DEPARTMENT OF ENVIRONMENT AND CONSERVATION

PAPUA NEW GUINEA'S NATIONAL BIOSAFETY FRAMEWORK

FINAL DRAFT

United Nations Environment Program

Global Environment Facility

DISCLAIMER:

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

MINISTER'S STATEMENT

The issues relating to Biosafety are new and many of us in Papua New Guinea are not fully aware of what is involved. That is why the Department of Environment and Conservation has been active in the last two years trying to develop a Draft National Biosafety Framework so that we have a system to address the safe use of modern biotechnology. One advantage is that people will be more aware of the benefits of biosafety and the dangers genetically modified organism's pose to the environment, biodiversity and human health. In simple terms, biosafety is all about "the safe handling, transfer and use of living modified organism's resulting from modern biotechnology".

As part of our obligation under the Cartegena Protocol on Biosafety, a new legal environmental agreement adopted in 2003 by the global community to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organism's resulting from modern biotechnology that may have an adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movement's. The National Government is committed to the task of ensuring that we promote the use of modern biotechnology for the greater benefit of the community while at the same time minimizing the risks they bring to our environment and human health.

This is what the National Biosafety Framework is all about. Comprising of a combination of a policy, legal instruments and administrative arrangements, the document outlines what we, as a government will do in promoting, regulating, monitoring and enforcing the rules relating to the development and use of the technology and its products in Papua New Guinea.

Finally, it has not been easy putting together the National Biosafety Framework, given the limited capacity and resources we have as well as technical requirements needed in the Cartegena Protocol on Biosafety. But, we have consulted widely and we have received strong support and assistance from many other government departments and agencies as well as international organizations. I want to acknowledge the commitment of all our stakeholders and the role they played in helping to develop our domestic biosafety measures.

Our challenge now is to implement the policy and regulatory regime, build up our human resource and institutional capacity, share information and work with our neighbors at the bilateral, regional and international level to ensure that the National Biosafety Framework contributes to improving our environment, economy and the quality of life for the people of Papua New Guinea.

HON. WILLIAM DUMA, LLB, LLM, MP
Minister for Environment & Conservation

20/10/2005

ACKNOWLEDGEMENT

The draft National Biosafety Framework for Papua New Guinea is a product of a process which started in 2003. The process has taken over 18 months involving wide public consultation with stakeholders through surveys, meetings supplemented by four national stakeholder workshops and public awareness activities. The process has been long and many people have assisted in the preparation and the development of the draft National Biosafety Framework.

I want to acknowledge the contributions and support of National Biosafety Biotechnology Committee (NBBC) members. The members are: Professor Lance Hill (Professor, School of Natural Sciences, University of Papua New Guinea), Mrs Rosa Kambuou (Principal Scientist, National Agriculture Research Institute), Dr Miok Komolong (Acting Director, Unitech Biotechnology Centre, University of Technology), Mr Tom Okpul (Lecturer, Agriculture Department, University of Technology), Mr Douveri Henao (Legal Advisor, Department of Justice and Attorney General), Mrs Rose Kavanamur (Environmental Health Advisor, Department of Health), Mr Johnny Moses, (Manager Certification, National Institute of Standards and Technology), Mr John Susub (Import and Export Manager, National Agriculture Quarantine Inspection Authority), Mr John Goava, (Legal Officer, Independent Consumer and Competition Commission), Mr Ian Onaga, (Codex Contact Point, Department of Agriculture and Livestock), and Dr Navu Kwapena (Secretariat, PNG Biodiversity Network).

I also wish to thank Dr Carmel Pilloti (OPRA), Mr Dagwin Suarkia (PNG IMR), Dr Vele Pat and Dr Samson Laup (CCRI) for their active participation and guidance during the workshops. I'm also grateful to Dr Keneti Faulalo and Dr Nizar Mohammed of the UNEP Biosafety program for their continued guidance to the Project. I thank Dr Abdul Moeed of ERMA New Zealand for reviewing the draft NBF and Professor Mohammed Wagih, former Director of the Biotechnology Centre, Unitech in providing guidance to the Project in the initial stages. In particular, I want to acknowledge the key role played by Mr Eric Kwa (Consultant) in developing some of the five key components of the National Biosafety Framework.

