National Biosafety Framework

Developed as part of the National Biosafety Framework Project by Vanuatu Quarantine and Inspection Services with financial support provided through UNEP-GEF.

GEF

United Nations Environment Program

Vanuatu Environment Unit

Vanuatu Quarantine Inspect ion Services

VANUATU NATIONAL BIOSAFETY FRAMEWORK PROJECT

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December 2005

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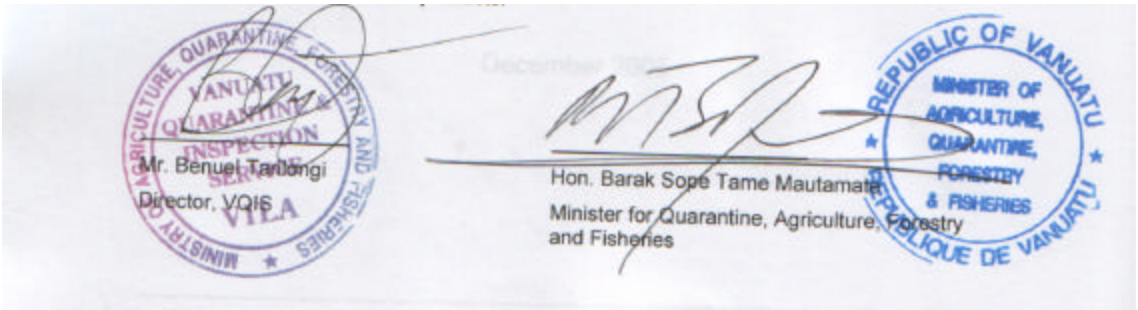
Forward

Vanuatu recognizes that it is venerable both economically and environmentally. Economically, because it has a small economy, based primarily on tourism and agriculture. Environmentally, because it has somewhat a porous defence against importation and invasion of living organisms, products of living organisms and other environmentally unfriendly factors which may pose significant threat to the flora and fauna, both those that are common and those that are endemic to the nation. This is in addition to threats to the people.

Economic development is synonymous with environmental destruction. For example, clearing of natural habitats to make way for construction of infrastructures may lead to decline or even loss of biodiversity. And if no proper environmental risk assessment is carried out, the loss in biodiversity would be significant. Similarly, introduction of foreign living organisms have the potential to impact negatively on the environment, including organisms that are endemic and those that have for many years been cultivated in Vanuatu. Negative impacts of economic development include those that are socio-economic, cultural and environmental. Socio-economic: those that may impinge on human health, as well as that for animals and plants, in addition to the economy. Cultural: those that may induce loss of biodiversity with significant cultural and traditional values. Environmental: those that may reduce total national biodiversity or even loss of some endemic organisms.

Recognizing that development allows for the growth of the nation and its people; at the same time contributing to environmental destruction, is one of the first baby-steps towards protecting, preserving, conserving and sustainable use of national biodiversity. Establishing appropriate legislations to allow for sustainable use, proper environmental risk assessment and management of the national environment is the next step. Conducting and making scientifically sound interpretation of environmental risks and decisions on appropriate strategies to counter negative aspects of economic development on the environment is also an important pro cedure in the complex network of protecting the national environment.

With these things in mind, the National Biosafety Framework (NBF) was developed to take into account national measures aimed to achieve the three objectives of the Convention on Biological Diversity. The three objectives are conservation of biodiversity, sustainable use of its components and fair and equitable sharing of resources arising out of the utilization of genetic resources. To realize these three objectives, the NBF has recommended amendments to relevant legislations and establishment of appropriate mechanisms to recognize and carter for the safe importation and use of living organisms, including living modified organisms and their products.



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Abbreviations

AFA	Agriculture Field Assistants
AIA	Advance informed assessment
BAC	Biodiversity Advisory Council
BCH	Biosafety Clearing House
CBD	Convention on the Conservation of Biological Diversity
CHM	Clearing House Mechanism
CPB	Cartagena Protocol on Biosafety
DARD	Department of Agriculture and Rural Development
EMC Act	Environmental Management and Conservation Act. No 12 of 2002
EU	European Union
GEF	Gobal Environment Facility
GMO	Genetically Modified Organism
LMO	Living Modified Organism
MEA	Multi-lateral Environmental Agreements
NCSA	National Capacity Self Assessment Project
OIC	Office International des Epizooties
PRA	Pre-Import Risk Assessment
SPRIG	South Pacific Regional Initiative on Forest Genetic Resources
TAG	Technical Advisory Group advising a Provincial Government and its staff
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
VEU	Vanuatu Environment Unit
VQIS	Vanuatu Quarantine and Inspection Services

Glossary

Assessment team	A group of not less than 5 people designated to conduct a pre-import risk assessment on a specific import application.
Biological product	Any product derived or extracted from a biological organism including the whole organism or a part thereof, whether alone or in combination with other products of diverse origin. Biological products indude genetically modified organisms (living or processed) for use as human food, animal feed, pharmaceuticals or other purposes.
Biodiversity	The variability among living organisms from all sources including terrestrial marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. Also referred to as Biological Diversity.
Biosafety	Minimising the risks from both the intentional and accidental introduction and spread of organisms with potential to have adverse economic, environmental and socio-economic impacts, including genetically modified organisms and their derivatives and processed products. In this sense, Biosafety is synonymous with biose curity, however the Cartagena Protocol (below) focuses on the biosafety risks associated with GMOs.
Biotechnology	Is the application of science and technology to the direct or indirect use of living organisms, or parts or products of living organisms, in their natural or modified forms.
Cartagena Protocol	An international treaty subsidiary to the United Nations Convention on Biodiversity that provides for international cooperation in the management of transboundary movements of living modified organisms.
Containment	Methods for preventing the movement of organisms and restricting them to a given , secure location.
Constitution	The Constitution of the Republic of Vanuatu.
Convention on Biodiversity	A United Nations Convention that came into force in 1992 to provide for international cooperation in the conservation and sustainable use of biodiversity.
Foreign organisms	Those species which enter ecosystems beyond their natural range through deliberate or accidental introd uction by humans. Also called alien species.
Genetic engineering	Refers to laboratory techniques that enable the transfer of specific genetic information [material] from one organism to another.
Genetically modified feed	Food for livestock consisting of or produced from a genetically modified organism.
Genetically modified food	Human food containing or produced from a genetically modified organism or including products from a genetically modified organism.
Genetically modified organism	An organism whose genetic composition has been altered by the application of modern biotechnology techniques.

Genetics Study of heredity and variation within and between species, including study of the biological markers or DNA that define the characteristics of organisms.

Living Modified Organism A term used to distinguish between living genetically modified organisms and products from those organisms that, while used for food or other purposes, are no longer alive and unable to reproduce or transfer genetic information.

Modern Biotechnology Application of *in vitro* techniques to manipulate and change the genetic structure of organisms.

New species A species of plant, animal, fungus or micro-organism not presently within Vanuatu.

New variety A new strain, variant or genetic modification of a plant, animal, fungus or micro-organism that is not presently in Vanuatu, although other strains or variants may be present.

Organism A living thing. Any biological entity capable of transferring or replicating genetic material [including sterile organisms, viruses and viroids.]

Pathway The route and means by which a foreign species or biotechnology product enters Vanuatu.

Precautionary Principle An obligation to take into account the need for caution where there is scientific and technical uncertainty about the adverse effects of an organism.

Processed biological product A secondary product that results from physical, chemical, radiological or other human processing (including cooking and preservation) of a biological product either alone or in combination with other products. Processing does not always remove biosafety risks including risks of pathogens or genetic modifications entering the human food chain or the environment.

Pre-import risk assessment Prior to the first import of a new organism or variety including genetically modified variety or its product the importing country will review information on risks and make a decision on whether to permit the import or not.

Transposed genes The altered genes of a genetically modified organism.

Acknowledgements

The National Biosafety Team has been active since 2003 to promote debate over biosafety issues confronting Vanuatu and to coordinate national response to the Cartagena Protocol. The Biosafety Team has been the driving force behind development of this Draft Strategy and includes

- Mr Sandy Hoffman MAEL, National Project Coordinator
- Mr Russell NARI, Environment Unit Deputy Director
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- Ms Tina LA'AU, Food Technology Unit of the Department of Trades and industry
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- Mr Ben WOTU, Customs and Revenue Section of the Department of Customs and Internal Revenue
- Mr Taaman MALOSU, Customs and Revenue Section of the Department of Customs and internal Revenue
- Mr. Sowany JOSEPH, Chamber of Commerce.

Development of this Framework was informed by the work of Ms Carol Quashie Williams, Ms Marie Hakwa, Kaltuk Kalmor and Catherine Malosu to assess the local situation on issues addressed by the Cartagena Protocol. Their reports are available from VQIS.

To ensure public participation in the initial development of the Framework a 3 day participatory workshop was held from 13-15 October in Port Vila. Workshop participants made a range of recommendations for the development of the National Biosafety Framework.

The Draft Framework draws on these inputs, scrutiny of legal and administrative provisions and additional consultations and has been drafted by Marie Hakwa, Tekon Timothy Tumukon and Jenny Whyte. A technical review was conducted by My Helen Sharpe, Solicitor, Environment Risk Management Authority, New Zealand.

1. Background

Vanuatu's economy is based on the beneficial use of environmental resources for subsistence and commercial purposes. Tourism, subsistence and commercial agriculture, forestry and subsistence and commercial fisheries are all important sectors of economic activity.

The potential for adverse impacts from the spread of living organisms beyond their natural range is well known. A wide range of plant and animal species have potential to reduce biological diversity of the environment; to affect environmental processes; to reduce the productivity of marine, forest and agricultural eco -systems; to provide vectors for disease; or make human habitats uncomfortable (box 1).

The costs of eradicating species with adverse impacts are often prohibitively high. There are clear economic advantages in preventing introduction of organisms with potential to have adverse impacts on health, environment or economic activities; enabling early interception of accidental introductions; and management of species and varieties after import.

In recognition of this the Vanuatu Government has well-established legal and administrative procedures for managing and preventing the introduction of potential animal and plant pests and disease organisms.

The advent of modern biotechnology has enabled creation of new varieties and strains of species through *in vitro* genetic manipulation. Genetically modified organisms (GMOs) have potential to provide economic benefits through increased productivity, reduced chemical usage and enhanced nutritional and health status of crops. However, they also present new risks including:

- cross-over of modified genetic material into natural biological populations;
- displacement of fertile natural biological populations;
- possibility of allergic health reactions to novel genetic material in common foods.

Box 1: The example of the Little Red Fire Ant (*Wasmannia auropunctata*)

Fire Ants are well known invasive species that have become established in a variety of countries with severe repercussions.

The Little Red Fire Ant was accidentally introduced to Sola. It is now established on many of the islands in TORBA Province.

The Fire Ant is able to infest houses, gardens, agricultural areas and forests. Although small, it has an extremely painful bite. Irritation from frequent bites can lead to infected sores on children. Gardening and agricultural work can be disrupted due to the discomfort from working in infested areas. Biodiversity is reduced as a result of stings affecting the health of small animals, including birds. In New Caledonia Fire Ants have spread a fungal pathogen that affects native forest species.

Eradication of the Fire Ant from TORBA Province would incur annual expenditure of hundreds of million vatu over a decade or more. Should the Fire Ant become established in adjacent SANMA Province it will have severe impacts on activities in the agriculture and tourism sectors.

Some people also hold ethical reservations about the application of these technologies, and the entry of genetically modified material into the human food chain.

Recognition of these concerns has fuelled extensive international debate about the environmental, health and economic risks associated with the unmanaged use and spread of GMOs. After years of negotiation the Cartagena Protocol, a subsidiary treaty to the United Nations Convention on Biodiversity, came into force in 2003. The Cartagena Protocol provides a range of measures to manage the transboundary movements of living modified organisms. Vanuatu became a signatory to the Cartagena Protocol in 2003. It is anticipated

that ratification of the Cartagena Protocol on Biosafety will take place in the first ordinary session of Parliament in 2005.

As a party to the Cartagena Protocol Vanuatu's Government has accepted responsibility to implement a minimum level of control over the import and export of living genetically modified organisms (LMOs). The National Biosafety Project has been operational since 2003 to inform and advise the Government on national responsibility under the Cartagena Protocol. The project has looked at a wide range of opportunities for the management of GMOs, including LMOs. The objective of the National Biosafety Project was to develop a National Biosafety (GMO) Framework to clearly define the policy, legal, administrative and technical instruments through which Vanuatu will:

- comply with the provisions of the Cartagena Protocol;
- outline and ensure safety for the environment, health and economy from the use and movement of the GMOs;
- provide for informed agreement to the use of GMOs at both national and individual levels.

Discussion led to a decision to integrate national GMO policy within the broader biosafety context. This effectively incorporates consideration of GMOs into the mainstream consideration of all biosafety risks. This Biosafety Framework is the resultant output. Key elements of this Framework reflect consideration that has been given to:

- The benefit of having a single point of contact for regulating and managing biological imports and their derivatives.
- The administrative and financial advantage of a single administrative pathway for the risk assessment and management of foreign organisms that may pose a biosafety risk. A single process will remove elements of uncertainty or confusion present in the current legal and *ad hoc* arrangements.
- The financial advantage of incorporating biosafety into the work and legal responsibility of existing organisations rather than creating a new stand alone administrative agency. Similarly there is a perceived advantage in building on the knowledge of existing institutions instead of starting from scratch with a stand alone institution.
- Recognition that the current rate of entry of GMOs into Vanuatu is low, and the risks posed by GMOs and their derivatives are best considered within the broader context of national biosafety. There is no benefit from addressing GMOs in isolation.
- Legal obligations accepted by Vanuatu as a signatory to the Convention on Biological Diversity and the Cartagena Protocol.
- The importance of providing opportunity for wide organisational and public participation in decision making processes on risk assessment and regulation of new species and varieties of organisms, including GMOs.
- Recognition that the science of GMOs is new and largely unproven. As a consequence decisions over GMOs are inevitably informed by ethical, social, cultural and religious views as well as technical science.

2. National Biosafety Framework

2.1 Aim

To minimise the risks from both the intentional and accidental introduction and spread of organisms with potential to have adverse economic, environmental and socio-economic impacts, including genetically modified organisms and their derivatives and processed products.

2.2 Scope

Biosafety management applies to the introduction and spread of all biological organisms with the exception of human beings[1]. This includes new variants or strains of organisms that result from traditional or modern biotechnology.

Biosafety management includes, but is not limited to:

- A risk analysis and decision making framework;
- Control over the introduction, release and establishment of new species or varieties of organisms (including monitoring, reporting and containment);
- Border control, surveillance and emergency response for the exclusion and eradication of unwanted organisms and associated pathogens;
- Information, education and awareness to allow informed use of organisms that may have potential to cause harm (including labelling of foods and animal feeds) and to facilitate community responsibility;
- A ***precautionary*** approach with respect to new organisms, including genetically modified organisms and their derivatives and processed products; and
- A system for liability and redress.

Given the unknown nature of modern biotechnology consideration of risks is not limited to risks recognised and understood at the present time. National biosafety requires consideration be given to potential risks, especially where imported organisms or their derivatives might enter the human food chain. Risks to elements of native biodiversity and agro-biodiversity are both recognised as important. The risks of unintentional intra and inter island spread of organisms as a result of natural or man-made disasters are also important considerations, especially where containment measures are implied. Where information is inadequate to confirm that risks are slight or manageable a precautionary principle will be applied. Applications will be refused until further information becomes available.

Biosafety provisions apply to all imports of living organisms with the sole exception of human beings. All importers of living organisms, including inter-government agencies, government departments and Ministries, private companies, NGOs and individuals are subject to biosafety pre-import risk assessment requirements. Biosafety requirements apply without exception to VQIS, Fisheries, Forestry, Agriculture and Rural Development and other Departments, along with the programmes they manage (including where organisms are introduced for application in the food industry or for bio-control purposes). To facilitate

[1] The application of modern biotechnology to humans is an area, which may need future consideration. Research is being undertaken in areas such as transgenic organ implants, and genetic engineering to eliminate genetic defects. However regulation of the movement of people for biosafety reasons has broad implications, and is not appropriate at this point in time.

regulation of living organisms VQIS will maintain and publish an electronic register of biosafety decisions.

Processed products and other derivatives of biological organisms, including but not limited to, human food, animal feed, agricultural supplements, and pharmaceuticals may also pose a biosafety risk, especially where they enter the human food chain or are incorporated into the environment. To facilitate entry of processed biological products the VQIS will publish electronically and regularly update a schedule of processed biological products with potential to pose a biosafety risk, noting the quarantine or biosafety risks posed by these imports where appropriate. Processed biological products not listed on this schedule will be exempted from pre-import risk assessment and allowed to be imported. This system reflects current procedures in place for screening quarantine risks.

