Technical Advisory Group are supported by the Environment Department as the focal point.

### (e) Focal Point

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

- provide secretariat services and support for the NCSD and Technical Advisory Groups;
- receive notifications to forward to the NCSD for consideration and communicate the NCSD's decisions;
- deal with requests for review of decisions and refer such reviews to the NCSD;
- arrange for information to be treated as confidential;
- conduct public awareness and education activities; and
- liaise with other Departments and agencies, both in Niue and overseas, in relation to the implementation and development of biosafety policy.

The Office of External Affairs is responsible for giving notifications to the Biosafety Clearing House and other external parties. This is consistent with current practice and procedures in the Government of Niue. The Environment Department will liaise with the Office of External Affairs in this regard.

The roles and responsibilities of the NCSD are further elaborated under the Administrative Systems section below. The Director of Environment is also specifically empowered to undertake functions to facilitate the focal point activities.

### (f) Operation of other laws

The associated roles of the Departments responsible for the enforcement of other relevant laws, such as quarantine, pesticides, export of living organisms, development and use of medicinal drugs for humans, and customs, are all recognised in the Draft Regulations. None of these other powers and responsibilities are affected in any way by the provisions of the Draft Regulations. Their operation is expressly preserved and any other relevant permits, such as quarantine permits, still need to be obtained by any prospective GMO importer.

### (g) Importation of LMOs

The Draft Regulations implement the **advanced informed agreements (AIA)** procedure set out in the Cartagena Protocol. Any importation of LMOs into Niue must be notified to the Environment Department as the focal point. The notification is made by the exporter or importer of the LMO or the Competent National Authority of the exporting country ("the notifier"). The advanced informed agreement procedure is subject to the timeframes prescribed by the Cartagena Protocol (see further below under Administrative Systems).

The Environment Department will acknowledge receipt of the notification and advise whether the NCSD's approval is required or whether the NCSD and Cabinet has determined that approvals under other laws, such as quarantine laws, are sufficient. Where the NCSD's approval is required, the Environment Department will pass the notification to the NCSD to consider. The notification will also be advertised in Niue by radio and newspaper and the community will be invited to make submissions.

Where the NCSD's approval is required, the NCSD will make a decision based on **scientific risk assessments** and taking into account the **precautionary principle**. An approval will only be given if the risk assessment has demonstrated that the GMO poses no adverse effects or there is a demonstrable benefit to Niue. The NCSD's approval must also be endorsed and approved by Cabinet. The Director of Environment must issue a permit before the GMO may be imported into Niue. The NCSD must notify Cabinet of any decisions it makes in relation to notifications, including decisions to prohibit the import. When informing a notifier of the outcome of the process, the NCSD must give reasons for its decision (except where the import is unconditionally approved).

The representative nature of the NCSD's membership ensures that all stakeholders will be aware of the existence of LMOs in Niue and the purposes for which they are intended to be used.

#### (h) Scientific risk assessments

The underlying presumption applying to risk assessments is that they will be the responsibility of the notifier and will be done at the notifier's expense. The NCSD has wide powers, however, to ensure that risk assessments are done by appropriate bodies and in a scientifically sound manner taking into account internationally recognised risk assessment methodologies and techniques.

Risk assessments will be reviewed by the Technical Group. Risk assessments shall be required to assess potential risks and to identify demonstrable benefits to Niue arising from the importation of the LMO. An approval shall only be given if a demonstrable benefit is established. Specific allowance is made to ensure that confidential information is treated appropriately.

#### (i) Exemptions

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

- in transit through Niue;
- proposed for contained use in Niue;
- 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;

- pharmaceuticals for humans that are addressed by other relevant agreements and international organisations; and
- pharmaceuticals for animal treatment in the event of an emergency that are addressed by other relevant agreements and international organisations.

A fast track exemption procedure applies to imports of pharmaceuticals containing GMOs in the event of a medical emergency. In such situations, the Director of Health may seek direct Cabinet approval for the importation.

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

All decisions to grant exemptions must be endorsed and approved by Cabinet before they take effect.

#### **(j) Review of decisions**

All decisions of the NCSD taken under the Act may be the subject of **review** on grounds consistent with those stated in the Cartagena Protocol. If the NCSD reviews and changes a decision, the amended decision must be endorsed and approved by Cabinet before it takes effect.

#### **(k) Other dealings in LMOs and GMOs**

The main focus of the Draft Regulations is to regulate the importation of LMOs and GMOs into Niue. However, the Draft Regulations also provide for the export, transit, use for food, feed and processing and contained use of LMOs and GMOs. In most of these cases it is left to the applicable domestic laws to fully regulate these matters, whether in Niue or in receiving countries.

The Draft Regulations provide for the development, contained use and testing of GMOs. Such activities are not permitted without the NCSD's approval and in accordance with any conditions imposed by the NCSD. The NCSD may impose any of the provisions relating to the importation of LMOs or GMOs to the development, contained use and testing of GMOs. Specific grounds for the development, contained use and testing of GMOs include an emergency response for bioremediation, treatment of outbreaks of disease or other threats to human health or the environment.

The Draft Regulations provide procedures to deal with unintentional releases and transboundary movements of LMOs. The Environment Department 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 LMOs. The person responsible for the illegal release and transboundary movement may be ordered to pay the costs of disposal of the LMO, including repatriation and destruction in another country.

## **(l) Criminal offences and enforcement**

Enforcement of the regulatory regime is provided through various criminal offences. A range of activities are prohibited including importing LMOs without notifications or approvals, failing to disclose or misrepresenting information relating to an LMO and fabricating risk assessments. It is also an offence to provide false information and disclose any confidential information associated with a notification. In addition to penalties of fines or imprisonment, an offender may be ordered to pay the costs of any required remedial action.

Environment Officers are empowered to enforce the Draft Regulations by monitoring, investigating, seizing and destroying LMOs. The Regulations specifically do not affect any enforcement powers under other laws such as quarantine, customs and excise. The cost of the destruction of a seized organism or the rectification of adverse effects may be recovered as a civil debt.

## **(m) Forms and fees**

All applications for notification are required to be in the prescribed form and accompanied by a fee of NZD1,000. The NCSD may require verification of the information provided in the form by way of a statutory declaration. Cabinet may also direct that issues of liability and redress will be addressed taking account of rules and procedures agreed to by the Parties to the Cartagena Protocol.

## **4.2 Draft Environment (Amendment) Bill 2006**

The Draft Environment (Amendment) Bill 2006 (Draft Bill) proposes to make amendments to the *Environment Act 2003* (the Act). These amendments ensure that the Draft Regulations are fully supported by the Act and facilitate the operation of the biosafety regulatory regime.

The Draft Bill inserts a new provision to make clear the Environment Department has responsibilities relating to the implementation of international conventions relating to the environment. Other amendments make clear that the Minister for Environment, or in his absence the Director of Environment, is the chairperson of the NCSD. The NCSD's powers are clarified to ensure that it can make decisions under the regulations. The Draft Bill also clarifies the range of penalties for breaches of the Act and Regulations.

## **4.3 Other legislative reforms**

In addition to finalising the Draft Regulations, other legislative amendments may be required as a consequence of the biosafety regime.

The Niue Island Plant Quarantine Regulations Notice will be amended to ensure that the Notice to Masters of overseas ships includes reference to the transboundary movement of LMOs and GMOs.

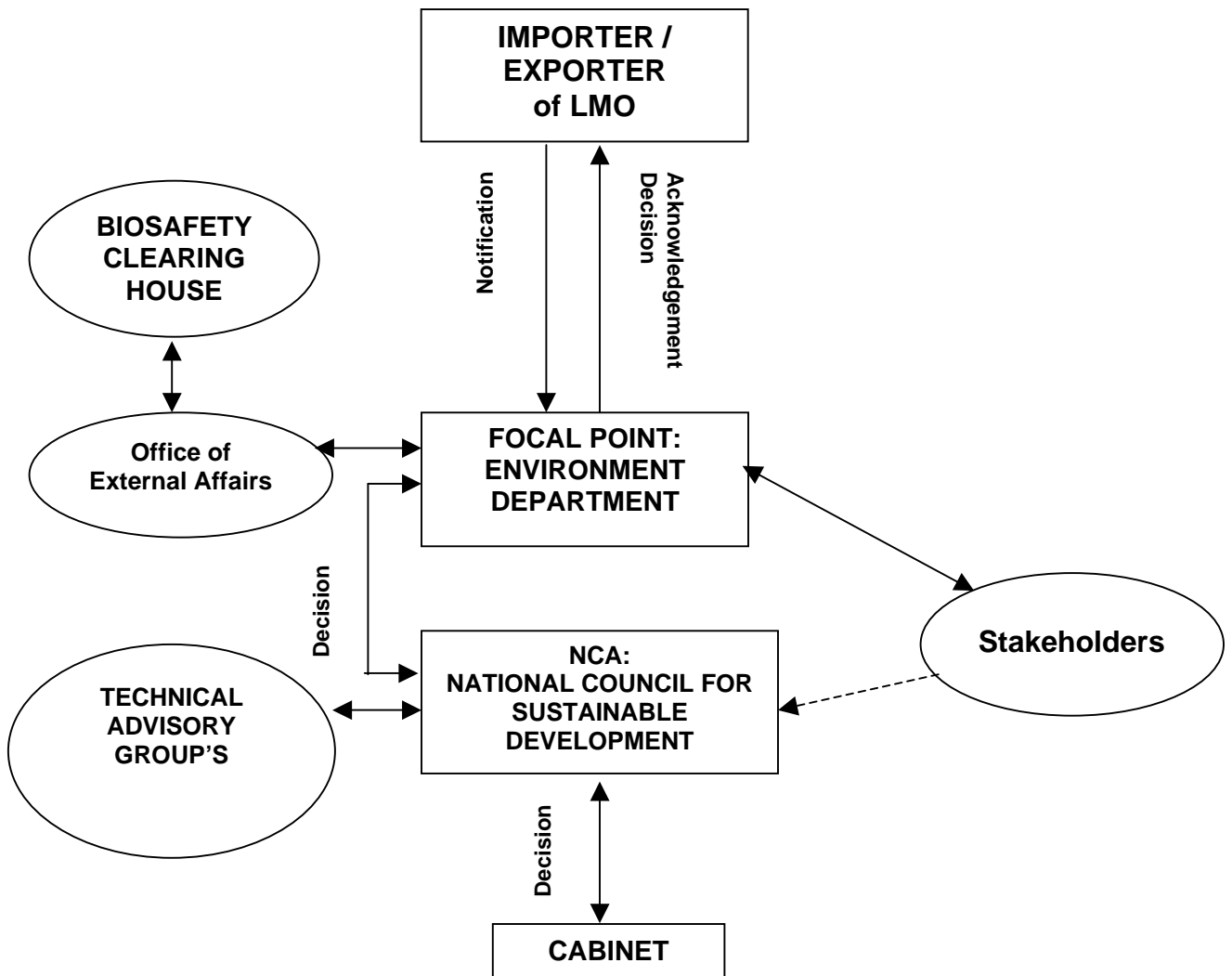
Consideration will be given to making other amendments to the laws of Niue to support the biosafety regime. This will include ensuring that the Draft Biosecurity Bill operates so that approvals for imports of LMOs and GMOs are carried out under the biosafety regime. Consideration may also be given to amendments in related areas such as food product and labelling laws, consumer rights and business licences.