Finally, I express my deepest gratitude to those in the Department of Environment and Conservation, particularly Secretary, Dr Wari Iamo and Deputy Secretary, Mr Robert Norombe for the continued support to the project. I also record my appreciation to Mr John Genolagani (First Assistant Secretary, Conservation Division), Mr Barnabas Wilmot (Assistant Secretary, Wildlife Enforcement Branch) DEC, Mr Goro Arigae, (Biosafety Project Assistant) and Mr Juda Nundima. Without your continued support, guidance and valuable inputs, the draft NBF would not have been finalized.

VEARI KULA
National Project Coordinator
Department of Environment and Conservation

TABLE OF CONTENTS

ACRONYMS

CNA	Competent National Authority
DEC	Department of Environment and Conservation
ERMA	Environment Risk Management Authority
GMO	Genetically Modified Organism
NBBC	National Biosafety and Biotechnology Council
NBF	National Biosafety Framework
NGO	Non-Governmental Organization
PIC	Prior Informed Consent
PNG	Papua New Guinea

1. GENERAL INTRODUCTION

1.1 Context for Papua New Guinea's National Biosafety Framework

Biosafety issues are becoming very contentious today given the uncertainty of the impact of genetically modified organisms (GMOs) on the environment, biodiversity and the people. There are those that view GMOs as an answer to alleviating world hunger and mitigating global health problems through the introduction of new and technologically advanced GMO for food, feed, food processing and pharmaceuticals. Then there is the other group that argue that GMOs pose a risk to the environment, biological diversity and the safety and health of the people.

Those that support GMOs comprise mostly the industrialized countries which have developed new technologies in developing a wide range of products, processes and services which have enhanced human health, agricultural production and environmental conservation. The opponents of GMOs consist mostly of developing countries which are the main recipients of GMOs as food, food processes and pharmaceuticals. The position of developing countries is a paradox: on the one hand they are the host of the global poor and hungry and on the other hand, they hold the majority of the world's biodiversity which are threatened by risks posed by GMOs.

PNG has not ratified the Protocol since it was opened for signature in 2000. Now that the Biosafety Protocol is in force, it raises a number of critical issues which PNG can no longer avoid, but must address to enable the global community to know the country's position on GMOs. In this context, PNG has begun to address issues of biosafety and biotechnology with the initiation of the UNEP/GEF Biosafety Project.

Several programs were undertaken under the Biosafety Project. These were:

- Reviews in 2003 on key aspects of biosafety and biotechnology.
- Hosting of the first National Biosafety Consultative Workshop in March 2004 to decide on national priorities and present findings of surveys.
- The formulation of a draft Biosafety Policy Framework.
- Hosting of the second National Biosafety Consultative Workshop in September 2004 to deliberate in draft Policy.
- The formulation of a draft Biosafety and Biotechnology Legal Framework.
- Hosting of the third National Biosafety Consultative Workshop in March 2005 to deliberate on the draft Bill.
- Presentation of documents for ratification of the Cartagena Protocol to the National Executive Council by DEC in March 2005 and ratification to the Cartagena Protocol on Biosafety before September 2005.

- External review of the NBF in June 2005 by Regional consultant.
- Hosting of the fourth National Biosafety Consultative Workshop in May 2005 to finalize draft National Biosafety Framework.
- Finalize and endorsement of draft NBF by Minister for Environment and Conservation before submission to UNEP.

These programs manifest the commitment of the Government in tackling issues of biosafety and biotechnology even before it ratifies the Cartagena Protocol. It is anticipated that the Parliament will ratify the Protocol before the end of 2005.

There exists strong evidence that there are already GMOs in the country which have been imported into the country mostly as food, feed or for processing. And with globalization, it is likely that GMOs will pass through PNG soil. As a developing country with a population of 5.1 million with 85% of the people living in rural areas and with over 700,000 biological species, biosafety and biotechnology issues pose a real challenge to PNG. On the one hand, it must develop new food production processes and also new pharmaceuticals to alleviate food security and health issues and promote sustainable development, and on the other hand, it must introduce innovative strategies to protect and conserve its unique and diverse biological diversity. The driving force for biosafety and biotechnology in PNG is improving the living conditions of the people through the sustainable use of GMOs and genetically modified products.