A small number of processed biological products may be internationally exempted from biosafety provisions as a result of legal international treaties. The VQIS will publish electronically a schedule of biological organisms and products exempted from biosafety provisions due to the operation of other international agreements for reference by importers and government officials.

The Department of Customs and Inland Revenue will continue to play their present role in intercepting imports that should have undergone pre-import risk assessment and bringing these to the attention of VQIS.

As part of this Biosafety Framework, VQIS will work with other in-country organisations to facilitate development of appropriate provisions for management, control and eradication of in-country biosafety risks.

2.3 Desired outcomes for 2015

Outcome 1: A consistent national approach to biosafety that is based on:

- A legally constituted process for biosafety risk assessment and pre-import risk assessment, which provides effective control over the introduction, establishment and management of new species or varieties of organisms (including GMOs).
- A legally constituted process for biosafety risk assessment and advance informed consent which provides effective management over the introduction and use of processed products including pharmaceuticals, food and feed derived from GMOs

Outcome 2: Effective and best practice risk analysis and management procedures are in place that place the onus for provision of information, monitoring and reporting on the importer.

Outcome 3: Effective networks including in-country networks and networks with regional organisations and agencies placed in other countries that enhance the technical expertise available in country.

Outcome 4: Individuals are able to make informed decisions on their use of particular species and products and are able to employ appropriate management measures.

2.4 Legal context

Several existing laws provide the initial legal context for biosafety management. These include the:

- Plant Protection Act No. 14 of 1997 which provides for the exclusion and effective management of plant pests (including aquatic plants) and quarantine pests through information sharing, risk assessment procedures and the issue of import and export permits.

- Animal Importation and Quarantine Act No.7 of 1988 [CAP.201], which provides controls on animal importation including the importation of animal products and biological products into Vanuatu.
- Environmental Management and Conservation Act No.12 of 2002 which enables management measures for the control of foreign organisms, makes the introduction of foreign organisms subject to environment impact assessment provisions and establishes the Biodiversity Advisory Council.

To provide for initial implementation of the Biosafety Framework, a range of amendments are needed to strengthen th is body of legislation, especially in their ability to recognise and address genetically modified organisms and to affirm a consistent national approach to biosafety issues. Recommended amendments are detailed in chapter 4.

In addition there is opportunity to use the Sale of Medicines (Control) Act [Cap.48] to record all importation of medicines that pose a biosafety risk. This is not at present implemented by the Department of Customs[2]. Recommendations in this respect are detailed in chapter 4.

Biosafety provisions relating to food safety exist in the Food (Control) Act No.21 of 1993. These are being expanded with the drafting of the food labelling regulations under the Food (Control) Act.

Implementation of comprehensive biosafety measures requires a range of new measures that are not enabled by existing legislation. Concerns and gaps in the current legal context include:

- The present legal and procedural distinction between the import of animals, plants and other living organisms.
- The risk assessment and management of human food and animal feed which contain GMOs or their derivatives.
- The risk assessment and management of processed products with potential to transfer pathogens to consumers, livestock, crops or the environment.
- The risk assessment and management of human pharmaceutical products containing or derived from GMOs. Present drug regulations are the Dangerous Drugs (Control) Act [Cap.12], which prohibits and controls the importation of narcotics; and the Sale of Medicines (Control) Act [Cap.48].

Discussion on these issues has already commenced in the context of a *model biosecurity law* drafted by the Pacific Community (SPC). As these concerns span the responsibility of several sectoral agencies, consultation will be required before legislative gaps can all be fully addressed. This should proceed as a matter of priority. Additional recommendations are detailed in chapter 4.

The Biosafety Framework gives priority to preventing the introduction of new risks not as yet present in Vanuatu through effective border and entry control. Strengthening of the mechanisms to support containment and management of intra-island and inter-island movements in organisms that present a biosafety threat is also required. At present these mechanisms are applied on an *ad-hoc* basis by several agencies. It is imperative that these arrangements continue where high priority threats are identified.

Strengthening internal biosafety is important, but is assigned secondary priority. Detailed mechanisms will be negotiated during the life of this Biosafety Framework. Capacity building at institutional and individual level is encouraged at an early stage to enable effective introduction of internal biosafety mechanisms and to minimise the spread of high-risk organisms.

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[2] Personal Communication with Acting Director of Customs Ben Wotu on 08 Nov. 04 at 3.05 p.m. (22544)

2.5 Constraints

A range of constraints has potential to influence implementation of the Biosafety Framework. These include:

- The fragmented nature of existing import and quarantine provisions within the Plant Protection Act (1997) and the Animal Importation Act (1988), and their indirect approach to organisms that are Prokaryotes, Eukaryotes, Fungi and Viruses.
- The low level of awareness of biotechnology issues generally, and of the issues of biosafety and GMOs in particular. As a consequence the potential benefits and adverse impacts of introduced organisms and varieties, including GMOs, are not well understood. Inadequate awareness is not confined to the general public. Some sectoral departments and their agents have limited understanding of biosafety, and have yet to place importance on biosafety within their work programmes.
- In the past staff of the Departments of Fisheries, Forestry, Agriculture, Health, Customs and Inland Revenue, Trade and Industry, and the Environment Unit and the Vanuatu Investment Promotion Authority have varied in their interpretation of the legal regime governing importation of living organisms. This does not promote understanding and inter-departmental co-operation. Effective implementation of a standard national biosafety framework requires a clear legal framework and comprehensive understanding of the responsibilities of each Department.
- The scientific techniques and language used in modern biotechnology are hard for people without specialist scientific training to understand. A low level of literacy contributes to low levels of participation in technical decision-making processes.
- Little commitment has been demonstrated either to voluntary personal responsibility on the movement of high-risk organisms or to voluntary personal eradication of local pest populations. Surveys conducted by the National Biodiversity Strategy and Action Plan Project suggest there is a tendency to assign responsibility to whoever introduced the species (Tapisuwe, 2001). This is emphasised in common nomenclature such as "Fish blong Government" and "Agriculture Rope"[3].
- There are significant risks from the potential spread of species such as Little Red Fire Ant that are already present in Vanuatu but not yet widespread. Existing provisions for containment of inter-island movements are inadequate. However, Departments have inadequate staff numbers and resources for post-release monitoring of new organisms (including GMOs) and managing response to accidental introductions and unintended impacts.
- There are significant gaps in in-country scientific and technical capacity that contribute to a lack of capacity to conduct genetic research, scientific risk assessment and monitoring impacts of species once introduced. Gaps are present in terms of technical equipment, operational costs and scientific skills. This makes the precautionary principle especially important.

Measures to address and minimise these constraints so as to provide an efficient and effective biosafety mechanism are included within the implementation strategies presented in chapters 4, 5 and 6.

[3] "Fish Blong Government", *Gambusia affinis*, was introduced to control malaria. "Agriculture Rope" is one local common name for Glycine *(Neonotonia wightii)* introduced by the Livestock Improvement Project of the then Department of Agriculture.

3. Administrative procedures providing for biosafety

3.1 National Competent Authority and National Focal Point

Signatories to the Cartagena Protocol undertake to nominate a National Biosafety Focal Point and a Competent National Authority with respect to dealings in LMOs. The National Focal Point is the designated authority and contact point for all matters relating to the Cartagena Protocol. The Competent National Authority has the technical and administrative capacity to process applications and coordinate the pre-import risk assessment process.

Vanuatu Quarantine and Inspection Services is designated the National Biosafety Focal Point and the Competent National Authority for ensuring national biosafety. This means VQIS is assigned responsibility to:

- administer the National Biosafety Framework;
- coordinate pre-import risk assessment processes;
- issue biosafety permits for items to be imported;
- conduct point of entry quarantine and biosafety checks and issue point of entry quarantine clearances;
- conduct or coordinate monitoring of biosafety conditions applied on imports, including rights of entry to inspect facilities and property for the purpose of ensuring compliance with biosafety requirements;
- implement inter and intra island biosafety measures, or liaise with other agencies able to conduct measures to manage, reduce or eliminate internal biosafety threats.

Many Government Departments share an interest in biosafety issues. A particular point of mutual interest is with the Environment Unit, which is responsible for ensuring that activities within Vanuatu do not cause undue environmental harm. VQIS is to liaise with other agencies in the implementation of the National Biosafety Framework to ensure harmonisation and consistency of border control with in-country processes.

3.2 Pre-import risk assessment

Pre-import risk assessment underlies modern biosafety mechanisms (box 2).

The administrative mechanism for pre-import risk assessment on the import and use of new species and varieties of organisms including new genetically modified strains, is outlined in figure 1, and described in detail in this section.

The following administrative process provides for pre-import risk assessment of new organisms and varieties, including genetically modified varieties, and processed biological products, including those which contain derivates of GMOs, to be permitted for use in Vanuatu. Its provisions exceed the minimum requirements of the Cartagena Protocol. Time limits cited represent the maximum time in which an action or decision can be taken under the Cartagena Protocol. Most decisions and actions will be taken in less than the maximum prescribed

Box 2: Pre-import risk assessment

Pre-import risk assessment is a key principle of modern biosafety mechanisms. It requires that adequate information is available prior to initial import to allow an informed decision to be made on the use of new species and varieties.

The Cartagena Protocol sets minimum standards for pre-import risk assessment to regulate the first transboundary movement of Living Modified Organisms (LMO's) between parties. The Protocol recognises that a country may introduce national regulations that go beyond the minimum requirements established by the Protocol.

Pre-import risk assessment procedures typically include the following essential steps.

- Notification
- Risk Assessment
- Requests for further information where necessary to make an informed decision
- Public participation
- Decision

time limit.

a. Any individual or organisation (including a government agency or local business) intending to import into Vanuatu any new species or variety (including genetically modified varieties, their derivatives or products) or a processed biological product listed on the schedule of processed biological products with potential to pose a biosafety risk must make a written application for permission to the Director of Vanuatu Quarantine and Inspection Services (VQIS). Administrative responsibility for notification and assessment may be designated to an officer within the VQIS in accord with normal administrative provisions. However, responsibility for all decisions, permits and official notifications is vested in the Office of Director.

All applications are subject to a non-refundable fee, which covers VQIS's administrative costs for vetting the application. Information required in the notification is detailed in appendix 1 and 2.

Application requirements also apply to species, varieties or products listed on the schedule of processed biological products that will transit Vanuatu.

b. Within a maximum of thirty days of receipt of the notification the VQIS must provide the applicant written acknowledgement of receipt of the notification application.

c. Within a maximum of sixty days of receipt of the notification VQIS will screen the application, make one of the following decisions and communicate this decision to the applicant:

- further information is required from the applicant to facilitate screening of the application.
- risk assessment is required in association with relevant agencies.
- an import permit for org anisms or their products not requiring risk assessment by domestic biosafety laws or as a consequence of other international agreements will be released.
- a transit permit will be issued for organisms or their products that are fully contained and will transit Vanuatu for a period not exceeding 12 hours during which period they will not be moved beyond the confines of a designated air or shipping port facility.
- the application is rejected because it is incomplete or is carrying false information.

d) Where a risk assessment is required the VQIS will:

- Notify stakeholders and the public inviting written comments.
- Establish an assessment team of at least five individuals. Composition of the assessment team should be decided in consultation with relevant sectoral departments. Membership of the assessment team should be based on relevant expertise and is not limited to members of the public service. A VQIS staff member within the team will act as secretary for the team.
- Liaise with regional organisations, independent scientific experts and agencies of other countries to obtain supplementary information.

Box 3: Precautionary Principle

The precautionary principle is a key principle of modern biosafety mechanisms. Uncertainty about the risks of dealing with an organism or its derivative does not constitute a reason for failing to take due measures to minimise or prevent those risks.

This principle is applied within the national biosafety framework as the obligation for the Government to exercise caution where there is scientific and technical uncertainty about the adverse effects of an organism or variety.

e) The assessment team will consider all information before it, may request further information as required and prepare a draft assessment report. The assessment report will include recommendations as to conditions to be applied, management and containment measures and reporting requirements. The assessment report must not include information deemed to be confidential for commercial purposes, although reference may be made to such information in the report and when reaching a decision.

Where there is inadequate information to confirm safety of the dealing in the new species, variety or product the assessment team will apply the precautionary principle.

f) The draft assessment report will be released to the applicant, stakeholders and the public for a period of 30 days during which time further written submissions will be received by the assessment team.

g) The assessment team will consider all information before it and finalise the assessment report including recommendations as to conditions to be applied, management and containment measures and reporting requirements.

h) The Director of the VQIS will receive and consider the assessment report and make one of the following decisions:

- further information is required before a decision can be made. Particular deficiencies in information are communicated to the applicant and assessment team.
- the application is rejected. Reasons are communicated to the applicant.
- an import permit will be issued specifying any conditions, management and containment measures and reporting requirements that will be attached to the permit.

i) Within a maximum of 270 days of receipt of the application the Director's decision is communicated to the applicant, stakeholders and the public. The decision is entered into the biosafety register and communicated to the Biosafety Clearing House.

The process will be terminated and no importation permit will be granted where:

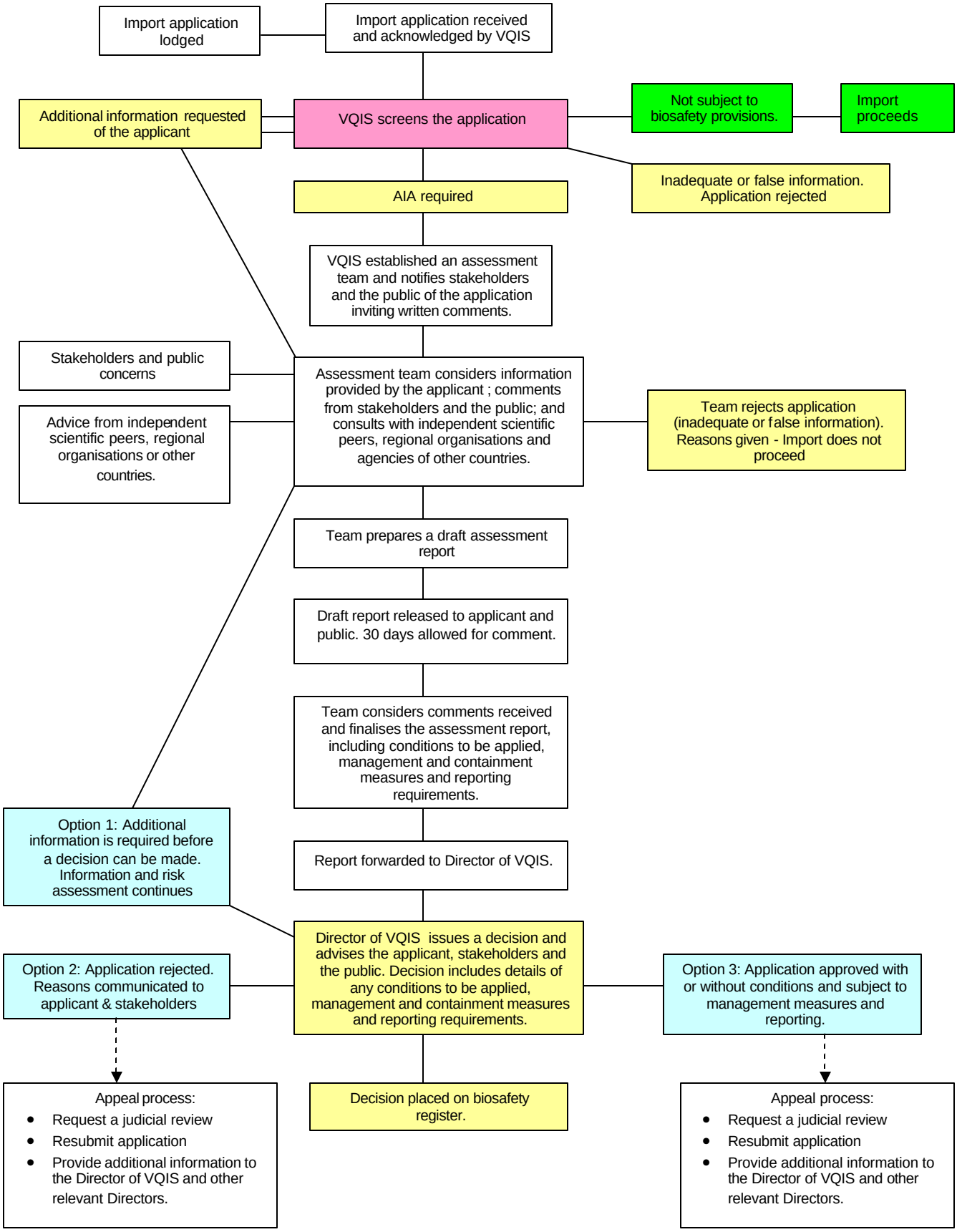
- VQIS or a member of the team conducting the risk assessment request further information of the applicant and it is not supplied within thirty (30) days.
- The applicant is found to have provided false or misleading information.
- The applicant refuses to provide information requested by the VQIS or its agents or does not agree with the VQIS on matters of confidentiality.

j) Where the applicant or a member of the public is dissatisfied with the Director's decision they may initiate one of the following processes for a review or reassessment:

- Where an applicant or a member of the public feels the process used or a decision taken was unlawful they may initiate a Judicial Review application with the Supreme Court of Vanuatu. Normal court procedure rules apply.
- Where an applicant has obtained additional information and feels an initial rejection is no longer warranted they may reapply and the application will be treated as a new application but remains subject to the same biosafety process and procedures.
- Where a member of the public believes new scientific or medical information throws into doubt a biosafety importation decision taken by the Director of VQIS they may notify in writing the Director of VQIS providing the new information that has become available. If the new information was not reasonably available to the importer at the time of import, the Minister of the relevant department may authorise a re-assessment of the species or variety. The re-assessment may lead the Director of VQIS to grant on-going approval for import and use of the species or variety, or it may lead to a change in conditions applied to the import, the cancellation of a permit or an order for the destruction of the new species or variety (including genetically modified varieties,

their derivatives or products). Re-assessment decisions must be based upon sound risk assessment standards and the precautionary principle. No compensation will be payable where an order for the destruction of a species, variety or product results from the re-assessment of a previously permitted will not

Fig 1: Administrative pathway for pre-import risk assessment.