## **5. ADMINISTRATIVE SYSTEMS**

### **5.1 Processing requests**

The Environment Department is responsible for administering the National Biosafety Framework and overseeing its implementation in accordance with the Draft Regulations. Part of this responsibility involves interaction with other relevant line agencies such as the Department of Agriculture, Forestry and Fisheries, Customs and the Health Department. It is important that the administrative systems established to implement the National Biosafety Framework are efficient and facilitate effective decision making, monitoring and enforcement.

The scope and structure of the administrative system to process LMO requests is established by the Draft Regulations. The process is conceptualised in the following flow chart:





**(a) Step 1: Submission of Notification**

First, the importer or exporter of an LMO (or the competent national authority in the country of export) (“the notifier”) must submit a notification to the Environment Department as the designated focal point. The notification must include information as outlined in the Schedule to the Draft Regulations, which incorporates Annex 1 of the Cartagena Protocol. This includes contact details, information about the LMO or GMO and intended use. The notification must also be accompanied by the prescribed fee of NZD 1,000.

**(b) Step 2: Processing of Notification**

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

The Department will also advertise the notification on the radio and in the newspaper and invite the community to make submissions.

After the Department has confirmed that the documentation is complete, it will send the application to the NCSD for risk assessment and consideration where this is required. The NCSD’s membership ensures that key stakeholders are represented.

**(c) Step 3: Risk Assessment and Advice**

A Technical Advisory Group will consider the notification and risk assessments and make recommendations on these matters and any issues of concern to the NCSD.

The NCSD then makes a decision about whether to allow the importation of the LMO or GMO into Niue. This decision must be made taking into account the risk assessment and the precautionary principle. Approval will only be given if the risk assessment identifies that the LMO or GMO has a demonstrable benefit to Niue. The NCSD must advise Cabinet of all its decisions in relation to LMOs or GMOs. If the NCSD approves importation of an LMO or GMO, this decision must also be endorsed and approved by Cabinet to have legal effect. Once endorsed and approved, the Director of Environment will issue a permit.

The NCSD must make its decision within 270 days of the 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 will bear the associated costs.

**(d) Step 4: Communication of Decision**

The NCSD's decision is communicated to the notifier via the Environment Department. The decision must be accompanied by reasons (unless the decision is unconditional approval to import). Approval, however, does not mean the LMO or GMO can be automatically imported. Other relevant laws must also be complied with, such as quarantine or biosecurity requirements.

**(e) Step 5: Appeal**

The notifier may seek review of a decision made by the NCSD on specified grounds. This includes where there is a change in circumstances that may influence the risk assessment or where additional scientific information has become available. Within 30 days of receipt of the request for review, the Environment Department must respond and forward it to the NCSD to review. The notifier must be informed of the outcome of the review within a further 30 days. The public must also be informed of the review of decision.

**5.2 Monitoring and enforcement**

Implementation of the National Biosafety Framework will include monitoring and enforcing the implementation of decisions made by the NCSD. The legislative framework empowers Environment Officers to inspect and monitor the use of LMOs and GMOs. They are also empowered to enforce the legal framework by seizing and destroying LMOs or 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. Penalties for breach of the biosafety regime include fines and imprisonment. A person who has engaged in an illegal release or transboundary movement of an LMO or GMO may also be liable to pay the costs associated with disposal of the LMO or GMO, including repatriation and destruction in another country.

Further monitoring and enforcement strategies will be developed during the implementation of the National Biosafety Framework.

**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 Niue is committed to building community support for the National Biosafety Framework – Tokaga Motu - and its implementation. Various public awareness activities have been undertaken during the course of the development of the National Biosafety Framework and its elements including:

- community consultation workshops on the development of the National Biosafety Policy;
- a booklet on biosafety issues (in Niuean and English) circulated at consultation workshops and public awareness events;
- discussion of biosafety themes at Environment Day and World Food Day;
- radio programmes broadcast (in Niuean and English); and
- Sponsorship of national sporting events.

Community support and understanding will be increased through ongoing public awareness activities. Target groups will be identified and specific material developed for their use, such as printed material and television programmes. This information will help the public to be informed and able to weigh the risks and benefits of modern biotechnology, including LMOs and GMOs.

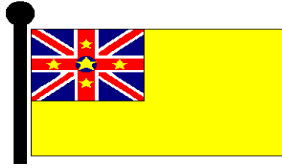
## **7. ANNEXES**

Annex 1      National Biosafety Policy for Niue

Annex 2      Draft Biosafety (Genetically Modified Organisms) 2006 Regulations

## ANNEX 1

# National Biosafety Policy for Niue



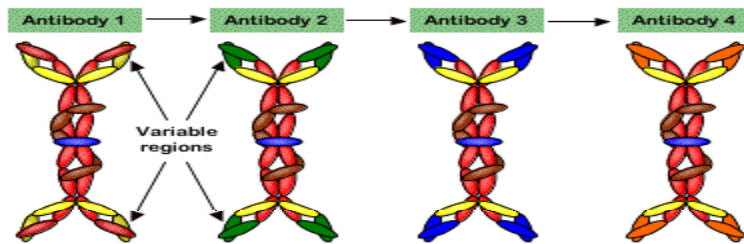
Government of Niue



# GOVERNMENT OF NIUE

TOKAGA MOTU

## NATIONAL BIOSAFETY POLICY



*Drafted by Fiona Ey: Tanoa Consulting Apia, Samoa.*

*August 2004.*

## CONTENTS

1. Introduction
  2. Objectives
  3. Guiding Principles
  4. Definitions
  5. Scope of Policy
  6. Responsibility for Biosafety
  7. Controlled Access and Biosafety Permits
  8. Process of Decision Making for Biosafety Permits
  9. Risk Assessment
  10. Risk Management
  11. Enforcement
  12. Emergency Measures
  13. Export and Transboundary Movement
  14. LMO's in Transit
  15. Cartagena Protocol Implementation
  16. Capacity Building
  17. Awareness Raising
  18. Regional and International Cooperation
- Annex 1 - Information required in applications relating to LMO's  
Annex 2 - Information required in applications relating to LMO products and derivatives  
Annex 3 – Risk Assessment Methodology  
Annex4–Transgenic Organisms

\*\*\*\*\*

## List of Abbreviations

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
COP/MOP	Conference of the Parties and serving as the meeting of the Parties to the Protocol
DAFF	Department of Agriculture, Forestry and Fisheries
DNA	Deoxyribonucleic Acid
ED	Environment Department
FAO	Food and Agriculture Organisation of the United Nations
GM	Genetically modified
LMO	Living Modified Organism

## 1. Introduction

Biotechnology and biosafety are new concepts to Niue. The introduction of modern biotechnology could potentially have a large impact on Niue given its environmental fragility, small size, isolation and economic vulnerability. Since 2002, the Government of Niue has been developing the National Biosafety Framework to address biotechnology issues through the use of biosafety methods. This policy forms part of that framework.

Biosafety is a way of reducing potential risks that result from modern biotechnology, or gene technology, and its products. Biotechnology is a scientific process of taking genes from one species and inserting them into the same or another species to produce new and desired characteristics. This may include resistance to disease or to pests.

Biotechnology has been used by farmers for centuries to crossbreed plants and animals. This has resulted in higher crop yields, bigger animals or stronger plants. Modern biotechnology can now transfer characteristics from one species to another. This could include inserting genes from bacteria into a plant to make the plant resistant to insects.<sup>1</sup> The products of modern biotechnology are often referred to as Living Modified Organisms (LMOs).

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

### BIOTECHNOLOGY AND NIUE

Biosafety is a means of protecting a country's biodiversity, or its environment, ecosystems, plants, animals and micro-organisms. The key aim of biosafety protection is to safeguard human health and the environment from any possible adverse effects of LMOs.