This paradox must be considered in the light of the country's limited human and institutional capacities in handling, using, managing and developing genetically modified products. At a more specific and practical level, the pertinent biosafety and biotechnology issues for PNG are:

- Increase awareness on biosafety and biotechnology;
- Conduct an inventory to establish number of GMOs in the country either as food, feed, food processes or pharmaceuticals;
- Developing an institutional framework for the assessment of GMOs;
- Develop regulations and guidelines for the safe assessment, handling, use, management and transfer of a GMO;
- Strengthen and improve human and institutional capacities for the identification, handling, storing and assessing of risks related to a GMO;
- Formulating appropriate policy and regulatory framework on biosafety and biotechnology;
- Strengthen and promote the precautionary approach;
- Strengthen and promote community participation in the determination, assessment, use, management and transfer of a GMO; and
- Strengthen institutional networking and coordination

These key issues provide the basis for the draft NBF. The draft Biosafety and Biotechnology Policy and the regulatory framework have been designed to address these issues and also to simplify some of them.

1.2 Key Elements of the National Biosafety Framework

There are five elements of the National Biosafety Framework. These are:

1. A National Biosafety Policy
2. A Regulatory Regime
3. A System to Handle Notifications and Requests
4. System for follow-up Actions such as monitoring and enforcement
5. A System for Public Information and Participation

These elements are considered in detail below.

2. BIOSAFETY POLICY

2.1 The Draft Biosafety Policy

2.1.1 Policy Development

The development of the draft Biosafety and Biotechnology Policy is a direct result of the Biosafety Project. The first step in the policy evolution process was the completion of several surveys conducted under the auspices of Biosafety Project in late 2003. The findings of the surveys were presented and deliberated at the first National Biosafety Consultative Workshop held in Port Moresby in March 2004.

There were several conclusions reached at the first workshop. The most important being the formulation of a biosafety and biotechnology policy. The stakeholders at the workshop agreed that there was a need to develop a policy framework on biosafety and biotechnology. A draft biosafety policy was formulated and circulated amongst stakeholders for review and comments. In September 2004, a second workshop was held to bring together the stakeholders to consider in detail and endorse the draft policy. At this workshop, the stakeholders deliberated on the draft policy and accepted the document. One key outcome of the 2nd workshop was to address GMOs rather then LMO's as outlined in the Cartagena Protocol on Biosafety.

2.1.2 Policy Objectives

There are nine major objectives of the draft Biosafety and Biotechnology Policy. These are:

1. To ensure the safe handling, use and management, importation, development, fermentation and field test of genetically modified organisms for the safety of

the environment, biodiversity and human health protection in Papua New Guinea.

2. To identify and strengthen institutional capacities for the assessment of risks associated with the handling, use and management of genetically modified organisms.

3. To strengthen national institutions engaged in the research and development of genetically modified organisms particularly for food, food processes and pharmaceuticals which contribute to the health and well-being of Papua New Guineans and their environment.

4. To promote the development of guidelines for the assessment, use, management and transfer of genetically modified organisms.

5. To regulate the trade in genetically modified organisms that may have harmful effects on the health of Papua New Guineans and their environment and biodiversity.

6. To actively promote the participation of all stakeholders.

7. To facilitate the active participation of local communities in the use, management and transfer of genetically modified organisms that may have an impact on their biological resources and their communities.

8. To increase and promote the awareness of Papua New Guineans in biosafety and modern biotechnology issues.

9. To strengthen the capability for biosafety policy research, analysis and formulation for the biotechnology sector.

A number of strategies have been identified in the Policy to enable the achievement of these Policy objectives. In the short term the Government will:

1. Develop a regulatory regime;
2. Introduce guidelines and regulations relating to the importation, development, field test, and fermentation of a GMO, Field Testing of GMOs, Risk Assessment and Risk Management Plan and Requirements for a GMO licence;
3. Set up an administrative system to handle requests as well as to develop a system for follow up actions such as monitoring and enforcement;
4. Promote public awareness on biosafety and biotechnology; and
5. Identify and develop programs for capacity building with DEC and other relevant government agencies.