3.3 Risk assessment and the risk assessment report

Assessment of risk is the critical step informing biosafety decisions. Risk assessment must be carried out in a scientifically sound and transparent manner and may draw upon expert advice and guidelines provided by relevant organisations such as the Food and Agricultural Organisation (FAO), the Office Internationale des Epizooties (OIE) and the International Plant Protection Commission (IPPC).

Risk assessment is carried out on a case by case basis. The required information varies according to whether the import is live or processed; for use in contained or open environments; for use as food, feed, medicine or biocontrol. A range of issues that might be considered during risk assessment are listed in Annex 2. While extensive, this list provides guidance only and is by no means exhaustive. Lack of scientific knowledge or scientific consensus should not be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

The Risk Assessment Report will:

a) identify the new organism, variety or product, including any novel genotype and phenotype characteristics associated with the organism or variety;

b) review the organism's autoecology, habitat requirements and habitat range;

c) review the proposed use of the organism, variety or product;

d) identify and describe any adverse effects the organism, variety or product may have on biological diversity in the receiving environment, taking into account risks to human health;

e) evaluate the likelihood that risks persist following any processing that has occurred;

f) evaluate the consequences should any adverse effects be realised;

g) describe risk management measures that will be put in place to minimise or eliminate any risks;

h) estimate the overall risk posed by the organism or variety based on the evaluation of the likelihood and the consequences of the identified adverse effects being realised;

i) recommend whether or not the risks are acceptable or manageable, including where necessary strategies to manage these risks.

Where there is uncertainty regarding the level of risk, further information on the specific issues of concern should be sought. Significant lack of certainty justifies declining the application or implementing prudent risk management and monitoring strategies in the receiving environment.

3.4 Provision for payment of a bond

A person or body acquiring a permit to import a living organism, new variety or processed product, whether for intentional release into the environment or contained use, may be required to pay a bond into the VQIS to be used for remediation of biosafety accidents.

Upon confirmation that all specimens of an organisation in containment or the wild have been eradicated the bond shall be refunded.

3.5 Register of biosafety decisions

The Director of VQIS will establish and maintain a register of organisms, varieties and products that have undergone pre-import risk assessment. This responsibility may be delegated in accordance with normal administrative procedures. The register will facilitate screening of applications and provide importers information on species, varieties and products previously considered for entry into Vanuatu and any conditions that apply to their use. The register will include information on:

- The full taxonomic name of the species or variety.
- A description that clearly distinguishes the variety, including details of any genetic modification present.
- The dates of all decisions on the species or variety.
- Details of the decisions, including any conditions imposed.
- The dates of any reviews of the decision.
- The outcomes of reviews of the decision.
- Classification of the species or variety into one of four classes:
    a) Import for contained use only, with no intention for release into the environment.
    b) Import for open uses, including release into the environment.
    c) Import not permitted.
    d) Exempt from pre-import risk assessment as a result of other international agreements or long standing presence in Vanuatu.

In addition to facilitate trade in processed biological products not requiring risk assessment by domestic biosafety laws the register will include:

- the schedule of products not requiring risk assessment as a consequence of the operation of other international agreements.
- the schedule of processed biological products that are subject to quarantine or pre-import risk assessment procedures (section 3.6).

An electronic copy of the register will be placed on an appropriate web site to facilitate public access. In the first instance enquiries will be referred to the web site.

Where risk assessment approves entry of a new species or variety, including genetically modified varieties or products there-of, normal point of entry quarantine and inspection provisions will continue to apply to each and every import. Inclusion of an organism on the biosafety register does not imply automatic entry of a consignment into Vanuatu.

3.6 Schedule of processed biological products with potential to pose a biosafety risk

The Director of VQIS will establish and maintain a schedule of processed biological products that have potential to pose a biosafety risk and are consequently subject to quarantine or pre-import risk assessment procedures. This responsibility may be delegated in accordance with normal administrative procedures. The schedule will facilitate importation of the wide range of products of biological origin imported into Vanuatu. Processed products not included on this schedule will be exempted from quarantine and pre-import risk assessment procedures.

The schedule will include information on:

- The name of the product and the full taxonomic species or variety from which it is derived.
- A description that clearly distinguishes the variety, including details of any genetic modification present.
- Date the processed product was placed on the schedule.
- Brief indication of the potential biosafety risk associated with the product.
- The dates of any reviews of the listing.

- The outcome of any review of the listing.
- Notes on geographical sources or manufacturing processes that are of particular concern.

An electronic copy of the register will be placed on an appropriate web site (the existing biodiversity site or a VQIS site) to facilitate public access. In the first instance enquiries will be referred to the web site.

The schedule of processed biological products that have potential to pose a biosafety risk will include as a category of product any product derived from a GMO.

3.7 Monitoring and enforcement

To ensure compliance with biosafety requirements, the provisions for pre-import risk assessment are complemented by monitoring and enforcement requirements. Monitoring refers to both measures to confirm compliance with biosafety requirements and the evaluation of the actual impacts on the environment and human health. Enforcement typically focuses on compliance with the regulatory regime.

Achieving the national biosafety goals will require:

- Monitoring movements and the use of live organisms or processed derivatives to ensure only permitted movements and uses occur and that these are in accord with risk management procedures.
- Monitoring of sites where organisms are held in containment to ensure compliance with risk management procedures.
- Audits to detect intentional or accidental releases of organisms held in containment.
- Monitoring of sites where there has been environmental release to ensure compliance with risk management procedures.
- Monitoring of sites where there has been accidental release of biological hazards to inform containment and where possible eradication.
- Containment and eradication of biological hazards.

VQIS is presently the principal agency involved in monitoring biosafety compliance through quarantine officers placed at key ports of entry into Vanuatu. Initial responsibility for monitoring will rest with the permit holder through a system of reports and audits.

3.7.1 Reporting

Onus is placed on the applicant to assist with monitoring of compliance with biosafety procedures through the provisions of regular reports to VQIS. The following reporting requirements will be imposed as conditions attached to all imports approved following pre-import risk assessment.

a) Living organisms held in containment or released into the environment

Six monthly reports will be a condition of any biosafety permit relating to living organisms held in containment or released into the environment. Reporting requirements will be specific to the organism and permitted use, however they would normally include:

- Information on the permit holder, the organism addressed by the permit and its use.
- An inventory of permitted organisms and their location.
- Information from on-site monitoring conducted by the permit holder.
- Documentation of compliance with conditions applied to the permit.

- Documentation of any breach of compliance with conditions applied to the permit and subsequent control or management measures put in place by the permit holder.
- Details of any movement of the permitted organism beyond the containment or release site, whether accidental or intentional, with information on management measures put in place to minimise all impacts.
- Details of management or containment initiatives implemented by the permit holder.

Reports will be lodged with the Director of VQIS or his nominee for scrutiny, entry into the biosafety register and further follow-up where required.

b) Processed products derived from biological organisms

Existing capacity constraints make it difficult to track the in-country movement and consumption of imported foods, feeds or other products following import. Consequently priority is given to monitoring compliance with import restrictions applied to processed products including pharmaceuticals, food and feed derived from GMOs.

This will require:

- monitoring compliance with import permit requirements that include biosafety risk assessment.
- monitoring compliance with labeling requirements.
- monitoring compliance with any conditions applied within import permits.

In addition to the role of VQIS the Director of Customs will exercise legal responsibility through the provisions of the Food (Control) Act No.21 of 1993 and the Customs and Inland Revenue Act, No.15 of 1999 following passage of the recommended amendments.

Six monthly reports will be a normal condition of any biosafety permit relating to the import and use of processed products and derivatives of organisms including genetic modifications, that pose a risk of passing genetic material, toxicity, allergenicity or pathogens to living species. Reporting requirements will be specific to the permit and permitted use, however they would normally include:

- Information on the permit holder, the organism addressed by the permit and its use.
- An inventory of imports during the reporting period.
- Documentation of compliance with conditions applied to the permit.
- Documentation of any break in compliance with conditions applied to the permit and subsequent control or management measures put in place by the permit holder.
- Any information pertaining to the product that may be relevant to its biosafety status including issues such as outbreak of disease at point of source.

Reports will be lodged with the Director of VQIS or his nominee for scrutiny, entry into the biosafety register and further follow-up where required.

Non-compliance with reporting requirements, including failure to supply reports, provision of inadequate reports, provision of false information or failure to provide additional information requested by VQIS, may be acceptable grounds for suspension of permit, automatic fine or eradication of stocks held. No compensation will be payable where an order for the destruction of a species, variety or product results from a failure to comply with biosafety requirements including reporting requirements.

3.7.2 Spot Checks and audits

Spot checks and audits motivate permit holders to comply with permit and reporting requirements and enable VQIS officers to ascertain that permit holders are honest in their reporting.

3.7.3 Point of entry

Normal customs, quarantine and phytosanitary inspection procedures will be applied to every movement under a biosafety permit at point of entry. This will include checking to ensure compliance with permit requirements and labelling requirements.

3.7.4 Ongoing and random spot checks

Where the Director of VQIS has reasonable grounds to suspect non-compliance with biosafety provisions a warrant may be obtained for the purpose of entering and inspecting a permit holder's premises or property. In addition officers of VQIS, or government officers authorised by letter from the Director of VQIS or warrant, may request the owner's or manager's permission to enter a permit holders' premises or property without advance notice to conduct random spot checks to monitor compliance with permit conditions and to conduct audits to confirm information provided in reports. Where permission to enter premises or property for the purpose of randomly monitoring compliance or conducting an audit is refused the VQIS may obtain a warrant to enter the premises or property to enable it to monitor compliance.

Non-compliance with risk management conditions, false reporting or refusing to allow VQIS designated officers to conduct an inspection or audit may be acceptable grounds for imposition of an automatic fine, suspension of permit or eradication of stocks held. No compensation will be payable where an order for the destruction of a species, variety or product results from a failure to comply with biosafety requirements.

As capacity of VQIS increases consideration can be given to sampling of imports to ascertain the presence of un-permitted varieties or genetic modifications.

3.8 Accident response procedures

Accident response procedures provide a guide to enable efficient and effective containment and eradication following the accidental escape of contained species or variants, or the unexpected spread of a species of variety released into the environment.

VQIS will develop accident response procedures for specific organisms or products approved for import following pre-import risk assessment.

4. Establishing the biosafety regulatory regime

4.1 Review of importation and quarantine legislation and procedures

VQIS will collaborate with other relevant agencies to initiate a review of importation legislation and procedures with a view to replacing the present set of legislative measures with a single integrated piece of legislation with procedures consistent to those set out in the National Biosafety Framework.

The current quarantine and inspection systems are weakened by:

- a high level of fragmentation
- separation of responsibility for plants and animals
- gaps and inconsistencies between the various sectors and administrative organisations.

As a consequence the current systems are inadequate to ensure sufficient coordination between all agencies to manage biosafety risks. It is difficult for the risk assessment procedure to cover all ecological, disease, pest, economic, and social risks associated with the entry of organisms and their processed derivatives.

The work of the National Biosafety Project has highlighted the need to strength the entire import system through a comprehensive review of all legislation and procedures. Without a move to a holistic and consistent import approval process ill-informed decisions may be made and gaps for entry will remain. The scope and extent of such a review will necessarily go beyond the scope of the Biosafety Project.

The following recommendations modify the existing legal and administrative system as interim measures that provide sufficiently for implementation of the National Biosafety Framework prior to completion of a holistic review of import legislation and procedures. Following Council of Ministers Endorsement of the Biosafety Framework the VQIS should approach the State Law Office to progress the required legislative amendments.

4.2 Imports of living organisms

A number of amendments to legislation are required to establish a consistent pre-import risk assessment procedure and remove current inconsistencies in approach. These amendments will encompass enforcement procedures and set out penalties. The administrative system for introduction of new species or varieties of biological organisms requires amendments to the following laws. A number of amendments will be made solely to harmonise the laws. This includes repeating provisions in related laws to ensure consistency and repealing existing powers to eliminate duplicity and overlapping of authority between government departments.

1. Animal Importation and Quarantine Act No.7 of 1988 [CAP.201]
    a. The description of the purpose of Cap 201 be amended to provide that it is "an Act to protect the health, environment and agriculture of the Republic of Vanuatu, and to regulate the importation of animals, plants and biological products into Vanuatu, and provide for the administrative framework for the control and regulation of all biosafety issues and for all matters connected therewith."
    b. Insert into the existing definitions of 'animal'[4], 'animal product'[5] and biological product'[6] definitions of new species or variety (including genetically modified varieties, their derivatives or products).

[4] Section 1 of the Animal Importation and Quarantine Act No.7 of 1988 [Cap.201] "any living stage of any member of the animal kingdom except human beings and includes arachnids, birds, crustacean, fish, insects and reptiles and also any fertilised egg or ovum;"

[5] Ibid, "any part of the animal including the flesh, wool, hair, skin, hide, bones, horns, hooves, feathers, and other portions of the carcass and viscera, blood, milk, fluids, semen, excreta and any other product that is wholly or partly derived from an animal or any part of an animal."

c. Expand the existing definition of biological product beyond organisms that are capable of causing disease in animals to include any organism that poses an environmental, health or socio-economic risk.

d. Expand the definition of animal product and biological product to include animal feed that is derived from GMO's and genetically modified pharmaceuticals for animals. Food derived from GMOs and intended for human consumption should continue to be excluded from the definitions.

e. Insert into the Act a definition of the precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for refraining from preventative measures including denying an application to import a GMO or a GMO product.

f. Redefine the functions and powers of the Principal Veterinarian Officer to include the responsibility to monitor and manage all biosafety conditions in relation to import permits. This function must be accompanied by corresponding powers of monitoring, surveillance, management, compliance and enforcement.

g. Insert into the Act a definition of new plant species or varietiyNote that this definition includes vectors, virus, microbes, bacteria, micro-organism, tissues and culture and non-living plant and plant parts that pose an environmental, health or socio-economic risk. This definition must include plant food or fertilizers that contain derivatives of GMO's, but for avoidance of doubt it must be clear that nothing in the Plant Protection Act or Cap 201 shall be deemed to affect any of the provisions under the Pesticides Act.

h. Amend the Act to say that it is unlawful to import any new species or variety (including genetically modified varieties, their derivatives or products) including fish without first obtaining an import permit from the Director of VQIS. This task is non delegable.

i. Amend the Act to say that any decision to grant an import permit for new species or varieties including GMO's and their derivatives must be in accord with the designated biosafety pre-import risk assessment procedures.

j. Amend section 4 of the Act to exclude introductions of living species and living modified organisms, food, feed and pharmaceutical products produced from GMOs from provisions for provisional import permits.

k. Amend the Act to provide that if the Principal Veterinary Officer applies to import a new species or variety (including genetically modified varieties, their derivatives or products) the normal pre-import risk assessment process applies, but the Principal Veterinary Officer must not be a member of the Assessment Team. The Assessment Team will make a recommendation to the Director of Quarantine who shall issue or reject the permit upon consideration of the recommendations received.

l. Amend section 18 (1) subparagraph (b) of the Act to provide that the Minister may in consultation with the Director of VQIS make orders prohibiting the landing of organisms not naturally occurring in Vanuatu for the purposes of the control and management of biosafety.

m. Insert a new provision that the Director of VQIS will establish a register of biosafety decisions (including decisions upon GMO varieties, their derivatives or processed products). The register will be placed on the internet to allow for public

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[6] Ibid, "any substance, chemical, organism or micro-organism having a biological effect on animals or their products, and includes drugs, medicines and remedies, hormones, growth promoters, antibiotics, protozoa, fungi, bacteria, viruses or parasites capable of causing any disease in animals (or if dead was so capable when living.)

access and copies of the register must be forwarded to the Director of Environment on a monthly basis. Normal powers of delegation of duties for this task may apply.

n. Insert a new provision that the Director of VQIS will maintain a schedule of processed biological products that have potential to pose a biosafety risk. The schedule will be placed on the internet to allow for public access and copies of the register must be forwarded to the Director of Environment on a monthly basis. Normal powers of delegation of duties for this task may apply.

o. The Cartagena Protocol provides that documentation accompanying a consignment of Living Modified Organisms for food, feed and processing must identify the consignment as LMO's and their relevant characteristics must be disclosed. Similar provisions must appear in this Act or subsequent regulations in relation to animal feed, or ingredients for processing animal feed.

p. Amend the Act to provide that the granting of an import permit for a living organism does not exempt the applicant from complying with the legal requirements set out in other Acts of Parliament.

q. Insert a new clause into the Act to provide that all government officers carrying out their designated powers and duties relating to biosafety are immune from liability unless it can it be proved by an importer or aggrieved person that the Officer acted in bad faith or failed to comply with the provisions of CAP201. The emphasis on "all government officers" is to cover all relevant departments involved in the biosafety regime.

r. Revoke the Plant Protection Act No. 14 of 1997. The office and powers of the Principal Plant Protection Officer and all-subsidiary legislation passed under the Plant Protection Act shall continue to remain in force but must be read to be consistent with the provisions of CAP201.

s. Amend the Act to say that any decision to grant an import permit for new species or varieties including GMO's and their derivatives must be based upon the relevant risk assessments procedures, consideration of any public representations and the recommendation from the Assessment Team.