Niue's environment is vital to its future sustainable development, particularly given Niue's small size, fragile ecosystems and limited biodiversity. Organic farming and tourism have been identified as key export earners and a critical part of Niue's economic development. These activities are heavily dependent on the pristine nature of Niue's environment. It is vital that Niue's vulnerability is not exacerbated by the adverse effects of deliberate or accidental releases of LMOs into the natural environment.

#### ***Local biotechnology and LMOs***

At present, there are no reported uses of biotechnology in Niue. In the 1980s, the Department of Agriculture, Forestry and Fisheries conducted low-level biotechnology

---

<sup>1</sup> eg Bt maize, which has been genetically modified using genes from soil bacteria so that it is resistant to insect pests.

work at the Vaipapahi Research Farm to strengthen the gene pool of certain species to improve plant and animal stock. This included:

- grafting plants of the same species (eg grafting different lime rootstocks to produce thornless lime trees);
- importing tissue cultures for agriculture (eg demonstration trials with different plant species); and
- artificially inseminating cattle.

These activities were later devolved to the private sector and gradually ceased by the 1990s. Such low-level biotechnology activities are not intended to be covered by this policy.

Modern high-level biotechnology activities require significant resources including specialised scientific skills and highly equipped laboratories. It is unlikely that Niue will become involved in modern biotechnology in the near future.

## **Imported biotechnology and LMOs**

Given the limitations on biotechnology activities originating in Niue, the main area of biosafety concern for Niue is the importation of LMOs, their products and derivatives, being the results of modern biotechnology conducted outside of Niue.

As at 2003, there have been no reported incidents of importation and use of LMOs in Niue. This may be due in part to a low level of awareness of LMOs and biosafety issues. However, this is an area that will grow in importance as the modern biotechnology industry continues to grow and change rapidly.

Biosafety must also be considered in the context of developments in Niue's key trading partners. For example, the production and sale of genetically modified (or GM) food in New Zealand, which contains LMOs, their products or derivatives, could potentially impact Niue through the importation of food products from New Zealand. LMOs used in imported food and pharmaceuticals are of particular concern for Niue.

### **CONTEXT**

The National Biosafety Policy must be considered in the context of other Niue Government policies including the:

- Integrated Strategic Plan 2003-2008 (Halavaka Ke He Monuina – A Prosperous Niue), which sets strategic objectives and guiding principles for the Niue Government's activities developing policy, legal and institutional structures; and
- Niue National Biodiversity Strategy and Action Plan (2001) which sets the policy framework for the conservation and sustainable management of Niue's biological resources

The National Biosafety Policy also implements Niue's international obligations under the:



- Convention on Biological Diversity (CBD)<sup>2</sup>; and
- Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena Protocol)<sup>3</sup>.

The aim of the Cartagena Protocol is to ensure an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology. LMOs may have adverse effects on the conservation and sustainable use of biodiversity. The Protocol also takes into account the risks that LMOs may pose to human health. It focuses on transboundary movements, or importing and exporting, of LMOs.

## **NATIONAL BIOSAFETY FRAMEWORK PROJECT**

Niue's National Biosafety Framework project *Tokaga Motu* was established in October 2002 with the assistance of the United Nations Environment Programme (UNEP). The objective of the project is to establish Niue's National Biosafety Framework in accordance with the Cartagena Protocol.

The National Biosafety Policy underpins and sets the direction for the National Biosafety Framework. The main elements of the Framework are:

- a biosafety policy to set the direction for the Framework;
- a regulatory system to provide a legal framework for the administrative system;
- Administration System;
- System to Handle Requests; and
- Public Consultation and participation;

Phase One of the project involved gathering base-line data about the status and use of modern biotechnology in Niue, existing legislation and capacity building activities relating to biotechnology and biosafety. The information collected by those investigations informed the development of this policy.

Two public consultation workshops were held in April 2004 to raise awareness about biosafety and to seek community views about the priorities, objectives and community involvement in the development of a biosafety framework. Further consultation workshops were held to seek community views on a draft of the National Biosafety Policy. Outcomes of these workshops have also been incorporated in the policy.

## **ACKNOWLEDGEMENTS**

The development of this policy has involved many people, of whom are named below. The contribution of many people through attendance at workshops and provision of written comments is gratefully acknowledged.

---

<sup>2</sup> The CBD came into force on 29 December 1993. Niue ratified the CBD in February 1996.

<sup>3</sup> Niue acceded to the Cartagena Protocol on 8 July 2002. The Protocol came into force on 11 September 2003.

---

The implementation of the project has been overseen by the National Coordinating Committee:

NBF Framework Manager	Mr Sauni Tongatule
NCC Chairperson	Mr. Ernest Nemaia
Quarantine	Mrs Crispina Konelio
Fisheries	Mr Paul Pasisi
Niue National Project Coordinator (NPC)	Mr Tom Misikea
Non Government Organisations	Mr Tauehega Mautama
Environmental Department	Ms Tagaloa Cooper
Biodiversity Unit	Ms Judy Nemaia-Tanevesi
HM Customs	Mr Sionepokau Sionetama
Health Department	Mr Sione Hetutu
External Affairs	Mrs Christine Ioane
Trader/Importer	Mr Birt Jessop
Environment Department	Mr. Haden Talagi
Health Department	Mrs. Katie Freddie (Policy Draft)
Crown Law	Ms Sinahemana Hekau
Secretary Of Government	Mrs. Sisilia Talagi
Trader and Importer	Mrs. Judy Culling
Director of Health	Dr. Harry Paka

## **2. Objectives**

The objectives of the National Biosafety Policy are:

### **CONTROL OF LMOs, LMO PRODUCTS AND DERIVATIVES**

To implement procedures to control the importation, and require labelling, of LMOs, LMO products and their derivatives into Niue.

### **ENVIRONMENT AND BIODIVERSITY PROTECTION**

To protect Niue's fragile environment and biodiversity, including genetic resources, through biosafety controls.

### **HUMAN HEALTH**

To protect the health of Niue's residents, taking into account the need for safe medicines as well as the advantages and disadvantages of modern biotechnology.

### **ECONOMIC DEVELOPMENT**

To protect niche markets for the national economy including eco-tourism, organic agriculture and fisheries, by using biosafety mechanisms.

### **CULTURE AND CUSTOMARY HERITAGE PROTECTION**

To protect Niue's unique cultural values and customary heritage that includes our traditional knowledge and genetic resources.

### **COMMUNITY PARTICIPATION**

To enable consultation and active participation by all stakeholders in the biosafety framework, including policy development, decision making processes, implementation and monitoring.

### **PUBLIC AWARENESS**

To undertake ongoing public awareness activities on biosafety issues with all stakeholders, including government, villages, schools and private organisations.

### 3. Guiding Principles

The implementation of the National Biosafety Policy should be guided by the following principles:

- thorough scientific analysis, assessment and evaluation to ensure that the benefits of introduction of any LMOs, LMO products and derivatives, outweigh the costs to Niue's sustainable development including human health, environment, culture, customary heritage, society and economy;
- the precautionary principle, so that 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;
- a culture of information sharing, collaboration and consultation between stakeholders;
- strong, effective and realistic procedures for monitoring and enforcement; and
- revision of the National Biosafety Policy as new technology and approaches are developed.

### 4. Definitions

There are a number of technical and scientific terms used in biosafety.

**Living modified organism (LMO)** is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. LMOs are also known as Genetically Modified Organisms (GMOs).

**LMO products and derivatives** are processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology. They include processed food products deriving from LMOs where the modified organism is no longer living. An example of an LMO product or derivative is refined processed oil deriving from genetically modified canola.

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

**Biotechnology** is any technological application that uses biological systems and living organisms to make or modify products for specific use. It may take the form of low level or high level/modern biotechnology.

**Low level biotechnology** includes the transfer of genes through low risk applications where the certainty of outcomes is high. This includes applications of plant grafting and artificial insemination and crossbreeding of the same species.

**Modern biotechnology** (or high level biotechnology) includes the transfer of genes through technological applications from one species to another. In this case, the level of certainty about the outcomes of applications is lower and this increases the risk of potential adverse effects. Examples include transferring animal genes into plants to achieve a desired result such as resistance to pests.

In a technical sense, modern biotechnology means the application of:

- in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- fusion of cells beyond the taxonomic family.

**Transboundary movements** is the movement of a living modified organism from one country to another country. This may be through export and import of LMOs.

**Risk assessment** measures the likelihood that an LMO will cause harm to the environment if released. Risk assessments enable informed decisions to be made about LMOs before they are introduced into Niue.

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

## 5. Scope of Policy

In line with the objectives outlined above, the policy adopts a broad approach to biosafety. The following are covered by the scope of this policy:

- LMOs; and
- LMO products and their derivatives.

This policy, including the administrative framework, Biosafety Permit process, monitoring and enforcement regime, applies to all these organisms and products. This includes

- pharmaceuticals for humans, including vaccines;
- medicines and vaccines for animals; and
- genetically modified foods.

Special provisions are provided to exempt human pharmaceuticals from the Biosafety Permit process in the case of a health emergency (see further below).

A similarly broad range of activities are covered by the policy including:

- import and export of LMOs;

- placing on the market of LMOs and products containing LMOs and their derivatives (such as food, seeds and animal feeds);
- contained use of LMOs (such as research in laboratories); and
- field testing of LMOs and large-scale or commercial releases into the environment (including cropping).

The most relevant activities for Niue are import, export and placing on the market. However, the policy extends to activities such as contained use and testing to take account of future developments.

## 6. Responsibility for Biosafety

Responsibility for administration of the National Biosafety Framework, including implementation of the National Biosafety Policy, lies with the Minister for the Environment and the Environment Department.