In the long term the Government intends to undertake a series of activities including:

1. Promote and strengthen the policy and regulatory regimes;
2. Promote and strengthen collaboration between stakeholders;
3. Strengthen the capacity of stakeholders in understanding and implementing the biosafety law and policy;
4. Increase public awareness on biosafety;
5. Encourage and strengthen public participation in biosafety and biotechnology matters;
6. Improve the administrative systems; and
7. Promote research and development of GMOs for food, food processes and medicines.

2.2 Relationship Between the Biosafety Policy and Other National Policies

The draft Biosafety and Biotechnology Policy complements several major national policies which have been adopted by the government. These include: (1) the Environment Policy 1976; (2) the Medium Term Development Strategy 2005-2010 (MTDS); (3) the National Agriculture and Livestock Policy 2001-2012; (4) National Food Security 2000-2010; (5) the National Health Policy 2001-2010; (6) the National Population Policy 2000-2010. Each of these policies is considered below.

2.2.1 Environment Policy

The 1976 Environment Policy is an expansion of Goal 4 of the National Goals and Directive Principles of the *Constitution*. The key element of the Policy is the promotion of the sustainable development concept captured by the term "wise use". The Environment Policy seeks to foster proper environmental management for the benefit of the present and future generations and the consideration of biodiversity protection and sustainable use in economic planning. There are five key principles of the Environment Policy. These are:

(a) Development must be economical, social and ecological;
(b) Wise use of non-renewable natural resources;
(c) Recognition of the ability of the environment to produce renewable resources;
(d) Safeguarding and wisely managing the wildlife and their habitat in the development process; and
(e) Planning to be applied to human settlement and urbanization.

The Biosafety and Biotechnology Policy embraces some of the principles promulgated by the Environment Policy. These include the precautionary approach; sustainable development and biodiversity conservation and protection.

2.2.2 MTDS

The MTDS is the principal national development planning tool for the government. The MTDS outlines the government's key development goals and aspirations for the next 10 years. The primary vision of the current MTDS is building partnership between the government and the people.

The MTDS promotes five national development goals. These are: (1) export-driven economic growth; (2) rural development; (3) poverty reduction; (4) good governance; and (5) promotion of agriculture, forestry, fisheries and tourism on a sustainable basis. The MTDS 2005 – 2010 adopts these five goals as the pillars for the development of PNG over the next five years and beyond. The government aims to achieve these five goals through a series of intervention strategies.

The draft Biosafety and Biotechnology Policy establishes a framework for the scrutiny of imported genetically modified products and the research and development of GMOs and the consequential development of genetically modified products to improve food production for the people and development of new pharmaceutical products, which enhance the health of the people of PNG.

2.2.3 National Agriculture and Livestock Policy

Agriculture has been described as the backbone of the country's economy. It is estimated that more than 85% of Papua New Guineans live in the rural areas of the country. These people live off their land, producing mostly subsistence crops. The main source of income for these rural dwellers is agricultural cash crops. The challenge for Papua New Guinea has and continues to be the development of strategies which will enable the 4, 412,169 people in the rural areas to harness their resources through agriculture production to enhance and improve their livelihood.

The Agriculture and Livestock Policy targets four main areas. These are: (1) sectoral policies relating to economic and other policies specific to the sector; (2) commodity policies relating to policies focused on expanding production on a sustainable basis; (3) other development policy issues relating to inter-sectoral and interacting policies and compliance; and (4) monitoring and evaluation policies relating to performance requirements of the sector.

The Biosafety and Biotechnology Policy affect's the Agriculture Policy in two main ways. The first is that the Policy articulates the government's position on the introduction of new food crops in the country and second it provides the framework for genetic engineering (biotechnology). The Policy promotes the introduction of new root and tuber crop varieties to boost household production. The introduction of these new food crops if genetically modified must meet the requirements set out in the Policy. If the root and tuber crop varieties are not genetically modified, they fall outside the scope of the Policy.