2. Plant Protection Act No. 14 of 1997

The Plant Protection Act No. 14 of 1997 is revoked. The office and powers of the Principal Plant Officer and all-subsidiary legislation passed under the Plant Protection Act shall continue to remain in force but must be read to be consistent with the provisions of CAP201. More specific recommendations are presented under the amendments to the Animal Importation Act above. This will effectively promote a single legislation that establishes a central authority for importation and biosafety management and control.

3. Environmental Management and Conservation Act No.12 of 2002

a. To avoid any doubt insert the definition of new species or variety (including genetically modified varieties, their derivatives or products) in the definition of an introduced foreign organisms in the Act.

b. Insert a new provision in the Act to provide that the function of the Biodiversity Advisory Council (amongst other things) includes providing advice to other authorities in relation to the protection and conservation of biodiversity.

c. Amend the Act to remove provision for regulation of the importation of foreign organisms but not to affect provisions relating to the Director's powers to require environmental impact assessment in relation to foreign organisms which are lawfully imported under the Animal Importation Act 1988.

4. Fisheries Act [Cap.152]

   a. Insert into the Act definition of new species or varieties of marine or freshwater fisheries species or varieties (including genetically modified varieties, their derivatives or products).

   b. Insert into the Act a provision that all imports of new species or varieties of marine or freshwater species are unlawful unless the Director of VQIS grants an import permit in accord with the National Biosafety Framework. Any such application must be assessed in accord with pre-import risk assessment processes and a resultant import must comply with biosafety requirements issued by the Director of VQIS.

5. Forestry Act No.21 of 2001

   a. Insert into the Act a definition of new species or variety.

   b. Insert into the Act a provision that importation of any genetically modified forestry species or GMO for forestry related research is prohibited unless the Director of VQIS grants an import permit in accord with the provisions of the National Biosafety Framework. Any such application must be assessed in accord with pre-import risk assessment processes and a resultant import must comply with biosafety requirements issued by the Director of VQIS.

6. Vanuatu Agricultural Research and Training Centre Act No.15 of 2002

   a. Insert into the Act a definition of new agricultural species or variety.

   b. Insert into the Act a definition of the precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for refraining from preventative measures including denying an application to import an GMO's.

   c. Insert into the Act a provision that the importation of any new agricultural species of variety is prohibited unless the Director of VQIS grants an import permit in accord with the provisions of the National Biosafety Framework. Any such application must be assessed in accord with pre-import risk assessment processes and a resultant import must comply with biosafety requirements issued by the Director of VQIS.

7. Animal Importation and Quarantine Regulations No. 14 of 1994

   a. Revoke the provisions of section 2(1) including all fish and fish products so as to amend the Act to provide that importation of fully manufactured foods, hermetically sealed and not requiring refrigeration for permanent storage requires an import permit from the Director of VQIS.

   b. Insert into the Act a definition of the precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for the Minister refraining from preventative measures including denying an application to import GMOs or GMO products.

8. National Scientific Research Council Bill

   In drafting the proposed National Scientific Research Council Bill the State Law Office should take attention of the need to:

   a. Insert into the Act a definition of new species or variety.

   b. Insert into the Act a definition of the precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for the Minister refraining from preventative measures including denying an application to conduct research involving the importation of GMO's.

c. Insert into the Act a provision that all research permits that involve the importation of new species or varieties are unlawful unless the research proponent also obtains an import permit from the Director of VQIS in accord with the provisions of the National Biosafety Framework. Any such application must be assessed in accord with pre-import risk assessment processes and a subsequent import must comply with biosafety requirements issued by the Director of VQIS.

4.3 Import of human pharmaceuticals that pose a biosafety risk

At present the legal and administrative structures necessary for assessment of the biosafety risk of human pharmaceuticals and other biological products deemed to be solely for human use are not in place. Further, some of the limited procedures in place, for example reporting of drug imports by Customs Officers to the Health Department, have not been routinely implemented.

Three possible opportunities have been identified from discussions over the regulation of the introduction of GMOs and medicinal products derived from GMOs. These opportunities provide a basis for the biosafety project to commence negotiations with the Department of Health.

Option 1: Amendment of the Sale of Medicines (Control) Act [Cap 48]. The following amendments provide for the addition of a biosafety assessment process to the Act:

a. Amend the Act to provide that importation of any medicine derived from or containing a GMO product for use in treatment, therapy or research is prohibited unless an import permit is obtained from the Minister of Health. The granting of such import permit is subject to the National Biosafety Framework, and must be assessed in accord with national biosafety policies. Any regulations to vet such applications must not offer less protection then that afforded under the Animal Importation Act [Cap 201] as amended.

b. Amend the Act to insert a provision that those medicines derived from GMOs or containing a GMO product already governed by other international agreements or organisations are exempted from biosafety risk assessment procedures but must complete biosafety notification processes for the maintenance of an accurate register of all GMO's entering the country.

c. Insert into the Act a definition of precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for the Minister to refrain from preventative measures including denying an application to import a GMO or GMO derived medicinal product.

For consistency there would be similar amendments to the Dangerous Drugs (Control) Act [Cap.12]

a. Insert into the Act a provision that the importation of any genetically modified medication or GMO for medicinal related research is prohibited unless an import permit is obtained from the Minister of Health. The granting of such import permit is subject to the National Biosafety Framework, and must be assessed in accord with national biosafety policies. Any regulations to vet such applications must not offer less protection then that afforded under the Animal Importation Act [Cap 201] as amended.

b. Amend the Act to insert a provision that those medicines derived from GMOs or containing GMO products and that are already governed by other international agreements or organisations are exempted from risk assessment procedures but must complete notification process for the maintenance of an accurate register of all GMO's entering the country.

c. Insert into the Act a definition of precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for the Minister to refrain from preventative measures including denying an application to import a GMO or GMO derived product.

Option 2: One alternative is to recognise that animal drugs and supplements already receive scrutiny by VQIS under the provisions of the Animal Importation and Quarantine Act No.7 of 1988 [CAP.201]. It would be possible to broaden the scope of this responsibility to include human drugs, although there would not be a strong link with the title and purpose of the Act.

Option 3: A third alternative is presented in the recommendation for a comprehensive and holistic review of import and quarantine measures (Section 4.1). This provides an opportunity to address the importation of human drugs within this new context.

Further discussion and debate is required to achieve consensus. As an initial step the VQIS through the National Biosafety Framework Project needs to make concerted effort to engage the Department of Health in the biosafety debate.

4.4 Import of food that poses a biosafety risk

The Food (Control) Act No.21 of 1993 does not require permits for importations of food. At present the Director of Customs only regulates the health and safety standards for food that is imported [7]. However, the Cartagena Protocol provides that documentation accompanying a consignment of Living Modified Food for food, feed and processing must be identified as LMO's and their relevant characteristics must be disclosed. In addition consumers will only be able to make informed decisions if food and feed derived from or containing GMO ingredients is clearly labelled. These are the minimum requirements imposed under the Cartagena Protocol.

In broadening biosafety to address processed food products consideration will need to be given to the following amendments to the Food (Control) Act No.21 of 1993:

a. Insert into the Act a definition of genetically modified food, to include any food containing an ingredient derived from a GMO. [8]

b. Amend the Act to state that it is unlawful to import any food (including genetically modified varieties, their derivatives or products), food containing genetically modified ingredients, or ingredients derived from GMOs for local processing without first complying with the provisions of the (Draft) Food Labelling Regulation.

c. Amend the Act to require that all persons wishing to import genetically modified food, or ingredients derived from GMOs for processing into food for human consumption must be clearly labelled as containing GMOs, and shall be subject to the biosafety provisions of CAP 201.

d. Prescribe regulations for mandatory food labelling on all genetically modified food, feed and ingredients containing derivatives of GMO's.

For consistency there would also be needed amendment of the Customs and Inland Revenue Act, No.15 of 1999

[7] Food (Control) Act No.21 of 1993 section 9(4)

[8] This is merely for consistency throughout the legal regime. This Food Act regulates (amongst other things) the importations, sale and distribution of food which is injurious to human health, unfit for consumption, adulterated, manufactured, prepared, packaged or stored under unsanitary conditions.

a. Amend the Act to provide that all importation of food and ingredients for processing is unlawful unless the consignment is identified and properly labelled in accordance with Draft Standards for labelling genetically modified food, feed and ingredients for processing. This can only be implemented if labelling laws are strictly applied on all food imports.

b. Insert into the Act a definition of precautionary principle, noting that uncertainty about risks and the ability to constrain or prevent adverse impacts is not a valid ground for the Minister to refrain from preventative measures including denying the entry of a consignment into Vanuatu.

c. Amend the Act to provide that all customs officers must immediately notify the Director of the VQIS if it is revealed in a customs declaration form or the Officer reasonably believes that a consignment or a person is bringing into Vanuatu any live animal, fish, plant, or a processed product that contains or is derived from a GMO. An Officer shall not be liable for any damages unless it is proven in a court of law that the Officer acted in bad faith in notifying the Director.

d. Amend the Act to provide that a customs officer may prevent a carrier from offloading any consignment containing living organisms, including GMOs, unless a valid import permit is held and the Director of VQIS has confirmed in writing that any remediation or reparation bond has been paid in full to the VQIS.

e. Once the draft food labelling regulations are enacted the Customs Act must contain provisions that assist in monitoring and enforcing this regulation. A similar measure will also be required for any future regulation of GMO derived pharmaceuticals for human use.

4.5 Redress and Liability

In international law the term 'liability' is associated with the obligation to provide for compensation for damage caused by activities, which pose potential risks to persons, property and the environment. In relation to certain activities, States have tended to opt to conclude international treaties establishing civil liability regimes, which channel liability for damage to private parties and operators.

Debate continues over liability issues under the Cartagena Protocol. Some developed countries believe that such matters can be addressed adequately through national laws. Article 27 of the Cartagena Protocol enables a process under which the [Conference of Parties to the Convention on Biodiversity acting as the] Meeting of Parties of the Protocol will consider substantive discussions on liability and redress within four years of the Protocol entering into force.

An additional process relevant for the future negotiations under Article 27 is the examination of the question of liability for damage to biodiversity under Article 14(2) of the Convention on Biodiversity.

The liability and redress system developed for Vanuatu must be included in the principal law regulating biosafety – i.e. CAP.201. Provisions should contain the following considerations:

a. Scope of the rules and procedures

The rules and procedures for liability and redress must apply to all new species or varieties including GMOs and any processed products that pose a biosafety risk (except GM pharmaceuticals for humans) imported into Vanuatu for any purpose or that have entered Vanuatu's territorial jurisdiction.

b. Channeling liability

i. Liability for all aspects of biosafety hazards must be clearly legislated for in Cap 201, and carried in the wording of the notification forms and import permit

conditions so that liability claims can be initiated within the ordinary rules for compensation in civil litigation (where applicable). For completeness it is noted that the Environmental Management and Conservation Act may provide a procedure for redress and liability.

CAP 201 should clearly provide that any person(s), agent or government department importing new species or varieties, including genetically modified varieties for use in food and feed and pharmaceuticals derived from GMOs, must comply with the conditions stipulated in the relevant import permit. Failure to do so will be a statutory offence and punishable with a fine and/or imprisonment.

The conditions of import must be worded so that all liability for accidents, escapes in transit, import and containment rests with the importer and the user. Specific provisions should provide that where a carrier or agent is used for transporting goods that pose a biosafety hazard they also bear liability either jointly or severally from their principal (i.e. the person deriving financial benefit from the importation of such goods.)

To ensure responsibility for liability can be met it may be necessary for an appropriate bond to be paid by the applicant to VQIS before a consignment is offloaded. Carriers may be refused permission to unload live organisms including tissue culture, seeds and embryos unless the documentation verifies appropriate permits have been issued in advance and (amongst other things) any bond requirements have been paid to the VQIS.

c. Access and standing

i. When escape of an organism damages a private person's property, public land (government) or customary land (representative of customary land owners) common law remedies of damages flowing from negligence will apply.
ii. An applicant may initiate judicial review proceedings against the Director and the Department of VQIS in accordance with the civil procedure rules no.49 of 2002.
iii. The Director of VQIS must take appropriate action when conditions of an import permit are breached by the domestic user. These should take the form of statutory offences incurring strict liability penalties.

d. Ancillary sources of compensation

Conditions of import or transit may require that an appropriate remedial or reparation bond be paid by the applicant before the consignment is offloaded. This can only cover costs for destroying a consignment that fails the statutory import permit requirements. Compensation is a separate issue and is linked to the requirement that importers of new species or varieties must demonstrate in their import application documentation capacity (including insurance cover or financial capacity where appropriate) to manage risks arising from release of the organism whether accidental or otherwise. Inability to respond to such risks may be grounds for the pre-import risk assessment team to recommend to the Director to refuse import. Options for ancillary compensation can either follow a set amount for damage claims or alternatively the competent court of law will decide the quantum of damages in applying the normal common law tests.

The National Biosafety Coordinating Council and other interest groups should debate further the issue of having a set limit to all compensation payments and the types of damages permissible. Possible categories of damage that may be considered may include harm to biological diversity, harm to life or health, damage to property, harm to the environment, and socio-economic damage.

e. *Time Limits for bringing claims and the competent court*

2. CAP 201 should identify the Supreme Court as the competent authority to hear claims for compensation in relation to biosafety, unless the Environmental Act identifies an alternative disputes resolution body to settle claims for damage to the environment. There must be a specific provision in the law to provide that there are no time limits to claims for damage to the environment or health caused by GMO's. This is recommended because otherwise the normal 6-year limit applies to claims for personal loss under the Statute of Limitations.

The administrative and legal changes recommended to strengthen national Biosafety measures have broad reaching repercussions for a variety of organisations. Passage of these amendments places a responsibility on the VQIS to:

a. Identify relevant budget and staffing requirements to coordinate biosafety notification and risk assessment processes;

b. Identify a pool of people with capacity to contribute to the Pre-import risk assessment process.

c. Identify strategies for the conduct of monitoring and spot checks, including sharing responsibility with relevant agencies.

d. Identify appropriate charges and fees to be enacted in the appropriate fees and charges legislation, as this is separate to the principal acts of authority.

e. Prepare the necessary register and schedules of species and varieties.

f. Prepare national biosafety standards, policy statements, procedural guidelines and manuals that may be required to facilitate implementation of the biosafety framework.

Further, the Department of Customs and Inland Revenue will need to revise declaration forms to cater for the importation of GMOs.

A range of capacity building initiatives will be necessary to support the effective introduction of the new administrative and legal provisions. A number of priority capacity building initiatives are proposed, both to strengthen institutions that will assist with biosafety and to build awareness and understanding of biosafety issues in the general public. These are presented in this section.