The Environment Department is responsible for:

- implementing the National Biosafety Framework, its Policy and Regulatory Regime;
- coordinating the administration of the Biosafety Permit process;
- coordinating activities across government agencies, including through the National Council for Sustainable Development;
- managing information associated with biosafety;
- monitoring activities under the Framework;
- coordinate and enforcement of the Framework.

In addition to the Environment Department's role as administering agency, the Focal Point responsibility under the Cartagena Protocol is undertaken by the External Affairs Office of the Premier's Department.

Biosafety is everyone's responsibility. **Many key stakeholders** play a vital role in the biosafety framework. Coordinating stakeholders and facilitating information exchange is a key function of the Environment Department. Key stakeholders have roles at various steps of the Biosafety Permit process, including the public consultation phases and in the National Council for Sustainable Development. Stakeholders are also involved in the ongoing awareness raising activities.

The range of stakeholders includes:

*Government stakeholders:*

- Department of Agriculture, Forestry and Fisheries (including Divisions responsible for plant protection and quarantine, livestock, fisheries and forestry);
- Environment Department;
- Department of Health;
- Public Works Department (Water Division);

- HM Customs;
- Police (including Immigration);
- Department of Justice, Lands and Survey;
- Economic Planning, Development and Statistics Unit;
- Premiers Department;
- Crown Law Office;
- External Affairs Department; and
- National Disaster Committee (in the event of accidental or intentional release).
- Education Department;

#### *Non-government stakeholders*

- business, including importers;
- civil society groups, including NGOs and agricultural associations, such as the Niue Organic Farmers' Association (NIOFA), Niue Growers Association (NGA);
- village leaders; and
- community.

The **National Council for Sustainable Development** (NCSD) facilitates communication and information sharing between government and non-government stakeholders about biosafety issues. This includes policy development, consideration of applications, monitoring and enforcement. It is also a mechanism to introduce accountability and transparency into the process. The NCSD's membership consists of representatives from the Departments of: Agriculture, Forestry and Fisheries (DAFF); Health; Economic and Planning; Police; Public Works; Community Affairs; Tourism Office, Chamber of Commerce, community interest groups and the Director of the Environment Department.

It is therefore, in regards to Biosafety issues for the NCSD, the National Project Coordinator should be present within the meetings in provision of the application and technical informations only.

## **INFORMATION MANAGEMENT AND COMMUNICATION**

Given the cross-cutting nature of biosafety issues, it is vital that information is shared across government. It is also important that the community is kept informed of activities. Awareness raising is an essential part of the biosafety framework, as identified in the policy's objectives.

The Environment Department is responsible for information and communication activities including:

- undertaking awareness raising activities with government and non-government stakeholders;
- coordinating information about applications for Biosafety Permits;
- circulating reports of meetings (within Niue, regionally and internationally) relating to biosafety by email and/or newsletter across government;
- maintaining a resource centre of biosafety information that may be accessed by government and the community; and

- communicating with the Biosafety Clearing House as required by the Cartagena Protocol.

## **7. Controlled Access and Biosafety Permits**

The National Biosafety Policy introduces a controlled access regime for LMOs, LMO products and derivatives.

Importation, use and development of LMOs, LMO products and derivatives is prohibited unless a Biosafety Permit has been granted. A Biosafety Permit will be required for any person who wishes to:

- import LMOs, LMO products and derivatives into Niue;
- sell or use LMOs, LMO products and derivatives;
- release LMOs, LMO products and derivatives into the environment; or
- engage in modern biotechnology practices.

Collectively, these are known as “LMO activities”.

### Applications for Biosafety Permits

People or companies who wish to engage in any LMO activities must apply to the Environment Department for a Biosafety Permit.

The application must include a range of information that will enable the application to be evaluated and to decide whether or not to grant a Biosafety Permit. The information must be sufficient to enable the Risk Assessment Panel to undertake a thorough risk assessment. The information required varies depending on whether the application relates to:

- LMOs; or
- LMO products and their derivatives.

The information requirements for each category are outlined in Annexes 1-2.

Previous or existing risk assessment reports should be provided to the Environment Department as part of the Biosafety Permit application. These will be considered by the Risk Assessment Panel in light of Niuean conditions. For example, a risk assessment of GM food conducted by Food Standards Australia New Zealand ([www.foodstandards.govt.nz](http://www.foodstandards.govt.nz)) may be filed with the Environment Department and considered by the Risk Assessment Panel.

## **8. Process of Decision Making for Biosafety Permits**

The administrative process for Biosafety Permits is as follows:



## 1. Application

- Applicant lodges an application for a Biosafety Permit with the Environment Department;
- Environment Department checks application for completeness and acknowledges receipt and date of application within 90 days of receiving it;
- 270 day decision-making timeframe commences on the day the application is received;
- Environment Department may ask applicant for further details and if so, the 270 day clock stops until the information is received;
- Environment Department and the applicant identify what information must remain confidential and reach an agreement to this effect.

## 2. Consultation – Community and Government

- Environment Department advises the National Council for Sustainable Development that an application for a Biosafety Permit has been received;
- Environment Department advertises (eg on radio and newspaper) that a Biosafety Permit application has been made and invites written public submissions within a specified timeframe.

## 3. Risk Assessment Panel

- Environment Department coordinates the risk assessment process and establishes a Risk Assessment Panel, drawing in relevant expertise from line agencies such as Department of Agriculture, Forestry and Fisheries and Department of Health depending on Nature of application;
- The Risk Assessment Panel (“the Panel”) analyses, assesses and evaluates the application including conducting background checks and analysing scientific information. Regional and international expertise may be drawn upon if necessary, including through the Biosafety Clearing House;
- The Panel may have regard to any Risk Assessment Guidelines to determine what is low, medium and high risk;
- The Panel must take into account the National Biosafety Policy, particularly its Objectives and Guiding Principles;
- The Panel should consider any appropriate risk management strategies;
- The Panel may ask the applicant for further information if required;
- The Panel makes a Risk Assessment Report which includes an identified level of risk, recommended action and any risk management conditions if required.

## 4. National Council for Sustainable Development Council (NCSD)

- NCSD considers the application, Risk Assessment Report and any community submissions having regard to the National Biosafety Policy, legislation and any guidelines;
- The Risk Assessment may be referred back to the Risk Assessment Panel if it is insufficient or new information has come to light;
- NCSD makes recommendation to Cabinet about whether to grant the Biosafety Permit and any risk management conditions that should apply;
- Environment Department notifies the public about the outcome of the Risk Assessment Report and the NCSD's recommendation to Cabinet by an open forum.

**5. Minister and Cabinet**

- The Minister for Environment takes the NCSD's recommendation to Cabinet;
- Cabinet decides whether or not to grant the Biosafety Permit and may impose conditions on that permit, such as safe handling and releasing to the environment and risk management requirements pending on NCSD's recommendations.

**6. Notification**

- The Environment Department notifies the applicant of the decision and reasons for decision within 270 days of receipt of the application. If necessary, the Environment Department may extend the 270 day period by a defined period of time;
- The Environment Department notifies the public (through radio, newspapers etc) and key stakeholders about the decisions;
- The Environment Department notifies the Biosafety Clearing House about the decision and provides copies of the risk assessment report to the Biosafety Clearing House.

**7. Possible appeal and reviews**

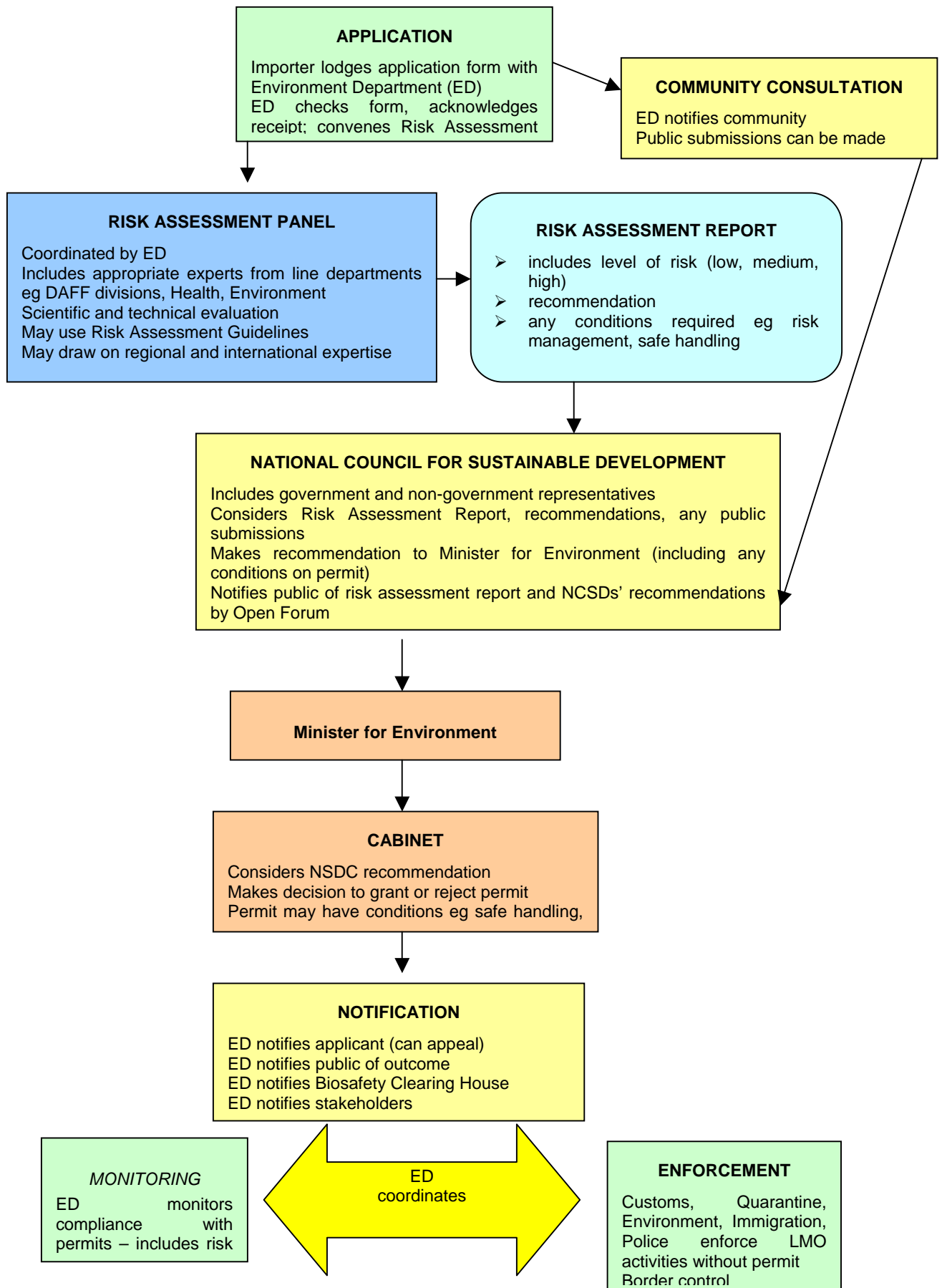
- If Cabinet decides to reject the Biosafety Permit, the applicant may lodge an appeal in the High Court;
- The applicant may apply for a review of a decision where there has been a change in circumstances or additional scientific or technical information is available. A further risk assessment may be conducted. The Environment Department will respond in writing to the review request within 90 days.