Biotechnology in the country is focused primarily on tissue culture. Most research and development institutions in the country concentrate their energies in this specific area of applied biotechnology. The only institution which has the capacity for advanced biotechnology research is the Papua New Guinea University of Technology Biotechnology Centre.

2.2.4 National Food Security Policy

Food security is a real concern for PNG. It was estimated in 2001 that about 29 % of the population or 1,505,328 Papua New Guineans are food insecure. This can partly be attributed to the disparity in the rate of population and the rate of food production. In 2004, it was estimated that the country's population was growing at 2.6 % while the growth rate of food production was 1.2 %. Given this dilemma, the National Food Security Policy 2000-2015 was formulated to "increase and diversify food production in Papua New Guinea in order to achieve greater self-sufficiency in food and attain food security at the national and household levels by the year 2015".

A number of strategies have been devised to achieve the goal of the Food Security Policy. These include: (1) diversification of food production and marketing; (2) improving food quality and safety; (3) adopting appropriate technology to sustainably intensify production systems and ensure sufficient supplies of food and (4) improve production, downstream processing, marketing and utilization of food.

The Biosafety and Biotechnology Policy has been fashioned to meet some of these objectives. Diversification of food production which entails GMO will fall within the ambit of the Biosafety and Biotechnology Policy.

2.2.5 National Health Policy

The ten year Health Policy is an ambitious action plan aimed at improving the delivery of health services to the people and strengthening the institutions responsible for the delivery of health services.

The Health Department has, in the light of the new MTDS 2005-2010, reprioritized its goals and objectives to meet the governments goals expressed in the MTDS. The Department has agreed to pursue five main goals in the short-term to provide the launching pad for the implementation of the Health Policy in the long-term. These reprioritized goals are: (1) disease control – particularly malaria and TB; (2) immunization; (3) safe motherhood and family planning; (3) HIV/AIDS and sexually transmitted infections; and (4) maternal mortality- reduce by three quarters, maternal mortality by 2015.

It is envisaged that these five national health goals will enhance the health status of the country in the long term. In the area of biosafety, the development of new medicines to control TB, cancer, HIV/AIDS and other sexually transmitted infections will be significant. The government has recognized the importance of biotechnology by issuing

permits to several international research and development institutions to conduct biodiscovery activities in PNG with the primary aim of finding new drugs to fight the above diseases.

2.2.6 National Population Policy

The National Population Policy is a very comprehensive document setting out in detail the population issues of Papua New Guinea and provides strategies to overcome some of these problems. The Policy is a key tool for decision-making for economic and socially development.

An important component of the Population Policy is that it embraces sustainable development as a key principle for development planning. The policy calls on the relevant government agencies to take into account environmental protection and conservation in the planning process because of the intricate linkage between Papua New Guineans and the environment. It also calls for the reduction in unsustainable production and consumption patterns as they have a significant impact on the health of the people and their environment.

The importation and research and development of GMOs must be considered against this Policy. Where the GMO will not lead to sustainable production and does not substitute unsustainable consumption patterns, it must be prevented from entering the country and if it is being developed in PNG, it must be prohibited from being released into the environment.

In the formulation of the draft Biosafety and Biotechnology Policy, the relevant considerations under these six policies and other related existing national policies were taken into account. The main focus of the Biosafety and Biotechnology Policy is to enhance and strengthen the government's goals and aspirations expressed in the existing national policies.

3. REGULATORY REGIME

3.1 Draft Biosafety and Biotechnology Bill

3.1.1 Development of the Bill

The formulation of the Biosafety and Biotechnology Bill is the culmination of all the preparatory work undertaken under the first and second stage of the UNEP/GEF Biosafety Project. The scheme of the Bill reflects the views and comments emanating from the first and second workshops, and also the findings of the surveys. The structure of the Bill complies with current national practice.