4.6 Strengthening institutional capacity

Capacity building at an institutional level primarily addresses the needs of the institutions that will be integrally involved in the Pre-import Risk Assessment process. The principal aim is to have suitably qualified officers responsible for managing national biosafety matters. The department of VQIS will need to accommodate within its institutional arrangements the lead role for facilitating these initiatives.

4.6.1 Legal training

A constraint identified in section 2.5 was the apparent uncertainty sectoral agencies have with respect to each other's roles within a biosafety regime. Implementation of the biosafety Framework requires amendment to the legislation and responsibilities of a wide range of Departments. To ensure all agencies fully understand their responsibilities within overall implementation of the National Biosafety Framework the State Law Office should provide legal training to all agencies and departments who have had their laws amended to implement the National Biodiversity Framework.

4.6.2 Vanuatu Quarantine & Inspection Services

Under existing quarantine arrangements all risk analyses are conducted by the Principal Plant Protection Officer, in the case of plants and plant products, and the Principal Veterinary

Officer, in the case of animals and their by-products. The risk assessment role requires technical and analytical skills to interpret available information and formulate an opinion on a new import. Risk analyses are conducted on the basis of IPPC and OIE risk analysis guidelines. There are no in-country standards or procedural manuals.

The department of VQIS may consider the following institutional arrangements to adequately address its risk analysis tasks:

a. The Director of VQIS will need to delegate responsibility for the biosafety administrative process to officers of the VQIS, in accord with normal administrative powers of delegation. The designated officers will need to become familiar with the provisions of the National Biosafety Framework and the legal regime in which it operates. In delegating responsibility, the Director must be mindful that responsibility for biosafety decision making and permitting imports are vested in the Office of Director.

b. The Director of VQIS will need to request the Departments of Forestry, Fisheries, Health, Custom and Inland Revenue, Agriculture and Rural Development, Trade and Industry and the Environment Unit to nominate biosafety contact points within their offices. Training of these designated officers to ensure understanding of their roles and responsibilities in national biosafety management will be required.

c. Prepare procedural manuals and checklists to provide for a standard and transparent risk assessment process. Draft hazard assessment and risk analysis guidelines are presented in appendix 2 for consideration.

d. Develop audit checklists or templates that will facilitate consistent spot checks and site inspections.

e. To increase the pool of officers able to assist with risk assessment process (throughout government and the private sector where appropriate), train individuals likely to contribute to pre-import risk assessment processes.

VQIS has technical capacity to implement these measures without recourse to development assistance, although their may be opportunities to liaise with the regional bodies such as SPREP, FAO Sub-Regional Office, USP and SPC to achieve a measure of consistency with other countries in the region.

4.6.3 Networking

Individuals involved in pre-import risk assessment will need to access information not physically available in Vanuatu and to interact internationally to obtain current scientific information and request reviews from peers in other countries. This will require a range of capacity building measures.

Firstly the officers delegated administrative responsibility for biosafety notification, advance informed assessment and the register of biosafety decisions will need access to computers connected to the internet. There may also be a need to invest in software to prevent misuse of internet privileges and computer protection software. This will incur additional recurrent cost to VQIS both in internet access time and periodic upgrading of computer hardware. Consequently, this measure will require a review of the Departmental Budget and the allocation of access to resources within the Department.

Secondly maintaining strong networks both within and between Government agencies contributing to the biosafety process will help to facilitate implementation of the National Biosafety Framework. The Biosafety Project has provided the groundwork for this networking. To consolidate this position VQIS will:

(a) Develop procedures to enhance cooperation and encourage information sharing on biosecurity issues. Officers designated responsibility for biosafety administration should be encouraged to take a lead in this process by circulating

newly available information to other departments and individuals who may contribute to the pre-import risk assessment process, and to Departments such Customs and Inland Revenue who assist with interception of imports.

(b) Develop expertise and technical capacity within relevant agencies to enable [efficient and] effective emergency response action to unwanted organisms.

Thirdly strong regional and international networks will assist VQIS and risk assessment panels to access information and guidance on living organisms (including GMOs) and processed products [that have potential to present a biosafety hazard], on impacts species have held in other countries and management measures that can minimise impacts. Towards this goal the VQIS will:

(a) Represent Vanuatu in regional and international forums organised to discuss the Cartagena Protocol and its provisions and implementation.

(b) Liaise with regional institutions such as the University of the South Pacific, the South Pacific Regional Environmental Programme, SPC and the FAO Sub-regional Office to establish links with personnel who can assist with gathering information and contribute to the pre-import risk assessment analyses.

(c) Link with international networks that may be formed from time to time e.g. the Invasive Species Network

(d) Establish links with international institutions such as the IPPC and OIE, which can help provide information, training assistance and expertise.

VQIS has technical capacity to implement these measures without recourse to development assistance.

4.6.4 Maintenance of the register and schedule

The responsibility of VQIS under the biosafety Framework requires maintaining databases and publishing this information on the internet. This may require training to VQIS officers in data management and internet site management. Relevant training courses are available in-country through institutions such as USP. Depending on the individual capacity of staff designated responsibility for these roles VQIS may need to identify development funding to enable their participation in appropriate training short courses. Alternatively regional debate toward setting up a Biosafety Clearing House Mechanism may lead to the creation of appropriate training opportunities.

4.6.5 Ability to respond to issues of liability and redress.

Informed debate is necessary to guide Vanuatu to make appropriate decisions on the issues of liability and redress. It is recommended that:

(a) VQIS request the State Law Office to facilitate a workshop on biosafety redress and liability systems that might be established for Vanuatu.

(b) An officer of the State Law Office work with the VQIS to participate in international debate on liability and redress issues within the Cartagena Protocol.

Following national level debate and awareness the VQIS with the State Law Office to draft a system for liability and redress.

4.6.6 Pre-import risk assessment teams

Conducting risk analyses requires sound scientific understanding of organisms and knowledge of specific procedures.

(a) Designated biosafety contact points within the Departments of Forestry, Fisheries, Health, Agriculture and Rural Development, Customs and Inland Revenue, VQIS and the Environment Unit need to receive training in risk analysis.

(b) Individuals who may be called upon to assist with the pre-import risk assessment of an import application will also need to receive training in risk analysis.

(c) The designated biosafety contact points will be provided access to computers, with internet connections and funds specifically budgeted for costs associated with risk analysis.

While there is expertise within VQIS to facilitate such training it may be appropriate for VQIS to source regional inputs to training.

4.6.7 Harmonisation of sectoral policies with biosafety goals

The speed of worldwide development in biotechnology and biosafety was not anticipated when current sectoral policies were developed. As a result many of the agencies that will be involved or affected by introduction of the National Biosafety Framework are silent on key biosafety issues, or have at best informal work procedures. At present none of the natural resource sectors have policies with respect to GMOs.

The Forestry Department's development plan (Department of Forestry, 1997) includes the objective "to protect and conserve biological, germplasm, cultural, historical and other non-timber forest values for the benefit of present and future generations", however the plan does not address range of biosafety issues. While the Department's afforestation and extension policy recognises that "exotic species will be supported where they have proven performance" current work programmes focus on the use of native forest species. The Department's research policy includes "development of tree improvement techniques to increase forest productivity." Promotion of plantation forests and agro-forestry may increase private interest in a range of internationally established plantation species. Participation in regional projects such as "*SPRIG"* could lead to the department introducing selected genetic strains of species not already present in country. Future introductions of new varieties and species will be subject to the provisions of the national biosafety framework.

The Fisheries Department does not have a formal overriding policy, only specific management policies on different fisheries resources. However the Fisheries Department has in recent years actively facilitated the importation of a range of marine and freshwater species. While initially imported for research trials, organisms are not kept in permanent containment and field trials lead to environmental release. The Fisheries Department recognises the need to conduct risk assessment on the importation of new species, but its process has not been formalised, is not fully transparent and is not standardised with the biosafety and import inspection procedures managed by VQIS.

The Agriculture Department and Livestock Department have also facilitated importation of a range of species in recent years. Given previous portfolio arrangements, both are aware of quarantine provisions and follow procedures of VQIS. However, in the past this process has overlooked a range of biosafety issues including invasiveness.

The National Biosafety Strategy and Action Plan gives priority to improving the management of the introduction of species, and has led to recent recommendations to expand the present Plant Protection and Animal Import controls to address environmental invasiveness. However the Strategy and Action Plan is silent with respect to the introduction of new varieties and GMOs.

A key capacity building need is consequently to harmonise sectoral policies and work plans to address issues raised in the National Biosafety Framework. Two strategies will enable this to be addressed efficiently.

Firstly, the National Capacity Self Assessment Project (NCSA) started within the Environment Unit in late 2004. The NCSA project will invest in building awareness and consensus for lateral and vertical integration and cross-sectoral collaboration on issues addressed in multilateral environmental treaties including the Cartagena Protocol. This provides a mechanism able to promote harmonisation of sectoral plans and work policies with the National Biosafety Framework and procedures. It is recommended that the National Biosafety Project Coordinator liaise closely with the Environment Unit and NCSA Project Coordinator to ensure biosafety issues are specifically included in the coordination and consensus building activities of the NCSA project.

Secondly as sectoral policies and annual work plans are progressively reviewed individual departments should move to:

a) recognise the overall guidance provided by the national biosafety framework;

b) harmonise and standardise their policies and procedures with respect to introduction and use of new species and varieties including live and processed GMOs with those set out in the national biosafety framework;

c) identify specific capacity building needs to strengthen their ability to participate in biosafety management and pre-import risk assessment.

d) identify specific measures to ensure work practices adhere to national biosafety requirements.

e) Communicate these measures to the relevant officials and public.

Box 5: Article 23 the Cartegena Protocol reads:

1. The Parties shall:
   a. Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
   b. Endeavour to ensure that public awareness and education encompass access to living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House."

4.7 Building public awareness, understanding and commitment

The public has the right to know and to have confidence in the information provided on biosafety and to contribute effectively to sound management and policy decisions.

The scientific techniques and language used in modern biotechnology are hard for people without specialist scientific training to understand. The Vanuatu public knows very little about products of genetic engineering, their advantages and their risks. Increasing public awareness on modern biotechnology and its application is necessary if individuals are to make informed decisions on whether to use GMOs or not. It is also necessary to allow custom landholders and chiefs to make informed management decisions about their land and natural resources. As a signatory to the Cartagena Protocol the Vanuatu Government has obligations to educate and involve the public and gauge opinion to assist in the development of biotechnology management strategies (Box 5). Given the low levels of scientific literacy this information should be delivered through media channels that the local people are comfortable with and can relate to. The information package design needs to be very simple and effective.

The four pillars of public participation based on the Rio Declaration are: capacity-building to enable public participation in a meaningful way; access to information; mechanisms for public

participation; and transparency of decision-making, including government accountability to the public.

Kalmor (2004) showed that the public is unaware of GMOs and related biosafety issues. A basic level of awareness is necessary for people to recognise the relevance and timeliness of biosafety issues. This level of concern helps motivate people to learn about the issues. Without this level of initial concern it will be hard to structure and target information activities to build the level of understanding necessary for informed decision making.

4.7.1 Target 1: Schools

Schools provide an effective medium for extending information throughout the country. The following opportunities have been given priority:

Teacher In-Service Training

The Department of Education organises regular in-service training for primary and secondary teachers. It is keen to involve other parties/institutions to present information and materials to teachers during these times. The National Biosafety Project and subsequently VQIS officers designated responsibility under normal administrative procedures should take the opportunity to

a) Liaise with the Department of Secondary, Technical and Further Education to present materials/information to teachers during in-service training workshops. The biosafety project could initiate this process by holding a 1-week in-service training during the school holidays.

b) Distribute printed information such as posters and leaflets through the Department of Secondary, Technical and Further Education.

Year 7 and 8 basic education Science and Social Science curriculum

A consultation and working committee appointed by the Curriculum Development Unit is tasked to gather information and develop a Year 7 and 8 basic education curriculum. It is recommended the National Biosafety Project and subsequently delegated officers within VQIS meet with the science and social science committees to advocate for the curriculum to include:

a. The economic, social and environmental risks that can stem from the intentional and accidental introduction and spread of organisms.

b. An introduction to genetically modified organisms, including both scientific, economic and values based information on the advantages and disadvantages of using GMOs/LMOs.

c. Information on basic risk and impact reduction practices including minimising spread, safe handling, and treatment methods such as dipping root crops in salt water.

d. An action learning activity for students to identify a species or variety that has had an impact on their environment; document the local introduction of the species or variety, its consequences and impacts; identify options for management of the problems and reduction of the impacts.

Year 10 Agriculture (Quarantine) curriculum booklet

The VQIS is reviewing the Year 10 Agriculture (Quarantine) curriculum booklet in 2005. The biosafety project coordinator should work closely with the VQIS to include the following information in the revised booklet:

a. Definitions of biotechnology, biosafety, GMOs/LMOs.

b. Information on the applications of biotechnology and uses of GMOs/LMOs.

c. Information on risk analysis.

d. Information on invasive species.

e. An exercise for students to research and report on advantages and disadvantages of using GMOs/LMOs.

Student competition

To support introduction of the new curriculum materials request the Department of Secondary, Technical and Further Education to run two national essay and speaking competitions for junior and senior secondary school students. To attract national interest and create wider awareness on LMOs/GMOs issues, attractive prizes would include settlement of the term's school fees, free return travel from the student's home island tot he school and student science packages. Media publicity could be organised for the winning entries to extend awareness to the general public. Topics will be in the form of questions or statements, from which students choose one issue to analyse and debate, with separate categories for junior and senior secondary students.

Live and Learn Project and Wan Smol Bag Theatre

The Live and Learn Project based with Wan Smol Bag Theatre is heavily involved in environmental programmes targeted at schools. Printed media, radio programmes and school visits by these groups are producing promising results. The National Coordinator of the Biosafety Project and subsequently delegated officers of the VQIS and should work with this group to advocate for biosafety issues, including GMOs, to be incorporated into their work programmes.

4.7.2 Target 2: Members of Parliament.

The Office of the Clerk of Parliament is willing to facilitate the delivery of biosafety information to Parliamentarians. It is recommended that the National Coordinator of the Biosafety Project and subsequently delegated staff of the VQIS liaise with the Clerk of Parliament to organise opportunities to

a) Brief the government minister or ministers responsible

b) organise seminar and audio visual presentations for members of parliament during breaks in session meetings. Printed information can be handed to MPs during this time. The information should include real examples such as an application to import a GMO is made to another Pacific Island country.

c) Use opportunities that may arise to include politicians and government officials in international forums and fact-finding missions to increase their familiarity with biosafety issues and regulatory models in place elsewhere.

4.7.3 Target 3: Provincial Technical Advisory Groups

The Provincial Technical Advisory Groups (TAGs) are units under the planning section of each provincial authority. A core function of the TAGs is to disseminate information from provincial headquarters and the central government to the community level. Provincial authorities have meetings at least once a year. The National Biosafety Project Coordinator VQIS and subsequently VQIS officers designated biosafety responsibilities should provide information to each Provincial TAG and request assistance from TAG members to inform rural communities and seek communities' cooperation on biosafety issues. This may require VQIS seeking development assistance to fund the costs of officers travelling to attend meetings of the Provincial TAGs. However, VQIS officers are stationed in Torba, Sanma, Shefa and Tafea and may be able to assist with this role to minimise costs.

4.7.4 Target 4: Agriculture Field Assistants

Agriculture field assistants have annual planning workshops. This provides an opportunity to work with them and inform them on biosafety issues, including GMO/LMO issues. The National Biosafety Project Coordinator VQIS and subsequently VQIS officers designated biosafety responsibilities should work with the Department of Agriculture and Rural Development to provide training concurrently with the annual Provincial meetings of agriculture field assistants. Training should address:

a. Awareness of invasive species and pest organisms, their economic, social and environmental impacts and ways rural communities can contribute to their management and/or eradication
b. Understanding of the terms GMOs and LMOs, including the advantages and disadvantages of using them.
c. Awareness of biosafety regulatory mechanisms and risk assessment procedures.
d. Risk mitigation strategies.

4.7.5 Target 5: General public

Biosafety is a cross-sectoral issue. Elements of the debate on LMOs and GMOs in particular can challenge religious beliefs and cultural views, while comparison of the costs and benefits of an import often involve subjective assessments. An informed public is necessary to allow participation in decision-making and management of biosafety issues, including GMOs/LMOs. The National Biosafety Project Coordinator VQIS and subsequently VQIS officers designated biosafety responsibilities should engage in an intensive public awareness programme including:

a. Television and radio interviews and debates on cultural, ethical and religious implications of modern biotechnology and biosafety involving NGOs, churches, women and youth groups. The cost of a 30-minute panel debate filmed for screening on VBTC and with a master tape to allow on-going use and reproduction of the programme is less than 70,000VT
b. Use of mass print media to increase awareness of food labelling, GMO as a symbol and its meaning.
c. Use of print media, displays and printed information materials to increase public awareness about species and varieties in Vanuatu that have already had significant biosafety consequences. This is very important for ports and airports.
d. Liaising with Wan Smal Bag Theatre to include biosafety issues in their plays, radio plays and school activities.