**8. Monitoring and enforcement**

- Monitoring of compliance with Biosafety Permits and other enforcement activities are undertaken by the Environment Department, Quarantine, Customs and Police/Immigration (see further below).

The Environment Department is responsible for ensuring that the indicated timeframes are met. These timeframes are maximums and the process may be completed in a shorter timeframe.

The administrative process, including decision-making, monitoring and enforcement, is outlined in the following flow chart using the example of an importer seeking a Biosafety Permit:



## 9. Risk Assessment

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

Risk assessments are based on a scientifically sound, transparent and logical approach. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk. Similarly, decisions should be able to be reviewed once new scientific information comes to light.

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

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

- any hidden costs, including the costs of long-term maintenance of surveillance and monitoring of LMO activities;
- the current status of biodiversity and the effects on biodiversity of introduction of LMOs, LMO products and derivatives;
- risks and possibility of unintentional release and the likelihood of containment;
- potential economic benefits and costs; and
- social and cultural factors including the welfare of the people, the effect of continuing outward migration, churches, traditions and customs.

A detailed risk assessment methodology is contained in Annex 3.

Risk assessments should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the particular LMO activities and potential impact on Niue. Previous risk assessments done elsewhere in relation to the same LMO, LMO product or derivative may be considered. However, such previous risk assessments should be evaluated in light of Niuean conditions.

Testing under local conditions may be conducted. However, this should only be done under carefully contained conditions and where the consensus of scientific opinion is that the LMO, LMO product or derivative is low-medium risk.

The risk assessment is considered in the framework of acceptable and unacceptable levels of risk. Further guidelines will be developed about what degrees of low, medium and high-level risks are acceptable or unacceptable.

As noted above the outcome of the risk assessment is reported to stakeholders through the NCSD. This way, the risks associated with the LMO may be discussed with stakeholders. Applicants who intend to undertake LMO activities, such as importers, are responsible for ensuring that risk assessments are carried out. Penalties are imposed for undertaking LMO activities without a Biosafety Permit.

As a general principle, the applicant should pay for part of the costs incurred on the risk assessment process.

## **10. Risk Management**

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

Risk management requirements should be considered by the Risk Assessment Panel and the NCSD. They should be included in recommendations to Cabinet so that they may be included as conditions on any Biosafety Permits issued.

Examples of risk management include:

- safe handling requirements for the transport and use of LMOs;
- labelling or marking requirements for any products that contain LMOs, LMO products or derivatives;
- limits on where or when LMO activities may be conducted; and
- ensuring that any LMO, LMO product or derivative has undergone an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use.

Any risk management requirements must be complied with by the person or company authorised to conduct LMO activities.

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

## **11. Enforcement**

Responsibility for enforcing the National Biosafety Policy and associated implementing legislation lies with a number of government agencies (i.e. Custom's, Quarantine, Environment, Immigration and Police).

---

## **BORDER CONTROL**

Given the very limited capacity to develop LMOs, LMO products and derivatives in Niue, importation will be the main source of LMO activities. Therefore border control is critical to enforce the National Biosafety Policy. There are a number of agencies involved in border enforcement: Customs, Quarantine, Immigration and Police. Coordination between these agencies is essential.

Standard border control methods should be extended to LMO activities. This should include searching of containers arriving by sea, air freight and passenger baggage. Goods may require cleaning as a risk management measure, such as steam cleaning of all used equipment or vehicles being brought into Niue.

Questions about importation of LMO, LMO products and derivatives should be included on all inward documentation, including passenger quarantine forms and goods manifests.

## **MONITORING AND ENFORCING COMPLIANCE WITH BIOSAFETY PERMITS**

Once a Biosafety Permit has been issued for LMO activities, those activities must be monitored for compliance with the permit and any risk management conditions. The Environment Department is responsible for monitoring LMO activities for compliance. Such monitoring is carried out at specified times, such as weekly, monthly, quarterly or annually, depending on the level of risk and duration of the activity.

To assist the monitoring role, Biosafety Permit holders should report to the Environment Department on a regular basis, timed to coincide with the monitoring visits.

## **COORDINATION OF ENFORCEMENT**

The Environment Department is responsible for ensuring that enforcement activities are coordinated between agencies. To assist this coordination function, biosafety and its enforcement should be a standing item on the agenda of the NCSD.

## **RESPONSIBILITY FOR ADVERSE EFFECTS**

Responsibility for any adverse effects associated with LMO activity lies with the persons or companies who have caused the adverse effect. Those persons or companies will be responsible for making good any damage, including compensating those adversely affected.

## **OFFENCES AND PENALTIES FOR NON-COMPLIANCE**

Implementing legislation will contain a range of offences for unlawful LMO activity and related acts and omissions including:

- engaging in LMO activity without a Biosafety Permit;
- unintentional or negligent release of an LMO, LMO product or LMO derivative; and
- knowingly withholding or falsifying information that should accompany a Biosafety Permit application.

Penalties for these offences should be substantial to provide a deterrent effect and to reflect the levels of risk to the environment and human health posed by LMO activity. They should also take into account any irrevocable or substantial damage to biodiversity, human health and livelihoods.

## **12. Emergency Measures**

### **UNINTENTIONAL AND UNAUTHORIZED TRANSBOUNDARY MOVEMENTS**

The External Affairs Office of the Premier's Department is the contact and the focal point for biosafety matters. It will act as the contact point for notifications of any unintentional transboundary movements, which is LMO activities originating from outside Niue that could impact adversely on Niue's biodiversity and human health. The External Affairs Office will refer any such communications to relevant agencies, as a matter of urgency. This may include notifying the Biosafety Clearing House. Similarly, the External Affairs Office will notify other countries of any unintentional transboundary movements of LMOs originating from Niue.

Matters concerning unintentional release of LMOs, high risk LMO activities or emergency measures may be referred to the National Disaster Committee.

### **HEALTH EMERGENCY EXEMPTION**

In the event of a health emergency, the Director of Health may apply directly to Cabinet for permission to import pharmaceuticals that contain LMOs, LMO products or derivatives. The Cabinet may authorise the import of such pharmaceuticals without following the Biosafety Permit procedure. However, the Cabinet must be satisfied that the health emergency is sufficiently serious to justify the exemption, when weighed against the potential risks to Niue's environment, biodiversity, economy and society.

### **13. Export and Transboundary Movement**

If a person or company wishes to export an LMO, LMO product or derivative from Niue, they must provide accurate information about the LMO, LMO product or derivative to the relevant authority in the importing country. Intentional transboundary movements of LMOs, LMO product or derivatives should be subject to safe handling, transport, packaging and identification requirements. Export and transboundary movements requirements should be consistent with Niue's commitments under regional and international trade arrangements.

### **14. LMO's in Transit**

LMO transshipped in Niue territories should not be offloaded unless the given approval from the Director of Environment and or the Minister of Environment. Vessel masters (i.e. yachts, aircrafts, Cargo ships, tourist ships, fishing boats and all other foreign vessels in port of Niuean territories) should inform the Environment Department of its consignment if the vessel containing LMO is trans-bounded to other destinations and LMO is known to be its consignment.

This is also referred to mercer vessels which sought refuge in Niue.

### **15. Cartagena Protocol Implementation**

The Environment Department is responsible for monitoring the implementation of Niue's obligations under the Cartagena Protocol and reporting to the COP/MOP on implementation measures. Copies of monitoring reports should also be given to the Biosafety Clearing House. As new guidelines and directions about biosafety are developed through the COP/MOP, these should be incorporated into the policy.