3.1.2 Objectives of the Bill

There are five main objectives of the Bill. These are:

1. To protect the health and safety of people and the environment, by identifying risks posed as a result of modern biotechnology, and by preventing, reducing and eliminating those risks through regulating genetically modified organisms;
2. To ensure that proper weight is given to both the long-term and short-term social, economic, environmental and equity considerations in deciding all matters relating to genetically modified organisms and to prevent threats posed by genetically modified organisms on the country's unique biodiversity;
3. To protect and sustain the potential of natural and physical resources against threats posed by genetically modified organisms to meet the reasonably foreseeable needs of future generations, and safeguard the life-supporting capacity of air, water, land and eco-systems;
4. To avoid, remedy or mitigate any adverse effects of activities on the environment by regulating in an integrated, cost-effective and systematic manner, activities and dealings relating to genetically modified organisms; and
5. To ensure that dealings with genetically modified organisms are regulated in a way that is consistent with Papua New Guinea's national interests.

The Bill stipulates that there are eight basic principles which must be considered in the pursuit of the objectives of the Bill. These are:

1. The protection and conservation of the ecosystem and the life-supporting capacity of air, water and soil;
2. The strengthening and enhancement of the social, economic and cultural wellbeing of the people and future generations; and
3. The maintenance and strengthening of traditional knowledge and practices that promote sustainable development and the capacity of people and local communities;
4. The application of the precautionary approach;
5. The sustainable use of biological resources;
6. The ecological integrity of ecosystems;
7. Science-based risk assessment and communication of biotechnology products; and
8. The economic and related benefits to be derived from the use of a particular genetically modified organism.

3.1.3 The Competent National Authority

The identification of an appropriate institution which should perform the functions of a competent national authority was discussed at length by the national stakeholders at the second National Biosafety Consultative Workshop. It was agreed that the DEC be designated as the Focal Point as well as the Competent National Authority (CNA). The Bill reflects this position by declaring the DEC as the Focal Point and the CNA.

The powers and functions of the CNA are:

- To administer and implement this Act;
- To establish mechanisms for the exchange of information with other countries, particularly those in the region;
- To provide advice to other regulatory agencies about genetically modified organisms;
- To monitor, adopt and implement international best practice in relation to the regulation of genetically modified organisms;
- To maintain links with international organizations that deal with the regulation of biotechnology and with agencies that regulate genetically modified organisms in countries outside Papua New Guinea; and
- To do all that may be deemed necessary to implement the policy and provisions of this Act.

The work of the CNA is undertaken largely by the Biosafety and Biotechnology Council (NBBC) created under the Bill. The NBBC will be administered by DEC which will also act as its secretariat. The NBBC will have the following powers and functions:

- To advise the Minister on the importation, development, field test, usage, handling, administration, labelling, monitoring and enforcement and awareness of genetically modified organisms in Papua New Guinea;
- To approve all licences relating to the dealing, usage, handling, importing, exporting, research and development, of genetically modified organism;
- To monitor, review and control negative impacts of genetically modified organisms on human health, the environment and biological diversity;
- To publish statements, reports and guidelines relating to the performance of its functions;
- To ensure that benefits of genetically modified organisms are maximized for the posterity and well being of the people of Papua New Guinea;
- To ensure the maintenance of ecological integrity;
- To promote and strengthen traditional knowledge and practices relating to the research and development and use of genetically modified organisms;
- To periodically review any decision made in relation to a licence under the Act;
- To regulate the import and export of genetically modified organisms;
- To enforce labelling of genetically modified organisms and their use;
- To develop regulations relating to genetically modified organisms;
- Promote sustainable development through the development and use of genetically modified organisms;
- To promote and monitor research and development of genetically modified organisms;

- To protect the rights of local communities over their biological resources where an activity relating to a genetically modified organism is directly or indirectly connected to customary land;
- To exercise any power in a manner that is not inconsistent with the requirements of a regulatory contract; and
- To carry out any powers, functions and duties vested on it by or under the Act or any other enactment.

The NBBC's foremost responsibility would be to assess and evaluate all applications concerning genetically modified organisms on a case-by-case basis. Other responsibilities would be to develop containment standards, application forms and guidelines for the users of those forms or other guidelines as appropriate. Matters such as the importation, exportation, sale, use and research and development of GMOs will be regulated by the CNA with the NBBC. All activities involving GMOs will require a licence from the NBBC. Notification regarding the transit of a GMO must be addressed to the CNA.

The DEC is therefore, the primary agency for all activities relating to genetically modified organisms.