Appendix 1: Import notification application requirements

The permit application is the first level of screening for all applications to import a new species or variety, including a genetically modified variety. The information must be truthful, and applications that include false or misleading information may be declined. Where an import permit was initially granted, and then found to have been based on false or misleading information the import permit may be deemed to be void and the importer required to re-ship or destroy the organisms at his or her own expense. A non-refundable fee must accompany every notification application lodged with the VQIS.

Information required in notification applications includes the following.

a) Name, address and contact details of the exporter.

b) Names, address and contact details of the importer in Vanuatu, who will be the legal entity responsible for the import.

c) Taxonomic status, common name, point of collection or acquisition, and characteristics of organism or parental organisms related to biosafety.

d) Centres of origin and centres of genetic diversity, if known, the distribution of the organism and a description of the habitats where the organism may persist or proliferate.

e) Name and description of any genetic modification or manipulation, including description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO. Resultant taxonomic status, common name, point of collection or acquisition, and characteristics of the organism related to biosafety.

f) Where there has been genetic modification or manipulation, centres of origin and centres of genetic diversity for the parental organisms and a description of the characteristics of these organisms and the habitats where they may persist or proliferate.

g) The domestic classification, if any, of the biosafety level of the organism in the state of export, or other states where use has been permitted or rejected. (e.g., whether it is prohibited in the State of export, whether there are other restrictions, or whether is has been approved for general release). If the organism or variety is banned or restricted in the State of export, the reason or reasons for the restriction.

h) The purpose of the introduction.

i) Intended dates of the transboundary movement (subject to approval being granted).

j) Intended use of the organism or products thereof.

k) Quantity or volume of the organism to be imported, whether the import is 'one-off' or repeated.

l) A risk assessment report consistent with criteria set out in Appendix 2

m) Suggested methods of safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

n) Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.

o) A declaration that the abovementioned information is factually correct.

Appendix 2: Draft Hazard Identification and Risk Assessment Guidelines

This appendix lists a range of issues that may need to be considered in the risk assessment of a new species or variety including a GMO or its derivatives. The list is indicative and additional issues may need to be considered for a specific import or as a result of advances in scientific understanding.

The table is divided into 4 parts. All applicants consider Part A, then one of Parts B, C or D as applicable:

- **Part A**: Basic information relevant to all applications.
- **Part B**: For living species and varieties that will be kept in containment and do not involve the intentional release of living organisms or living genetic material into the environment.
- **Part C**: For living species and varieties that will be released into the environment.
- **Part D**: For processed products and derivatives of new species and varieties, that are not alive but pose a risk of passing genetic material or disease pathogens to living species.

Each part starts with generic issues that must be considered in all instances as well as lists of issues relevant to the form, nature and intended use of the organism.

Outline of the draft hazard identification and risk assessment guidelines.

Part A: Information to be given by all applicants	
Background Information	**Contribution to the assessment**
Taxonomy of the organism to the lowest level possible. The location where the organism, or the parent organisms of a GMO, will be sourced. Specific characteristics that distinguish the variety being introduced (if any). Habitat requirements and preferences of the organism. Autoecology of the organism, including: · Adaptive characteristics · Interaction with other organisms, including environmental factors necessary for its survival and growth and consumer organisms Description of the natural range of the species or variety. Knowledge of pests, diseases and predators that affect the species in its natural range Details of other places and countries to which the species has been intentionally or accidentally introduced. Details of behaviour of the organism in other places to which it has been introduced. Purpose or reason for the introduction of the organism. Information on any risk assessments already conducted (for example to meet requirements of other countries) including contact details of the agencies involved. Biosafety measures applied to the import in the source country and other countries that have undertaken biosafety risk assessments.	Background information. Understanding of the behaviour of the organism in the environments in which it is present. Insight into use of the species or variety elsewhere, including any problems that may have occurred. Understanding of the benefits that justify the introduction.
Additional information where a GMO	**Contribution to the assessment**
• Genetic details, including the intended location of the inserted DNA in the final construct, and the number of copies that will be present. • Details of the modification including o The biological source of the donor DNA o The host organism or tissue o The vectors or the method for the transfer of DNA • Specific traits that distinguish the variety being introduced. • The markers or sequences that will enable the GMO to be identified in the laboratory and under field conditions. • Habitat requirements and preferences of both parent organisms. Autoecology of both parent organisms, including: • Adaptive characteristics which may increase the potential for introduction or spread	Background information. Precise description of the genetic material being considered. Understanding of the nature of the GMO. Understanding of the behaviour of the parent organisms. Understanding of benefits that justify introduction. Understanding of experience of other countries. Understanding of options for risk management.

• Genotypic and phenotypic instability Natural range of both parent organisms. Detail of other places and countries to which the host organism has been intentionally or accidentally introduced (ie where, when and why?). Details of behaviour and effects of the host organism in other places to which it has been introduced. If the organism or produce of the organism may be exported: • the location and value of markets . • Vanuatu's position in respect to international trade of related un-modified organisms . **The situation in client countries in terms of regulatory status and consumer acceptability.**	

PART B: For living species and varieties that will be kept in containment and that do not involve the intentional release of living organisms or living genetic material into the environment	
Containment information	**Contribution to the assessment**
Description of the level of containment proposed, including location or locations as appropriate, and the containment facility if appropriate (this must comply with internationally accepted standards). Justification of the containment level proposed.	Background information Understanding of the containment system. Understanding of level of risk of escape.
Risk Assessment information	**Contribution to the assessment**
Description of situations that could lead to accidental release of the organism, variety or genetic strain into the environment. Details of possible risks in the event that there is an unintentional release of the organism, variety or genetic strain into the environment, and a statement of how likely and serious these risks are, including: • occupational health and safety risks for persons involved; • risk to the environment; • potential to become a predator or pest of environmental or commercial resources; • invasive potential; • potential to spread or convey pathogens to environmental or commercial resources; • potential for use (including consumption if a food product) to convey pathogens to humans or the human food chain; • adaptive characteristics which may increase the potential for introduction or spread; • Adverse effects on other organisms. Description of management measures that minimise these risks.	Range of potential hazards including but not limited to: • Toxicity, allergenicity or pathogenicity of the GMO for humans, through occupational or other exposure routes; • Toxicity, allergenicity or pathogenicity of the GMO for other organisms, including animals, insects, aquatic organisms, plants, fungi, • Indirect ecological effects on biodiversity or habitat; • Spread of GMO in the environment as a weed or pest; • Adverse effects on soil, air and waterways • Other adverse effects, direct or indirect (eg social, cultural, economic)

If a GMO, genotypic and phenotypic stability, including information on the risks of the genetic material of the organism transferring to natural or cultivated populations of the same or other organisms. Whether the site (within the host genome) of integration of the resultant transgene is known and, if so, details of any secondary effect that could result from the integration, or further integration at the site.	Potential for any secondary adverse effect (e.g. increased toxicity, pathogenocity, differing behaviour).
Risk management information	
Precautions proposed to be taken to prevent any unintended dispersal of the organism, variety or GMO, or any heritable material from the organism. The arrangements for transport or movement if the species, variety or GMO are to be transported or moved outside the facility. The arrangements for destruction and disposal of the organism both when no longer required or in the event of accidental release into the environment. The actions proposed in the case of an unintentional release of the species, variety or GMO from containment; Any other actions and precautions proposed to be taken by the applicant or that are necessary to minimise any risks posed by the proposed introduction. The qualifications, experience and intended role of each person involved in the proposed import.	Risk management strategies to limit the potential for escape of the contained organism into the environment, through escape from the facility, through dispersal during transport, disposal or as a result of a natural or man-made disaster; as well risk to workers from exposure; any other risk that the proponent has identified or that the Regulator can foresee.
GMO CULTURES - Additional information if the volume of a GMO culture exceeds 10 litres	
The size of the proposed project, in terms of the volume of the GMO culture produced and the area of the facility affected; The main products, by-products (if any, including effluents) and the concentrations of these products and by-products at different stages of the production process. How genetic stability of the GMO will be checked, and at what frequency.	Background information relevant to culture and its use. Monitoring strategies to detect possible mutations or other unforeseen effects, and risk management strategies to ensure product purity or any other risk from procedures used.
The plan, procedures and data collection program to be used to ensure the purity of the main products. The facility to be used for the proposed project; including: • The physical arrangement for each working unit involved; • The operational procedures of each unit; and • How the intended level of physical containment of GMO's is to be achieved. • Arrangements for personnel management including supervision, training, health surveillance and emergency care. • The project design dealing with the risks mentioned in the risk assessment above (i.e. all known risks, in particular to people or to the environment).	Risk Management strategies necessary to limit the spread of the GMO outside the facility, ensure that personnel are trained in appropriate procedures, and supervised adequately, or address any other risk from procedures used.

PLANTS - Additional information where a new species or variety is a whole plant, or is to be used in conjunction with a whole plant	
Whether the plant or its parent organisms are a weed or closely related to plants that are weeds and if so the weeds to which it is closely related. The stage of development the plant will be allowed to reach. Whether soil, or soil substitute, will be used as the growing medium for the plants, and how that medium will subsequently be sterilised or disposed of. Physical identification of the growing site.	Potential for harm to the environment if the plant escapes into the environment and potential for spread as a weed. Potential for spread of the plant e.g. if the plant produces pollen or seed; and the approach proposed to mange the potential. Risk management measures to reduce potential for spread of the plant outside the facility.
ANIMALS - Additional information where a new species or variety is an animal or used in connection with an animal	
The number of animals to be held in containment, as well as any other animals involved. The arrangement for breeding animals or for ensuring that the animals do not breed. The physical identification of animals (including tagging, marking etc).	Potential for escape of the import and any genetic modifications it contains into other animals or broader environment. Risk management strategies to prevent escape of the import and any genetic modifications from the fac ility.
CLINICAL TRIALS - Additional information – where a new species or variety is for use in clinical trials with human beings	
The disease to be treated or prevented by the use of the organism. How the organism or vector is prevented from multiplying in the host. The period over which the organism will be detectable in the person or his or her excretions. If the organism imported is a defective virus, the potential for acquiring the capacity for viral replication by complementation or recombination with intracellular viruses. Safety in pregnancy, and potential for teratogenicity. The potential for the organism to cross the placenta of a pregnant person or animal. Whether the organism produces spores. Whether the viability of the organism is compromised by desiccation. Methods of sterilisation and disinfection that are active against the organism, including susceptibility to ultraviolet or ionising radiation. The potential for the organism to spread from persons to whom the organism has been adm inistered to other persons or species, and the likely mechanism and frequency of such spread. The potential for the organism to be disseminated into the	Background information relevant to assess the range of potential hazards and their magnitude and likelihood. Potential for escape of the organism into other humans, or into other animals or broader environment. Potential for escape of the organism into the environment. Potential for increased pathogenicity for humans or animals. Potential for harm to a human mother or foetus. Potential for escape and survival of the organism in the environment. Risk management strategies for preventing escape of the organism in the environment, effectiveness of those strategies. Potential for exposure of humans or animals to the organism. Identification of potential routes of escape and possible management methods to control the potential for escape.

environment through human waste during or after the trial. Proposed methods for disposing of waste containing the organism. Whether, at the end of the trial, live organisms will be carried by a person to whom the organism has been administered and, if so. The potential for dissemination of the live organism through family contact, or to the general population.	
Clinical Trials involving a GMO: The host range of the parent organism from which the vaccine or vector is constructed. Assessment of the potential any of the genetic material in the vaccine, medication or its vector to become incorporated in the whole or part of the genome of the cells of treated people or others. An assessment of whether the susceptibility of a person to the GMO could be affected by: • The state of the person's health at the time of the treatment (for example, immunosuppression, or superimposition of other disease); or • Other treatments, such as drugs. Measures intended to be taken to minimise the potential for wider dissemination.	Potential for somatic mutation with possible hazards to health of treated people, e.g. causing cancer. Potential for harm to health of the treated person, or any other person(e.g. health professionals) in the event that they are exposed. Likelihood that use of medicines or other treatments, or pre-existing medical conditions, will result in increased hazards as a result of exposure to the organism. Strategies to limit escape of the organism into the environment and exposure of treated humans or animals to the environment.

PART C: Where new species or varieties will be intentionally released into the environment.	
Background information on the release	**Contribution to the assessment**
• The number of organisms to be released. • The number of releases of the organism that are proposed. • The proposed dates for the release or releases. • The number of sites, the location of the sites for proposed release (including geographical location, and references and GPS coordinates), the area of land to be used and the reasons for the choice of location or locations for the releases or releases. • Description of the physical and natural environment found at the release site or sites, particularly features that may minimise or exacerbate any undesirable effects of the organism. • The methods to be used to ensure batch to batch consistency, if large scale production is required to produce organisms for release. • Details of the measures that have been taken, or will be taken, in the production process to ensure	Background information relevant to a number of risks including scale of exposure and the potential for spread of the organism outside the release area and consequently the capacity to manage any possible hazards. Relates to assessment of magnitude and likelihood of risk. Quality control information. Risk management strategies to prevent spread of the organism outside the release area.

quality, and purity of organism intended to be released. • Arrangements for importation and transportation of the organism to and from the release area.	
Risk Assessment information	
General information The proximity of the release site, or sites, to population centres, centres of agricultural activity, or the habitat of biota that might affect, or be affected by, the proposed release. Details of all known risks associated with release of the organism, variety or genetic strain into the environment, including: • invasive potential • potential to spread or convey pathogens to environmental or commercial resources • potential to become a predator or pest of environmental or commercial resources , including cultural resources. • potential for use (including consumption if a food product) to convey pathogens to humans or the human food chain • occupational health and safety risks for persons involved • Adaptive characteristics which may increase the potential for introduction or spread • Adverse effects on other organisms • Genotypic and phenotypic instability Description of any known predators, parasites or pathogens of the organism in Vanuatu, and their present distribution. Description of management measures that minimise these risks. The current distribution of the species or related species in Vanuatu. Factors that normally control populations of the species in the natural environment (for example, pathogens, herbivory and physiological stress). Interaction between the organism and the environment • Whether release of a proposed organism could prejudice any beneficial function of the organism or other organisms in the environment. • On the basis of contained experiments. o The survival times of the organism in habitats relevant to the release environment. o The growth rate and generation time of the organism in the ranges of environmental conditions characteristic for the place and date of release;	Range of potential hazards including but not limited to: • Toxicity, allergenicity or pathogenicity of the organism for humans, through occupational or other exposure routes; • Toxicity, allergenicity or pathogenicity of the organism for other organisms, including animals, insects, aquatic organisms, plants, fungi, • Indirect ecological effects on biodiversity or habitat; • Spread of the organism in the environment as a weed or pest; • Adverse effects on the physical environment, including soil, air and waterways Potential for indirect effects or increased risks because of the location of the release. Potential secondary ecological effects of the organism. Potential for persistence of the organism outside the release area. Potential for increased fitness of the organism compared to the parent organism (relating to potential to become a pest or weed). Potential for loss of the modified phenotype Potential for escape of the organism outside the release area and/or to become a pest or weed in the environment.