### **16. Capacity Building**

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

- strengthening and building the capacity of the administrative framework, including handling requests for LMO activities and developing technical expertise to undertake risk assessments and management;
- strengthening national technical facilities such as equipment and laboratories for risk assessment and inspection purposes and facilities to store and dispose of LMOs; and
- strengthening information systems, including links to the Biosafety Clearing House and a database of applications and information stored in Niue; and



- building the capacity of key stakeholders, both government and non-government, to participate in and contribute to biosafety issues, including the administrative framework.

External technical assistance may be sought for these capacity building activities, through, for example, the Global Environment Facility.

## **17. Awareness Raising**

Awareness raising goes hand-in-hand with capacity building and is one of the objectives of the policy. As noted above, the Environment Department is responsible for ensuring that the government and community is kept informed of biosafety issues and activities. Awareness raising activities may include:

- workshops;
- radio and television programmes (including for screening on inbound flights); and
- distribution of written material such as posters and pamphlets (including at the airport).

Awareness programmes will include simplified information that limits the use of scientific language so that it may be easily understood. Various groups may be targeted including villages, schools, farmer groups, tourists or travellers to Niue and private organisations. Different LMOs or LMO products and derivatives may be targeted for awareness raising where they pose a particular risk to Niue or are likely to be brought into the country. This may include seeds and GM food.

## **18. Regional and International Cooperation**

Information sharing and collaboration is also vital at regional and international levels. This includes information sharing with the Biosafety Clearing House, participation in the activities of the COP-MOP and collaboration and coordination with multilateral organisations such as SPREP, Secretariat of the Pacific Community, Pacific Islands Forum Secretariat, FAO and other relevant bodies.

---

**ANNEX 1 - INFORMATION REQUIRED IN APPLICATIONS RELATING TO LMOs**

1. Name, address and contact details of the importer.
2. Name, address and contact details of the exporter.
3. Name and identity of the LMO and the domestic classification, if any, of the biosafety level of the LMO in the country of export.
4. Intended date or dates of the transboundary movement, if known.
5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
6. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO.
9. Intended use of the LMO or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
10. Quantity or volume of the LMO to be transferred.
11. Any previous and existing risk assessment report consistent with requirements of the Cartagena Protocol.
12. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
13. Regulatory status of the LMO within the country of export (for example, whether it is prohibited in the country of export, whether there are other restrictions, or whether it has been approved for general release) and, if the LMO is banned in the country of export, the reason or reasons for the ban.
14. Result and purpose of any notification by the exporter to other countries regarding the LMO to be transferred.
15. A declaration that the above-mentioned information is factually correct.

---

## **ANNEX 2 - INFORMATION REQUIRED IN APPLICATIONS RELATING TO LMO PRODUCTS AND DERIVATIVES**

1. Name, address and contact details of the importer.
2. Name, address and contact details of the exporter.
3. Name and identity of the LMO product or derivative.
4. Name and identity of the LMO used in the product or derivative and the domestic classification, if any, of the biosafety level of the LMO in the country of export.
5. Scientific or technical information about the LMO used in the product or derivative, if available, such as taxonomic status, common name, point of collection or acquisition, characteristics and origin of the relevant organisms.
6. Intended use of the LMO products and derivatives.
7. Any previous and existing risk assessment report consistent with requirements of the Cartagena Protocol (such as that provided by Food Standards Australia New Zealand – [www.foodstandards.govt.nz](http://www.foodstandards.govt.nz))
8. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
9. A declaration that the above-mentioned information is factually correct.

### ANNEX 3 – RISK ASSESSMENT METHODOLOGY

To fulfill its objective, risk assessment entails, as appropriate, the following steps:

1. An identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
2. An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
3. An evaluation of the consequences should these adverse effects be realized;
4. An estimation of the overall risk posed by the LMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
5. A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
6. Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.

Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

**Recipient organism or parental organisms:** the biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

**Donor organism or organisms:** taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

**Vector:** characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

**Insert or inserts and/or characteristics of modification:** genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

**Living modified organism:** Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

**Detection and identification of the living modified organism:** suggested detection and identification methods and their specificity, sensitivity and reliability;

**Information relating to the intended use:** information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

**Receiving environment:** information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Risk assessments will also take into account the broader considerations identified in the National Biosafety Policy.

\*\*\*\*\*

#### **Annex 4 – Transgenic Organisms;**

To consider:

- a. Pharmaceuticals for Human use?
- b. Pharmaceuticals for Animal use?
- c. LMO's in transit?
- d. LMO's that are used in containment only?
- e. LMO's that are destined for food use only?
- f. LMO's destined for food and feed use?
- g. LMO's intended to be released into the environment?
- h. Products derived from LMO's?
- i. LMO's produced within the borders of Niue?
- j. Imported LMO's only?
- k. Animals intended for food use?
- l. Farm animals?
- m. Other animals – pets, domesticated animals
- n. Micro-organism's when used in diagnostic kit?
- o. Animal or Human cells in culture?
- p. LMO Crops?
- q. LMO for Marine-ecology?
- r. Fisheries?
- s. Any other form of LMO's?

## ANNEX 2

# Draft Biosafety (Genetically Modified Organisms) 2006 Regulations



## **BIOSAFETY (GENETICALLY MODIFIED ORGANISMS) REGULATIONS 2006**

### **NIUE** Arrangement

#### **PART I: PRELIMINARY**

1. Short title and commencement
2. Interpretation
3. Objectives
4. The precautionary approach

#### **PART II: IMPORTING GENETICALLY MODIFIED ORGANISMS**

5. Approval required for import of genetically modified organisms
6. Procedure for application to import genetically modified organisms
7. Processing the application
8. Deciding the application
9. Review of decisions

#### **PART III: OTHER ACTIVITIES RELATING TO GENETICALLY MODIFIED ORGANISMS**

10. Export of genetically modified organisms
11. Transit of genetically modified organisms
12. Use for food, feed and for processing
13. Development, contained use and testing of genetically modified organisms

#### **PART IV: EXEMPTIONS, ENFORCEMENT AND OFFENCES**

14. Unintentional releases and transboundary movements
15. Illegal releases and transboundary movements
16. Offences
17. Dealing with organisms contravening these Regulations
18. Exemptions

#### **PART V: ADMINISTRATIVE FRAMEWORK**

19. The role of the Council
20. The Department
21. The Director

**THESE REGULATIONS** are made on the \_\_\_\_\_ day of \_\_\_\_\_  
by Cabinet pursuant to section 32 of the Environment Act 2003.

2006

---

## PART I PRELIMINARY

### 1. Short title and commencement

- (1) These Regulations may be cited as the Biosafety (Genetically Modified Organisms) Regulations 2006.
- (2) These Regulations shall come into effect on the date that they are made.

### 2. Interpretation

- (1) In these Regulations –

“Act” means the Environment Act 2003;

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

“Authority” means the Council;

“biological diversity” has the same meaning as in the *Convention on Biological Diversity*;

“Biosafety Clearing-House” means the 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;

“Competent National Authority” has the same meaning as in the *Cartagena Protocol*;

“contained use” means any activity, undertaken within a facility, installation or other physical structure, which involves genetically modified organisms that are controlled by approved measures to limit their contact with, and their impact on, the external environment;

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

“Council” means the Environment Council established under section 15 of the Act;

“Department” means the Environment Department established by section 5 of the Act;

“develop” means genetic modification of a living organism; field testing or fermentation of a genetically modified organism;



“Director” means the Director for Environment;

“environment officer” means an environment officer appointed under the Act;

“export” means intentional transboundary movement from Niue to a place outside Niue;

“exporter” means a person who exports or arranges the export of a genetically modified organism.

“import” means intentional transboundary movement into Niue from a place outside Niue;

“Importer” means a person who imports or arranges the import of a genetically modified organism;

“genetically modified organism” has the same meaning as “living modified organism” in the Cartagena Protocol; and includes genetically modified human cells and tissues maintained outside the human body, and animal cells and tissues maintained in laboratories for research and investigation;

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

“micro-organism” means any microbiological entity, cellular or non cellular, capable of replication or of transferring genetic materials, including viruses, viroids, human, animal and plant cell in culture;

“Minister” means the Minister responsible for environment matters;

“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;

“notifier” means any person giving notification of an intended transboundary movement of a genetically modified organism;

“Office of External Affairs” means the office responsible for external administrative matters;

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

“Technical Advisory Group” means any group of technical and/or scientific experts which is appointed by the Council to assess risks associated with the application of GMO's as required in the Regulations and the NBF;

“transboundary movement” means the movement of genetic modified organisms from Niue to another State, or from another State to Niue whether or not that State is a member of the Cartagena Protocol;

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

### **3. Objectives**

The objectives of these Regulations are to –

- (a) protect Niue's people, environment (including biodiversity) and culture from the adverse effects of genetically modified organisms;
- (b) facilitate Niue's economic development by providing for beneficial uses of genetically modified organisms and modern biotechnology after appropriate scientific assessment and analysis; and
- (c) provide for public awareness and participation in matters relating to genetically modified organisms and modern biotechnology.

### **4. The precautionary approach**

- (1) All persons exercising functions, powers and duties under these Regulations shall recognise and provide for the precautionary approach.
- (2) For the purposes of paragraph (1), the precautionary approach means that in the event of threat of harm to the environment or human health, a lack of scientific certainty regarding the extent of adverse effects shall not be used to postpone a decision to minimise the potential adverse effects or threat of harm.

---

**PART II  
IMPORTING  
GENETICALLY MODIFIED ORGANISMS**

**5. Approval required for import of genetically modified organisms**

- (1) No person shall import any genetically modified organism into Niue unless prior written approval has been given by the Council under these Regulations.

**6. Procedure for application to import genetically modified organisms**

- (1) Every person intending to import a genetically modified organism shall, before importation, apply to the Council for approval.

- (2) The application shall include a risk assessment which shall -

- (a) be undertaken in a scientifically sound manner taking into account internationally recognised risk assessment methodologies and techniques;
- (b) be based upon the information supplied in the application, and other available scientific evidence to identify and evaluate possible adverse effects on the environment and risks to human health;
- (c) identify all risks and benefits relevant to the genetically modified organism.

- (3) The application shall be in the form specified in the Schedule and shall be accompanied by the required fee.

- (4) An applicant may indicate that certain information is of a confidential nature, if it is information other than –

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

- (5) If the Director is satisfied that the nature of the information justifies it being kept confidential, the information may only be provided to members of the Council and Technical Advisory Group, undertaking the relevant risk assessment and environment officers.

- (6) No person to whom the information has been provided under paragraph (4) may disclose it to any other person, and it may not be used for any commercial purpose except with the written consent of the notifier.

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

- (a) the notifier shall be advised of the reasons for the decision;
- (b) the Director shall consult with the notifier if requested; and
- (c) the decision may be reviewed under regulation 9.

- (8) Upon receipt of a decision under paragraph (7)(a) the applicant may withdraw the application and have returned all information, documents and reports provided in support of the application.

## **7. Processing the application**

- (1) (a) The Director shall acknowledge receipt of the application within 90 days.  
(b) Failure to acknowledge receipt does not constitute consent to the importation of the genetically modified organism.
- (2) The Director shall notify the application by radio and newspaper, and invite submissions from the community.
- (3) The Council shall review and assess the application and any submissions.
- (4) The Council may at any time -
- (a) request additional information from the notifier;
  - (b) require verification by statutory declaration of any information provided;
  - (c) seek additional information from any source;
  - (d) advise the notifier that the time required for the determination of the matter is to be extended by a stated period;
  - (e) defer its decision until costs associated with the application have been paid.

## **8. Deciding the application**

- (1) The Council may approve the development, field testing, contained use, fermentation or processing of a genetically modified organism if:-
- (a) there are no adverse effects of the organism; or
  - (b) there is a demonstrable benefit to Niue; or
  - (c) the requirements of other applicable laws are sufficient to manage the risks of the organism; or
- (d) the activity is necessary as an emergency response to threats to human health or the environment.
- (2) The Council may impose such conditions on the approval as it thinks fit.
- (3) Any approval given by the Council shall be endorsed by Cabinet before the activity may be commenced.
- (4) The Council shall provide its decision, with reasons, no later than 270 days after considering the application.
- (5) An approval given under this regulation may be withdrawn or suspended by the Council on the grounds that there is a significant risk to the environment (including biodiversity), or human health.

---

**9. Review of decisions**

- (1) Any person may request a review of any decision made under these Regulations, on the grounds that –
  - (a) a change in circumstances has occurred relating to the risk assessment on which the decision was based;
  - (b) significant additional relevant scientific or technical information has become available; or
  - (c) the person is adversely affected by the decision.
- (2) The Council shall decide whether to review the decision within 30 days of receiving the request, and shall –
  - (a) give reasons in writing for its decision;
  - (b) indicate whether a further risk assessment is to be undertaken.
- (3) The Council may decide to review any decision made under these Regulations on its own motion, and in that event the applicant shall be informed of the review within 30 days.
  - (4)
    - (a) The Council may decide to advertise on radio or TV Niue indicating the request for reviewing of decision.
    - (b) The Council shall, in exercising its functions under the Act, observe reasonable standards of procedural fairness, act in a timely fashion and observe the rules of natural justice, and without prejudice to the generality of the foregoing, the Council shall –
      - (i) give to persons who are or who are likely to be affected by such decision an opportunity to make submissions to and to be heard by the Council, or otherwise consult with such persons in good faith;
      - (ii) have regard to all the evidence adduced and to the matters contained in any such submissions or otherwise received in the course of such consultations;
      - (iii) give a written statement of its reasons for making such a decision.
- (5) No change of decision made under this regulation shall avoid the requirement to give notice of, or provide risk assessments for, subsequent imports of the genetically modified organism.

---

**PART III  
OTHER ACTIVITIES RELATING TO  
GENETICALLY MODIFIED ORGANISMS**

**10. Export of genetically modified organisms**

- (1) No person shall export a genetically modified organism to any Party unless –
- (a) the export has been notified to and approved by that Party's Competent National Authority;
  - (b) the export complies with any conditions imposed by that Party's Competent National Authority.
  - (c) the Department has been notified of the export.
- (2) A notification given under paragraph (1) shall contain –
- (a) the information specified in Annex 1 to the *Cartagena Protocol*;
  - (b) any further information required by the Department or the relevant overseas Competent National Authority.
- (3) No genetically modified organism may be exported to a non-Party without the approval of the Council, which shall take into account the requirements of these Regulations, and the objectives of the *Cartagena Protocol* and which has been endorsed by Cabinet
- (4) A genetically modified organism shall not be exported to a non-Party until the approval has been endorsed by Cabinet.

**11. Transit of genetically modified organisms**

- (1) No genetically modified organism may be brought into Niue in transit to any other country unless –
- (a) regulation 6 has been complied with;
  - (b) any condition imposed under regulation 6(4)(b) is met; and
  - (c) the requirements of any law relating to customs and excise, quarantine and any other relevant matter are complied with.

**12. Use for food, feed and for processing**

- (1) No person may import any genetically modified organism for use as food, feed or for processing unless –
- (a) regulation 6 has been complied with, if it is being imported into Niue for the first time; and
  - (b) all relevant laws regulating its use are complied with.

- (2) Where approval is given for the importation of a genetically modified organism for use as food, feed or for processing under any other Act, and the organism will be exported from Niue, the Department shall arrange with the Office of External Affairs;
- (a) to 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) to give other notifications and information in accordance with Article 11(1) and (3) of the *Cartagena Protocol*.

### **13. Development, contained use and testing of genetically modified organisms**

- (1) No person shall engage in any activity relating to the development, field testing, contained use, fermentation or processing of a genetically modified organism without prior written approval from the Council.
- (2) Any contained use, development, field testing, fermentation or processing of a genetically modified organism within Niue shall be in accordance with any condition, requirement or restriction -
- (a) imposed by the Council; and
  - (b) required under any other relevant law.
- (3) Applications for approvals under this regulation shall –
- (a) be in an approved form;
  - (b) contain such information as is determined by the Director;
  - (c) be supported by such further information and verification as may be required by the Council; and
  - (d) be accompanied by the fee set in regulation 19(5)(e).

## **PART IV EXEMPTIONS, ENFORCEMENT AND OFFENCES**

### **14. Unintentional releases and transboundary movements**

- (1) Any person who causes or becomes aware of the unintentional release or transboundary movement of a genetically modified organism shall immediately notify the Department and provide such information as the Director may require.
- (2) An unintentional release or transboundary movement for the purposes of this regulation, is one which –
- (a) has not been approved under these Regulations; or
  - (b) arises from the breach of a condition of any approval given under these Regulations.

- 
- (3) Upon notification under paragraph (1), the Department shall –
- (a) give notice of the unintentional release or transboundary movement to –
    - (i) the members of the Council;
    - (ii) the Biosafety Clearing-House;
    - (iii) any affected or potentially affected person; and
    - (iv) such international organisations which the Director sees fit; and
  - (b) 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 paragraph (3) shall comply with Article 17(3) of the *Cartagena Protocol*.

## **15. Illegal releases and transboundary movements**

- (1) No person may permit, arrange, assist with, counsel, procure, aid or abet a release or escape, or transboundary movement of a genetically modified organism unless in accordance with these Regulations.
- (2) In addition to any other penalty imposed for a breach of this regulation, 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.

## **16. Offences**

- (1) A person commits an offence shall be liable upon conviction to a fine not exceeding 1,000 penalty units or to imprisonment for a term not exceeding 10 years, or to both who –
  - (a) imports a genetically modified organism into Niue in respect of which no notification has been given as required by regulation 7;
  - (b) does not obtain the approval required under regulation 6;
  - (c) fails to fully disclose all information known to be relevant to genetically modified organism in an application relating to it;
  - (d) imports a genetically modified organism into Niue without having an approval required under regulation 8 or 11
  - (e) fails to comply with any condition or requirement imposed under regulation 8;
  - (f) fabricates any risk assessment, or misrepresents any matter associated with a risk assessment undertaken in accordance with these regulations;
  - (g) fabricates or misrepresents any scientific or technical information relied upon for the purposes of requesting a review of any decision under regulation 9;
  - (h) exports a genetically modified organism in respect of which no notification has been given as required by regulation 10;



- 
- (i) exports a genetically modified organism without having an approval required under regulation 10;
  - (j) provides any false or misleading information in relation to a notification of export given in accordance with regulation 10;
  - (k) fails to obtain an approval for an activity related to the development, contained use, field testing, fermentation or processing of a genetically modified organism in accordance with regulation 13;
  - (l) fails to comply with any condition, requirement or restriction applying to the development, contained use, field testing, fermentation or processing of a genetically modified organism under regulation 13;
  - (m) undertakes any activity relating to a genetically modified organism when the approval required under these Regulations is suspended or has been withdrawn;
  - (n) breaches regulation 14 in relation to an unintentional release or transboundary movement of a genetically modified organism;
  - (o) breaches regulation 15 in relation to an illegal release or transboundary movement of a genetically modified organism; or
  - (p) fails to comply with any other obligation or requirement imposed under these Regulations.
- (2) Any person who provides false information in respect of an application or notification 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 regulation 6 commits an offence and shall be liable upon conviction to a fine not exceeding 50 penalty units.
- (4) In addition to any penalty imposed under this Regulation, an offender may be ordered to pay to or reimburse the Government the costs of any remedial action taken or needed to rectify the consequences of any breach.