• Whether the organism is expected to remain in the environment after release and if so for what period of time; and details of any environmental risks posed by the organism during the period. • The capacity of the organism to disperse within the release area or areas, and if any, the dispersal mechanism. • Whether the organism is likely to be able to establish in the wider environment from the release area or sites. • Whether the organism will be able to form long-term survival structures, such as seeds or spores. • Whether interactions between pathogens and the organism are possible and, if so: o the incidence and distribution of relevant pathogens; o possible effects of interaction. • Whether the organism is likely to show any competitive advantages in mixed populations under the conditions at the release site or sites, and, if so, details of the nature of the advantages. • Any other environmental risks that may be posed by the organism. <u>Information about previous assessments or approvals</u> • The results of any **applications** made for approval of the release of the organism, or any derived genetically modified products, by any other Regulator in any other country, including information about conditions (if any) attaching to the approval. • If the organism or GMO has been previously released in Vanuatu or another country, any beneficial or adverse consequences of the release.	Time during which post-trial monitoring will be required. Potential for transfer of the introduced genes to other organisms, posing risks. These may include transfer of herbicide resistance genes to weeds, or antibiotic resistance genes to micro-organisms. Potential unintended effects. Potential of the organism to become a weed or pest in the environment. Potential for the organism to escape and persist in the environment outside the release area Background information relating to the risk assessment broadly and a variety of issues, e.g. how the same or a similar application has been handled overseas, and experience with previous releases.
Additional information *where the organism is a GMO*	**Contribution to the assessment**
• Whether the species, or a closely related organism, is present at or near the site of the proposed release and, if so, description of the population or populations. • Genotypic and phenotypic stability/instability. • Possibility for transfer of genetic traits between the organism and other species present at or near the site of the proposed release. Adverse affects that might result. • Whether the vector can transfer to other hosts and, if so:	Potential toxicity, allergenicity, infectivity, or pathogenocity for humans or other organisms. Potential for escape and persistence outside the release area. Potential for transfer of any introduced genes to related species. Background information relevant to unintended gene transfer by the vector to other hosts. Any other risks associated with the organism. Potential for persistenc e of the GMO and the introduced genes in the environment if the GMO escapes outside the release area.

o the potential host range; o the expected mechanism of transfer ; o the likely consequences. • Whether the recombinant vector will be present in the final construct and if not, how it will be removed. • If no vector will be involved, how the DNA will be introduced and how many copies of the gene will be inserted. • How the modification will change the phenotype of the organism to be released and the effects of that modification. • Secondary genetic effects that may be anticipated. • The intrinsic genetic features, if any, of the GMOs that will regulate survival in the environment, including a statement on how stable those features are. • The genetic changes, if any, that will be included in the GMOs to limit or eliminate any capacity to reproduce or transfer genes to other organisms. • Whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the GMO.	
• Whether the new genetic trait will be able to be transferred to other organisms found at the release area and surrounding environment and, if so: o the organisms to which the trait can be transferred and the frequencies at which it can be transferred, including information about the species that have been tested for transfer and the rationale for selecting the test species; o the transfer mechanisms involved; o the techniques that have been used to demonstrate transfer; • any possible adverse effects of the transfer including any advantage over members of the species that do not contain the transgene and the environmental risks posed by such an advantage. • Whether the GMO could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect. • Whether the GMO could produce any novel metabolites that could be accumulated through the food chain.	Potential impacts for other living things. Potential for risks related to the undesirable changes.
• Risks the GMO may pose to the health and safety of people including: o toxins that may be expressed by the proposed	Potential for toxicity or allergenicity of the GMO to humans. Potential for pathogenicity of the GMO to humans.

GMO that are not found in the parent organism; o Pathogenic properties in the GMO (especially those that are not found in the parent organism or are increased from those of the parent organism); o Occupational health and safety risks to personnel dealing with the GMO; o Safety risks to the wider community.	Potential exposure routes and risks for people working with the GMO. Potential for adverse effects due to increased exposure in particular occupations. Potential exposure routes and risks posed by the GMO for the wider community.
Risk Management information	**Contribution to the assessment**
• Proposed measures for monitoring the effects of the release, including monitoring for: o the survival or presence of the released organism beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods; o impacts on other species , including characteristics and abundance; o any other hazards or adverse effects. • Mechanisms to be used to prevent dispersal of the GMO into other ecosystems. • Proposed measures for limiting the dissemination or persistence of the released organism in the environment. • Measures for disposing of the organism when the release is complete and any waste derived from the organism. • Proposed release-site supervision procedures and any safety procedures to be undertaken by staff, including procedures for on-site supervision of the release. • Proposed measures for informing persons covered by the permit conditions and for informing the public about the release • Proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the VQIS. • Contingency measures that will be in place to rectify any unintended consequence if a hazard becomes evident during the course of the release.	Risk management strategies to limit persistence of the GMO at the release area, to limit escape of the organism from the release area. Monitoring strategies to detect any adverse effects. Risk management strategies for cleanup in the event of escape from the release area, or if other hazards become evident.
Additional information where the organism is a GMO	**Contribution to the assessment**
• Proposed measures for monitoring any risks posed by the release, including monitoring for: o the survival or presence of the genetic modification beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods; o transfer of the introduced genetic material to	Monitoring strategies to detect any adverse effects, including [unintended] transfer of GMO or introduced genes from the release area. Risk management strategies to limit persistence of the GMO at the release area, to limit escape of the

other species; • Proposed measures for limiting the dissemination or persistence of the GMO or its genetic material in the environment. • The methods that will be used to minimise the effects of any transfer of the inserted genetic trait to other organisms. • The specific experimental methods proposed for detecting the presence of the GMO or transferred genetic material, in a host organism. • measures for disposing of the GMO when the release is complete and any waste derived from the GMO.	GMO from the release area.
PLANTS - Additional information for a plant	**Contribution to the assessment**
• Information on weediness including: o Members of the family of the plant or parent plants that are known to be weeds in any environment; o The potential for cross-pollination between the species and relatives known to be weeds; o The potential for the new variety to have competitive advantage and become a new or more aggressive weed. • Information about the seeds of the organism including: o whether the organism to be released will be capable of setting and allowed to set seed and, if not, whether this is planned for a later release. o If the organism is to be allowed to set seed – whether the mature seed is expected to shed from, for example, an ear, capsule or pod, the seed dispersal mechanism and the proportion of seed likely to remain in the environment following harvest. o The length of time the seeds may be capable of being dormant. • Whether the organism can be dispersed by vegetative propagation, and if so, the possible mechanisms. • Information about the capacity of the plant to add substances to, or subtract substances from, the soil (e.g. nitrogen or toxic compounds) and if so a description of all such effects.	Potential for the GMO to become a weed. Resulting environmental impact. Potential for spread of the organism from the release area, or for persistence of the organism at the release area after the release. Possible effects on the soil biota or soil properties.
Additional information where the plant is a GMO	**Contribution to the assessment**
• Information about any desirable or undesirable effects on the parent plant that may result from expression of the transgene, or an associated	Potential for unintended effects of the genetic modification and the potential impact of those effects.

insertion-related mutation, in the GMO (for example, reduced fertility, increased disease prevalence, production loss, grain shedding), including the likelihood of any such events. • Information about pollen and pollination including: o the mechanism of pollen spread (by insect vectors or by other means) in the plant population; o pollen viability for the parent plant and the GMO; o potential pollinators for the parent plant and the GMO, and their range and distribution in Vanuatu. • Quantitative data on successful cross-pollination between the parent plant, the GMO and its wild relatives. • If sexually compatible plants live near a site of the proposed release, the likelihood and extent of cross-pollination with the GMO that may occur. • If cross-pollination with the GMO were to occur, the likely resulting plants and an assessment of whether they would survive and compete well with unaffected plants. • Whether there is any likelihood that the introduced gene could cause greater toxicity (for animals, including human beings) in the proposed GMO than in an unmodified plant. • The potential of the new GMO variety having competitive advantage and being more aggressive or weedy. • Whether any products of the GMO could concentrate in the natural or human food chain to levels which become pathogenic, and available data (if any) on that subject. • Whether the biodegradability of the GMO will be different to that of the parent plant and, if so, assessment of the differences. • Assessment of the possible effects of the genetic modification on native species, including resistance of insect populations to insecticide and abundance of prey or parasites. • Information about the resistance of the GMO to a chemical agent (for example a herbicide) and the environmental risks related specifically to that resistance, e.g. transfer of herbicide or pesticide resistance genes to compatible species. • Information about the resistance of the GMO to a biological agent (e.g. an insect or fungal disease) and any environmental risks related to that resistance.	Potential for gene transfer through cross-pollination of the GMO with other plant species. Potential for escape of the GMO or introduced genes from the release area through cross-pollination with other plant species. Potential for and rate of gene transfer through cross-pollination of the GMO with other plant species. Potential for escape of the GMO or introduced genes from the release area through cross-pollination with other plant species. Potential for toxicity to humans and animals. Potential for exposure of humans and organisms to GMO residues in the environment. Potential for indirect adverse effects on native animals, insects, prey, parasites and ecosystems. Potential hazards for invertebrate-control measures (where this would pose a direct threat to the environment or human health). Potential secondary ecological effects on populations of prey or parasite species of insects targeted by a GMO. Potential for GMO to become a weed where usually controlled by the herbicide.

MICRO-ORGANISMS - Additional information when the organism is *a micro-organism* (not living in association with a plant or animal and not a live vaccine)	**Contribution to the assessment**
• Information on the range of species with which the proposed organism can interact. • Any known interaction between the micro-organism and closely related micro organisms in the environment of the release area. • The effect the organism may have on the distribution or abundance of species with which the organism can interact. • The effect the organism might have on [insects, birds, animals or humans] other organisms, including humans, that may eat it or be exposed to it. • The expected effects of the micro-organism on local soil chemistry (for example, pH, mineral leaching and nutrient levels). • Any possible effects of the micro-organism on local water quality. • The effects of the micro-organism on soil organisms known to be beneficial to plants (for example, Rhizobium, Azospirilum, Frankia and mycorrhizal fungi) and that are likely to be in a release area or nearby sites to which the micro-organism might spread. • Any known interaction between the micro-organism and other micro organisms in the environment of the release area. • The expected survival and dispersal of the micro-organism, including dispersal in natural waters, soil and upon various surfaces. • Whether the micro-organism produces spores. • Whether the micro-organism is resistant to desiccation. • Methods of sterilis ation and disinfection available, including susceptibility to ultraviolet or ionising radiation.	Potential for exposure of non-partner plants and animals. Potential ecological hazards. Potential health hazards for humans, other animals and plants. Potential alterations in soil structure and chemistry. Potential hazards for water quality. Potential hazards to beneficial soil biota. Potential for distribution beyond the release area. Methods of control in event of unintentional dispersal beyond the release area.
Additional information where the *micro-organism is a GMO*	**Contribution to the assessment**
• The effects of the GMO on the partner plant species, and consideration of how it will be monitored. • Any secondary effect that the GMO might have on the partner plant species. • Whether the modification is likely to cause any	Potential ecological hazards (e.g. through pathogenicity of the GMO). Potential for the transferred trait to increase the fitness of the partner plant species.

change to the range of host plant species susceptible to infection by the organism. • The effect the genetic modification might have on [insects, birds, animals or humans] organisms that may eat the plant. • If the micro-organism is associated with food crops, whether the proposed GMO could affect the suitability of produce for consumption by animals or human beings and, if so, the likely effect. • The expected effects of the genetic modification on local soil chemistry (for example, pH, mineral leaching and nutrient levels). • Any possible effects of the genetic modification on local water quality. • The effects the proposed genetic modification might have on soil organisms beneficial to plants (for example, Rhizobium, Azospirilum, Frankia and mycorrhizal fungi) and that are likely to be in a release area. • Information on whether symbiotic relationships are enhanced or reduced and the implications for environmental welfare. • Any known exchange of genetic material between the parent organism and plant pathogens. • What happens to the genetic modification when dead material decomposes.	Potential for exposure of non-partner plants to the GMO. Potential ecological hazards. Potential toxicity, allergenicity, or pathogenicity for food crops associated with GMO. Potential alterations in soil structure and chemistry by the GMO. Potential hazards posed by the GMO for water quality. Potential hazards posed by the GMO to beneficial soil biota. Potential for gene transfer from the GMO to plant pathogens.
Additional information for *a micro-organism living in association with a plant*	**Contribution to the assessment**
• Where the micro-organism is associated with a plant, the identity, distribution and ecology of the associated species, including the specificity of the interaction and the range of species with which the proposed organism can interact. • Whether the associated plant has an extended history of use or consumption, if so, details of the use. • The effect the organism may have on the distribution or abundance of the host plant or other species with which the organism interacts. • If the micro-organism is associated with used crops or plants, including those which have cultural uses, the likely effect on that useability (e.g. a frond being rendered more difficult to weave with.) • The effect the proposed organism might have on organisms that may eat the plant. • The expected effects of the proposed micro-organism on local soil chemistry (for example, pH,	Potential for exposure of non-partner plants to the GMO. Potential ecological hazards. Potential alterations in soil structure and chemistry. Potential hazards for water quality. Potential hazards to beneficial soil biota. Potential for distribution beyond the release area. Methods of control in event of unintentional dispersal beyond the release area.

mineral leaching and nutrient levels). • Any possible effects of the proposed micro-organism on local water quality. • What happens to the micro-organism when plant material is decomposed. • The effects the proposed micro-organism might have on soil organisms known to be beneficial to plants (for example, Rhizobium, Azospirilum, Frankia and Mycorrhizal fungi) and that are likely to be in a release area. • Any known interaction between the micro-organism and closely related micro organisms in the partner plant and in the environment of the release area. • The expected survival and dispersal of the micro-organism, including dispersal in natural waters, soil and upon various surfaces. • Whether the proposed micro-organism produces spores. • Whether the proposed micro-organism is resistant to desiccation. • Methods of sterilisation and disinfection that are available, including susceptibility to ultraviolet of ionising radiation.	
Additional information where the micro-organism in association with a plant is a GMO	**Contribution to the assessment**
• The effects of the proposed GMO on the partner plant species, and consideration of how these effects will be monitored. • Any secondary effects that the proposed GMO might have on the partner plant species. • Whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism. • The effect the genetic modification might have on organisms that may eat the plant. • If the micro-organism is associated with food crops, whether the proposed GMO could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, the likely effect. • The expected effects of the genetic modification on local soil chemistry (for example, pH, mineral leaching and nutrient levels). • Any possible effects of the genetic modification on local water quality. • The effects the proposed genetic modification might	Potential ecological hazards (e.g. through pathogenicity of the GMO). Potential for the transferred trait to increase the fitness of the partner plant species. Potential for exposure of non-partner plants to the GMO. Potential ecological hazards. Potential toxicity, allergenicity, or pathogenicity for food crops associated with GMO. Potential alterations in soil structure and chemistry by the GMO. Potential hazards posed by the GMO for water quality. Potential hazards posed by the GMO to beneficial soil biota.

have on soil organisms known to be beneficial to plants (for example, Rhizobium, Azospirilum, Frankia and mycorrhizal fungi) and likely to be in a release area. • Any known exchange of genetic material between the parent organism and plant pathogens.	Potential for gene transfer from the GMO to plant pathogens.
Additional information for *a micro-organism living inside or on an animal*	**Contribution to the assessment**
If the organism is a micro-organism living in or on animals (including an organism living in larger hosts, and micro-organism applied externally to an animal (for example, bacteria to prevent fleece rot), the following information should be considered: • The identity of the partner species, including the specificity of the interaction and the range of species with which the proposed organism can interact. • Whether the parent organism has an extended history of use or consumption, if so, details of the use. • Whether the new micro-organism or its residues will be within the products of the animal used or consumed. • Any new capacity the associated micro-organism will provide for the host species (for example, ability to degrade plant or pasture toxins). • Whether the competitive advantage, ecological fitness, biology or distribution of the host will be altered and relevant data (if any) on the subject. • Any secondary effects expected to result from the introduction of the proposed micro-organism to the host (for example, information about any possibility of the genetic modification being transferred to other organisms in the host). • Whether the micro-organism will be excreted or otherwise leave the animal and, if so, the time period that it is expected the micro-organism can survive outside the host animal. • Information on other animals or micro-organisms that may be exposed to the micro-organism in faeces or decaying carcasses of the animal, and the possibility of any secondary effects in these animals or micro-organisms.	Background information. Potential for gene transfer from the GMO to the host or other organisms in the host.
Additional information *where the micro-organism living inside or on an animal is a GMO*	**Contribution to the assessment**
• Whether the proposed GMO might be capable of establishing in, or on, other animals, including feral animals. • Other likely effects (including secondary effects) on	Potential for exposure of non-target animals plants, soil and local water to the GMO.

other plants or animals in the agricultural and natural environments. • If the proposed GMO will establish in an animal, whether the GMO will be excreted or otherwise leave the animal and, if so, the time period that it is expected the GMO can survive outside the animal.	Potential for risks, including secondary effects, on animals, plants soil and local water quality.
LIVE VACCINES - Additional information where the micro-organism is *a live vaccine for use in animals*	**Contribution to the assessment**
• The disease to be treated, or prevented, by use of the vaccine. • The species on which the vaccine is to be used. • The host range of the parent organism from which the vaccine is constructed. • The level and duration of immunity produced in the target species after administration of the vaccine. • The period over which the vaccine will be detectable in the target animal. • Whether the vaccine or its by-products are excreted or otherwise leave the animal, and if so whether components of the organism or its products may be consumed or taken up by other organisms and the effects on these organisms. • Proposed methods for disposing of waste containing the vaccine. • Whether live vaccine organisms will be carried by animals and, if so, the potential for dissemination of the vaccine organisms through contact between animals, and measures intended to be taken to minimise that potential. • Whether residues of the vaccine may be present in the meat or other products of the animal. • Effects the vaccine may have on a pregnant animal. • Whether the vaccine may cross the placenta of a pregnant animal. • Whether the vaccine is teratogenic at any stage of gestation. • Whether the use of the vaccine is likely to affect its subsequent use for vaccination against other diseases or affect the usefulness of other vaccinations. • The potential of vaccine to spread from vaccinated to unvaccinated animals or to other species (including human beings), and if the potential exists, the likely mechanism and frequency of such spread. • Whether the susceptibility of the target to the vaccine organism could be affected by the state of	Background information relevant to animal health risks. Potential for risks to non-target animals. Potential for harm to a pregnant animal or its foetus. Potential for indirect harm to animal health. Potential for exposure to the vaccine. Risk management strategies to limit exposure and escape of the vaccine from the release area.