## **17. Dealing with genetically modified organisms contravening these Regulations**

- (1) For the purposes of enforcing these Regulations, all environment officers may exercise the powers relating to investigating, monitoring, prosecuting and preventing the continuation of any breach that are vested in them in any law.
- (2) In relation to any genetically modified organism which has been imported into Niue, or developed, tested, used, released, fermented or processed in contravention of these Regulations, or which is or remains in Niue in breach of these Regulations or any condition applying to the organism under these Regulations, an environment officer may –
- (a) seize the organism;
  - (b) destroy the organism as determined by the Council or the Director; or
  - (c) deliver up the organism to an officer of another Department to be dealt with in accordance with the law.

- (3) The cost of destroying any seized genetically modified organism, and of rectifying any adverse effects from a genetically modified organism as a result of breach of these Regulations may be recovered as civil debt from any person making use of the organism in contravention of these Regulations.
- (4) Nothing in these Regulations shall affect the powers to search, seize and deal with items under laws relating to plant and animal quarantine, customs and excise and any other law that has application to the development, use, handling, storage or movement of genetically modified organisms.

## 18. Exemptions

- (1) The Council may exempt the importation of a genetically modified organism from the need for approval if the genetically modified organism is –
  - (a) to be in transit through Niue;
  - (b) to be the subject of contained use within Niue;
  - (c) for direct use as food, feed or for processing;
  - (d) agreed by Parties to the *Cartagena Protocol* to be unlikely to have adverse effects on biological diversity or pose a risk to human health or the environment;
  - (e) of a type that the Council, with the endorsement of Cabinet, has determined falls under the scope of any notification given under Article 13 of the *Cartagena Protocol*, and if all requirements of other laws are met in relation to its import into Niue; or
  - (f) a pharmaceutical for human consumption or emergency animal treatment that is addressed by other relevant laws or agreements and subject to the control of other international organisations.
- (2) The Director of Health may apply to the Council for an exemption from the requirement to obtain an approval of any pharmaceutical containing a genetically modified organism on the grounds of a medical emergency.
- (3) When granting an exemption under this regulation, the Council may impose any conditions or requirements relating to the use, storage, handling or movement of the genetically modified organism to minimise any impact on the environment, including biological diversity or human health.
- (4)
  - (a) The Council may require the first import of an organism under regulation 6 (2) to be subject to a risk assessment in accordance with Annex III of the *Cartagena Protocol* and decision by the Council.
  - (b) The Council's decision shall be given in writing not later than 270 days after notification is received.
  - (c) failure to make or communicate a decision within 270 days is not consent to the importation of the genetically modified organism.
- (5) Exemptions under this regulation shall not take effect until endorsed by Cabinet.

---

**PART IV  
ADMINISTRATIVE FRAMEWORK**

**19. The role of the Council**

- (1) The Council shall perform the functions of the Competent National Authority under the *Cartagena Protocol*.
- (2)
  - (a) The Council may appoint a Technical Advisory Group to advise it in relation to genetically modified organisms and the applications of modern biotechnology.
  - (b) The functions of the Technical Advisory Group may include –
    - (i) considering and reporting on any application made under these Regulations, including applications to review decisions;
    - (ii) considering and reporting on any other matter relating to the use of genetically modified organisms in Niue;
    - (iii) investigating any matter relating to the implementation of the *Cartagena Protocol* in Niue; and
    - (iv) recommending policies in relation to genetically modified organisms and the applications of modern biotechnology in Niue.
- (3) The Council shall –
  - (a) oversee implementation of the requirements of the *Cartagena Protocol*, including the Advanced Informed Agreement Procedure (AIA);
  - (b) establish appropriate and cost effective means for undertaking risk assessments, including determining–
    - (i) the appropriate bodies within Niue or elsewhere to undertake the risk assessments;
    - (ii) the scope of risk assessments and the methodologies to be applied; and
    - (iii) the cost of risk assessments, and the persons liable to pay these costs.
  - (c) make decisions under these Regulations, including –
    - (i) exempting certain genetically modified organisms from the requirements of Part I (Article 13 of the *Cartagena Protocol*;) and
    - (ii) reviewing decisions (Article 12 of the *Cartagena Protocol*;)
  - (d) approve any forms required to implement these Regulations,
  - (e) set fees for processing applications under these Regulations.
  - (6) The Council may develop policies, standards and procedures in relation to these Regulations including –
    - (i) monitoring the development, field testing, fermentation, release, use, handling and transboundary movement of genetically modified organisms within Niue, and other matters related to the application of modern biotechnology;

- (ii) risk assessment and risk management applying to any aspect of the development, field testing, fermentation, release, use, handling and transboundary movement of genetically modified organisms within Niue, and other matters related to the application of modern biotechnology;
  - (iii) identification and evaluation of adverse effects associated with genetic modification and the introduction of genetically modified organisms into Niue;
  - (iv) containment standards to be applied to any authorised use, development, field testing or release of a genetically modified organism;
  - (v) responding to unintentional and unlawful transboundary movements;
- (f) In developing such policies, standards and procedures, the Council shall take into account -
- (i) the impacts of genetically modified organisms on communities and areas within Niue;
  - (ii) the customs and traditions of Niue.

## 20. The Department

- (1) The Department shall be the National Focal Point for all purpose associated with the *Cartagena Protocol*.
- (2) For the purposes of these Regulations the Department may –
- (a) provide secretariat and support services to the Council and any advisory committee;
  - (b) deal with requests for the review of decisions in accordance with Article 12 of the *Cartagena Protocol*, and refer such matters to the Council with such reports and additional information as required;
  - (c) arrange for certain information to be treated as confidential in accordance with these Regulations and the *Cartagena Protocol*;
  - (d) conduct programs of public awareness and education in relation to genetically modified organisms and applications of modern biotechnology, and facilitating public participation in relation to the processes prescribed by these Regulations and envisaged by the *Cartagena Protocol* in relation to their use and development within Niue;
  - (e) liaise with other Departments and agencies, and work 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 Niue;
    - (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 Niue, or proposed to be imported into Niue, 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 Niue in the field of biosafety; and
- (f) facilitate appropriate bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of genetically modified organisms, and for the sharing of information and the enhancement of institutional capacities for the purposes of applying the provisions of the *Cartagena Protocol*.

## 21. The Director

- (1) For the purposes of these Regulations, the Director may –
- (a) approve the provision of assistance and support to the Council and advisory committees;
  - (b) require further information to be provided under the Advanced Informed Agreement Procedure;
  - (c) make arrangements for the keeping of certain information confidential in accordance with the provisions of these Regulations and the *Cartagena Protocol*;
  - (d) prepare information and reports required by the *Cartagena Protocol*;
  - (e) arrange for the monitoring and reporting of the effects to the environment and on human health arising from genetically modified organisms and the application of modern biotechnology within Niue;
  - (f) approve and implement any appropriate program of public information and education concerning genetically modified organisms and the implementation of the *Cartagena Protocol*; and
  - (g) do any other act or thing necessary to manage the risks and maximise the benefits associated with genetically modified organisms and the application of modern biotechnology within Niue.
- (2) The powers of the Director shall be exercised consistently with decisions of the Council.
-

**SCHEDULE****NOTIFICATION OF TRANSBOUNDARY MOVEMENT OF A GENETICALLY  
MODIFIED ORGANISM TO NIUE***Annex 1 of Cartagena Protocol*

1. Name, address, telephone and facsimile numbers and email address of -
  - (a) notifier
  - (b) exporter
  - (c) importer(s)

(state the nature of the relationship between the notifier and the exporter or importer)
2. Name and identity of the LMO –
  - (a) Domestic classification
  - (b) Biosafety Level of LMO in the state of export
3. Purpose of the transboundary movement to Niue –
  - (a) import for release
  - (b) import for contained use
  - (c) transit through the Niue (if so, give full details of destination and other relevant approvals)
  - (d) direct use for food, feed or for processing

(Give full details of proposed purpose and means of release, contained use, transit or use as food, feed or for processing.)
4. Intended date/s and means of transboundary movement -
5. Taxonomic status –
  - (a) Common name
  - (b) Point of collection
  - (c) Characteristics recipient organism/or parental organism
6. Centres of origin -

(Describe the habitats where the organisms may persist)
7. Describe the nucleic acid or the modification introduced -
  - (a) What was the modification technique used for the development of the organism?
  - (b) What are the resulting characteristics of the genetically modified organism?
8. Give full details of the intended use of the Genetically Modified Organism.

- 
- 9. Give full details of the quantity and volume of LMO to be transferred.
  - 10. Has your organisation undertaken a risk assessment of the transferred LMO? (Attach any available report and all supporting information and data)
  - 11. Give full details of proposed method(s) for –
    - (a) safe handling
    - (b) storage
    - (c) transport and use
    - (d) packaging and labeling
    - (f) monitoring and reporting on effects
    - (g) disposal and emergency procedures
  - 12. Regulatory status of LMO within the country of export – (State any reason for any previous rejection of approval or ban of the LMO, 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.

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

.....  
Signature

.....  
Date

Approved by Cabinet at the Cabinet Chambers, Alofi, this      day of                      2006.

SIGNED by the Premier

\_\_\_\_\_  
Hon. Mititaiagimene Young Vivian

COUNTERSIGNED by the Clerk to Cabinet

\_\_\_\_\_  
Georgina P. H. Tukiuha

These Regulations are administered by the Environment Department.