the [target] host at the time of vaccination (for example, immunosuppression, or superimposition of other disease); or other treatments, such as drugs.	
Additional information where the *live vaccine for use in animals is a GMO*	**Contribution to the assessment**
• The potential for the genetic material of the vaccine organism to become incorporated in whole, or in part, into the genome of any cells of the vaccinated host. • The period over which the vaccine GMO will be detectable in a test animal, or its excretions. • Whether the GMO or its residues will be present in any consumed product of the animal. • If the GMO is a viral vaccine, the potential for the nucleic acid of the virus in the vaccine to be rescued, or to be restored to wild type, by recombination or complementation with intracellular viruses. • The potential of the genetic modification to spread from vaccinated to unvaccinated animals or to other species (including human beings), and if the potential exists, the likely mechanism and frequency of such spread.	Potential for somatic cell mutation, with possible health risks, such as causing cancer. Potential for exposure of humans or other organisms to the GMO. Potential for pathogenicity of the GMO for animals or other organisms. Potential for exposure of humans and animals to the GMO.
ANIMALS - Additional information where *the organism is an animal*	**Contribution to the assessment**
• Whether the animal is fertile and whether it will be allowed to breed. • Whether the proposed arrangements for handling any offspring are the same as initial animal or animals, and if not, the proposed differences.	
Additional information where the *animal is a GMO*	**Contribution to the assessment**
• Potential for the genetic modification to cross the placenta of a pregnant animal. • The capacity of the GMO to interbreed with any species native to, or currently present in, Vanuatu. • Whether the modified genetic material can be transmitted by means other than by reproduction normal for the species; and if so, the likelihood of that genetic material entering gene pools of natural populations. • Whether the modified genetic material can be transmitted to any other species; and if so, the expected mechanism of transfer, and the likely affected species.	Potential for the transferred trait to increase the fitness of the host animal. Potential for gene transfer to native or wild populations through interbreeding with the GMO. Potential for indirect ecological effects as a result of toxicity. Potential hazards from gene transfer from the GMO, including but not limited to: • Direct effects on the abundance of feral populations; • Indirect ecological effects e.g. effects on prey or predator species of feral populations; • Indirect risks to health, through spread of infectious disease;

• The effect the GMO might have on the food chain. • The potential for the GMO to produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators. • Any agricultural, environmental or disease control problems caused by feral populations of the same species. • The likelihood of the novel generic material entering the wild gene pool (for example, by interbreeding with modified farm animals). • The effect that the entry of the novel genetic material into a wild gene pool might have on the distribution and aburdance of the wild population; or on the ability of the wild population to cause agricultural or environmental problems; or in contributing to the spread of infectious disease. • If no wild population exists, the likelihood of the modified characteristic enhancing the ability of the species to establish feral populations. • Mechanisms proposed for preventing dispersal of the GMO into other ecosystems.	
BIO-CONTROL - Additional information where an *organism is to be used for biological control*	**Contribution to the assessment**
• The species targeted for biological control. • The direct effects the organism has, or is expected to have, on the target species. • The host range of the organism. • The indirect effects the organism is expected to have across the host range. • The non-target organisms that have been tested for susceptibility to the organism. • How the organism will be transmitted from one target individual and population to another, and what factors affect the transferability. • The consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals. • The consequence of the removal, or reduction, of the target species on biodiversity. • The possible secondary effects on other organisms, for example predators, prey or parasites of the target species.	Background information. Potential for exposure of non-target organisms to the GMO. Potential for secondary ecologic effects. Changes in the ecosystem resulting from a reduction in population of the target organism (including effects on predators, prey or parasites).
Additional information where an organism is to be used for biological control is a GMO	**Contribution to the assessment**
• The genetic response that may be invoked in	Potential hazards of the GMO relating to the specific

populations of target organisms as a result of the use of the GMO (for example, increased resistance to the modified organism), and the expected evidence for the response. • If the modified genetic traits can be transmitted to other organisms that are likely to be in the environment, any effects those other organisms are likely to have on non-target species. Whether the GMO produces metabolites that may have adverse effects on other organisms directly, or indirectly through concentration in the food chain, and if so the likely effect.	biological control method. Potential for adverse effects on non-target organisms (or organisms to which the modified genetic material has been transferred). Potential toxicity to non-target organisms.
BIO-REMEDIATION - Additional information where an organism is to be *used for bioremediation*	**Contribution to the assessment**
• Identification of the target substrate for bioremediation. • The effect of the organism on the target substrate. • Other substances that can be metabolised by the organism and that cannot be metabolised by the parent organism. • Whether the organism will be self-sufficient if added to the contaminated site or whether additional measures may be required (for example, provision of supplementary nutrients, growth factors, or other environmental modifications). • Any metabolites produced by the organism that may have adverse effects on other organisms directly, or indirectly, for example through concentration in the food chain. • Effects the organism or its by-products might have on other organisms that ingest it. • Effects the organism or its by-products might have on water, air or soil quality. • Whether the organism will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences. • The organism's life expectancy after bioremediation.	Background information relating to all potential hazards. Potential for survival of the organism. Potential toxicity of the organism to humans and other organisms. Potential effects on water, air or soil quality (including but not limited to effects on soil biota). Potential for escape from the release area, and risks related to this. Potential to exist in the environment after its intended use.
Additional information where an organism used for bioremediation is a GMO	**Contribution to the assessment**
• The substances other than the target substrate that can be metabolised by the organism and that cannot be metabolised by the parent organism. • Other adverse effects relating to the genetic modification.	

HUMAN FOOD - Additional information where a GMO is to be used for food for human or animal consumption	Contribution to the assessment
• Current foodstuffs produced from the parent organism and description of any differences that might be present in the GMO variety. • Known or suspected allergenicity or toxicity present in the parent organism or foods derived from the parent organism. • Whether the GMO is a major component of the food as eaten or a minor component (for example yeast cells in beer). • Any expected changes to the nutritional structure of the food as a result of the genetic modification. • Changes in micronutrients and/or bioavailability of micronutrients as a result of the genetic modification. • Description of processing needed or commonly applied before consumption, including any difference in the processing of the GMO from the parent organism. • If the organism is intended to be used as a food for human or animal consumption , any metabolites produced by the GMO that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects. • Possibility of any metabolites from the GMO concentrating in the food chain, if so description of these metabolites, pathways and tests that show whether these reach toxic levels. • Information from studies that show the GMO food products do not have potential toxicity or allergenicity.	Background information. Potential alternations in the nutritional quality of the GMO food product. Potential toxicity or allergenicity of the GMO or GMO products for humans or animals.

PART D: For processed (not alive) products and derivatives of new species and varieties including genetically modifications, that pose a risk of passing genetic material, toxicity, allergenicity or pathogens to living species.	
General Information	**Contribution to the assessment**
In addition to the general information, information should be provided on • The purpose of the import (food, feed for livestock, industrial uses etc.). • Whether there will be a single import or on-going import of the product. • Source or sources of the imported product	Background information Ability to assess risks specific to the point of origin. Understanding of the containment system.

• If there will be multiple imports
  o any variability that may be expected in the product imported.
  o Normal quarantine and inspection measures that will apply to every import.
• Description of the processing that has occurred.
• Whether the risk of concern is associated with a major component of the product being imported or is a minor component.
• Whether and how processing destroys any pathogens, toxicity, quarantine risks that might be present in the unprocessed product.
• Known pathogens or toxicity in the unprocessed source that might remain active in the processed product.
• Whether the product poses any risk of transferring pathogens, toxicity or allergenicity to consumer organisms (including humans, other animals and plants).
• Whether the product poses any risk of transferring pathogens or toxicity to the physical environment, including residues in soils, contamination of water etc.
• Environmental risks including:
  o potential to spread or convey pathogens to environmental or commercial resources.
  o potential to enhance the vigor or viability of pests.
  o potential for use (including consumption if a food product) to convey pathogens to humans or the human food chain.
• Any occupational health and safety risks for persons involved in handling or using the product.
• Any other factors of concern associated with the product.	

Risk management measures	
• Information including education and labelling provided to the consumer or user. • Advice on occupational health and safety issues. • Information on measures that prevent contaminants or byproducts affecting the physical environment, biodiversity, human health or productive systems.	
Additional information where the product is *derived from a GMO*	**Contribution to the assessment**
• Current products produced from the parent organism and description of any differences that might be	Background information.

present in the GMO variety. • Whether the GMO is a major or minor component of the product. • Where the product is used within primary production systems, any expression of the genetic modification that could be manifested in the outputs of the production system. • Where the product is used within primary production systems any expression of the genetic modification manifest in by-products of the productive system, including contamination of soils, water or biodiversity. • The survival periods of any metabolites derived from the product in the physical environment, including contamination of soils, water or biodiversity. • Methods of containment, collection or remediation should byproducts contaminate environmental systems.	
Additional information where the GMO product will be used as a food or animal feed.	

• The species to which the product is to be fed. • Any changes to the nutritional structure of the food as a result of the genetic modification. • Changes in micronutrients and/or bioavailability of micronutrients as a result of the genetic modification. • Description of processing needed or commonly applied before consumption, including any difference in the processing of the GMO from the parent organism. • If the organism is intended to be used as a food for human or animal consumption, any metabolites produced by the GMO that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects. • Possibility of any metabolites from the GMO concentrating in the food chain, if so description of the metabolites that might concentrate, pathways and tests that show these do not reach pathogenic levels. • Information from studies that show the GMO food products do not have potential toxicity or allergenicity. • The period over which the product will be detectable in the target species.	Potential alterations in the nutritional quality of the GMO food product. Potential toxicity or allergenicity of the GMO or GMO products for humans or animals.

• Whether by- products are excreted or otherwise leave the animal, and if so whether active components may	

be consumed or up-taken by other living things. • Where appropriate, proposed methods for disposing of waste containing any residues or byproducts of the. • The period over which any residues remain present /active within the target species, the potential for dissemination through the food chain and the consequences of dissemination through the food chain. • Whether the product or its by-products may cross the placenta of a pregnant animal. If so whether it is potentially teratogenic at any stage of gestation of any animals. • Whether the susceptibility of the target to the product could be affected by the state of the host at the time of vaccination (for example, immunosuppression, or superimposition of other disease); or other treatments, such as drugs.	Background information relevant to animal health risks. Potential for risks to non-target animals. Potential for harm to a pregnant animal or its foetus. Potential for indirect harm to animal health. Risk management strategies to limit exposure and escape of the vaccine from the release area.
Additional information where the food or feed is derived from a GMO	**Contribution to the assessment**
• The potential for the genetic material to become incorporated in whole, or in part, into the genome of any cells of the host. • The period over which the genetic material will be detectable in a test animal, or its excretions. • Whether the GMO or its residues will be present in any product of the target species. • The potential of the genetic modification to spread to non-target animals or to other species (including human beings), and if the potential exists, the likely mechanism and frequency of such spread.	Potential for somatic cell mutation, with possible health risks, such as causing cancer. Potential for exposure of humans or other organisms to the GMO. Potential for pathogenicity of the GMO for animals or other organisms. Potential for exposure of humans and animals to the GMO.

Appendix 3: Organisms not requiring biosafety assessment

The initial import of all living organisms or their products for a specific purpose will normally undergo a thorough pre-import risk assessment. The assessment decision will be placed on the biosafety register and will normally be specific to a particular species or variety (including genetically modified variety) and specified uses.

Organisms not requiring pre-import biosafety assessment :

- Repeat importation of organisms for uses that are consistent with a previous biosafety decision included in the biosafety register. However, quarantine considerations to prevent the introduction of pathogens and pests will apply to each and every importation of the permitted organism.
- Organisms or their products exempt as a consequence of international agreements.
- Organisms or their products exempt as a consequence of domestic biosafety laws.
- Processed foods that do not include GMOs and that are not on the list of reserved processed foods.

Appendix 4: References

Animal Importation and Quarantine Act No. 7 of 1988 [Cap.201]

Animal Importation and Quarantine Regulations Order No. 14 of 1995

Anon (2003). Public participation and the Cartagena Protocol on Biosafety: a review for DFID and UNEP. Part III: a practical guide.

Asian Development Bank (2001) Vanuatu. Agriculture and Fisheries Sector Review 2000. ADB, Manila.

Bakeo, W., Acting Team Leader REDI Unit, Department of Provincial Affairs. Personal communication. 2004.

Biosecurity Australia (2003). Import risk analysis handbook, Agriculture, Fisheries, Forestry – Australia, Canberra.

Buleguli, L. S., Clerk of Parliament. Personal communication. 2004.

Convention on Biological Diversity, 5 June 1992

Customs and Inland Revenue Act No.15 of 1999

Dangerous Drugs (Control) Act [Cap. 12]

Department of Agriculture (1995) Policy Statements for Departmental Divisions and Areas of Operation. Department of Agriculture, Port Vila.

Department of Forests (1997) National Forest Policy Statement. Department of Forestry, Vila.

Dorras, J., Wan Smolbag Theatre. Personal communication. 2004.

Draft Food (Regulations) undated document, Public Health Department.

Environmental Management and Conservation Act No.12 of 2002

Fenua, T., Secretary to Members Parliament. Personal communication. 2004.

Fisheries Act [Cap. 158]

Food (Control) Act No.21 of 1993

Forestry Act No. 26 of 2001.

Gordon, N., Audits Officer Dept of Customs and Inland Revenue. Personal communication. 4 November 2004

Hadfield, S (2000) Vanuatu Development of Division of Agriculture and Rural Development Corporate and Business Plan. Unpublished.

Heywood, V. H. (1995) Global Biodiversity Assessment. UNEP , Cambridge.

Hosea, S., Manager of Central Medical Stores. Personal communication. 8 November 2004.

International Plant Protection Convention (2004). Pest risk analysis for quarantine, including analysis of environmental risks and living modified organisms. International standards for phytosanitary measures. Publication no. 11. Rome.

Iorinmal, L. Curriculum Development Unit. Personal communication. 2004.

Joseph, S. and Malosu, C. (2003). Public awareness and participation. Port Vila, Vanuatu.

Kalmor, K.T. (2004). Capacity building programme report for Vanuatu national biosafety project. Port Vila, Vanuatu.

Laban, S., Environmental Health Officer, Public Health Department. Personal communication. 27 Oct. 2004.

Mackenzie, Ruth, Burhenne-Guilmin, Francoise. La Vina, Antonio G.M. and Wersman, Jacob D. incorporation with Ascencio, Alfonso, Kinderlerer, Julian, Kummer, Katharina and Tapper, Richard (2003). *An explanatory Guide to the Cartagena Protocol on Biosafety*.IUCN, Gland, Switzerland and Cambridge, UK.

Mael, S. H., Coordinator, Biosafety Project (VQIS). Personal communication. 2004.

Malosu, C. Environmental Impact Assessment Officer, Vanuatu Environment Unit. Personal Communication.2005.

Mara. T. Coordinator, National Capacity Self Assessment Project , Vanuatu Environment Unit, Personal Communication. 2005.

Ministry of Education (2000). The importance of quarantine in Vanuatu. Notes and activities for Year 10 Agriculture teachers and students. Port Vila, Vanuatu.

Nirua, J., Acting Director, Department of Secondary, Technical & Further Education. Personal communication. 2004.

Office of the Gene Technology Regulator (2002) Risk Analysis Framework for Licence applications to the Office of the Gene Technology Regulator. Office of the Gene Technology Regulator, Canberra.

Plant Protection Act No.14 of 1997

Rio Declaration on Environment and Development. Principles 9 and 10.

Sale of Medicines (Control) Act [Cap.48]

Secretariat of the International Plant Protection Convention (FAO) (2004). Pest risk analysis for quarantine pests, including analysis of environment risks and living modified organisms. ISPM No.11. Rome.

Tapisuwe, A. 2001. Invasive pest species in Vanuatu. Unpublished report to the Environment Unit.

Tarilongi, B., Director of VQIS. Personal communication. 8 November 2004.

The Cartagena Biosafety Protocol to the Convention on Biological Diversity

Vanuatu Agricultural Research and Training Centre Act No. 15 of 2002

Wotu. B., Acting Director of Customs. Personal communication. 8 November 2004