3.1.4 The Precautionary Approach

The precautionary approach is a key element of the environmental policy and law of PNG. The Environment Policy of 1976, Goal 4 of the *Constitution* of PNG and the *Environment Act* 2000 entrench the position of the precautionary approach in PNG. The Bill also adopts the precautionary approach by requiring the provision of risk assessment and risk management plans.

3.1.5 Importation, Exportation and Transshipment of GMO

The Bill sets out simple provisions governing the importation, exportation and transshipment of GMOs. The advanced informed agreement is an integral component of the Bill. Where a person intends to import or export a GMO, the importer or exporter is required to obtain a licence from the NBBC before he or she can undertake the activity.

3.1.6 Research and Development of GMO

Any research involving modern biotechnology requires a licence under the Bill. The Bill spells out certain conditions that must be met before a licence for the activity is issued. These conditions include obtaining the **prior informed consent** of the local communities and local government bodies and rules about **benefit sharing** arrangements. This is a unique feature of the Bill.

3.1.7 Exemptions

One of the contentious issues that had to be resolved by the stakeholders during the three consultative meetings was the need to exempt certain organisms and processes that are

considered vital to the health and welfare of Papua New Guineans from the provisions of the Bill. It was agreed that because some of these processes or organisms are important for trade purposes they must be exempted under the Bill. A compromise was finally reached at the third consultative workshop to include a provision empowering both the Minister and the NBBC to exempt certain processes and organisms from the provisions of the Bill.

Under the Bill certain genetically modified organisms can now be exempted from the provisions of the Bill. The exemption provisions also enable the NBBC to exempt certain genetically modified organisms from the AIA procedure.

3.1.8 Regulations

The Bill makes provision for the development of Regulations to supplement the Bill. Some of the areas requiring Regulation include:

1. Research and development of genetically modified organisms;
2. Containment of genetically modified organisms;
3. Importation of genetically modified organisms;
4. Exportation of genetically modified organisms;
5. Handling of genetically modified organisms;
6. Field Testing of genetically modified organisms;
7. Risk assessment of genetically modified organisms;
8. Labelling of genetically modified organisms;
9. Charges and fees relating to research and development, importation, exportation, handling and use of genetically modified organisms;
10. Participation of local communities in the research and development, handling and use of genetically modified organisms and related activities; and
11. Criteria for determining what is or is not a genetically modified organism;
12. Establishing institutional biological safety committees, their powers and functions and criteria for appointment;
13. Equitable distribution of benefits arising from the development and use of genetically modified organisms derived from the country's biological resources.

A draft Regulation has already been formulated for approval with the Bill. The Regulation is entitled:

- Biosafety and Biotechnology (Information Required for a Genetically Modified Organism Licence, Risk Assessment and Field Testing) Regulation.

3.1 Relationship between the Biosafety and Biote chnology Bill and existing Laws

There are several pieces of legislation which have a direct bearing on biosafety and biotechnology issues in PNG. They can be categorized under two main headings: (1) research and development; (2) import and export.

3.1.1 Research and Development of GMO

There are several laws which fall under this category. The principal ones are tabulated below.

Name of Legislation	***Purpose and Objective of Legislation***	***Responsible Agency***	***Status of Legislation***
National Agriculture Research Institute Act 1996	• Establishes the National Agriculture and Research Institute (NARI) • Empowers the institute to undertake research into any branch of biological, physical and natural sciences related to agriculture; cultural and socioeconomic aspects of the agricultural sector, especially of the smallholder agriculture and matters relating to rural development	NARI and also Department of Agriculture and Livestock (DAL)	Current
Medical Research Institute Act (Consolidated to No.20 of 1998)	• Establishes the Institute of Medical Research (IMR) • Empowers the institute to conduct and foster research into: (1) any branch of medical science or biology; (2) anthropological and sociological aspects of health and ill-health; and (3) matters relating to public health generally	IMR and the Department of Health (DOH)	Current
National Aids Council Act	• Establishes the National Aids Council (NAC) • One of the functions of the Aids Council is "to initiate, encourage, facilitate and monitor research, whether medical, epidemiological, psychological, sociological, legal and otherwise, on or in relation to HIV/AIDS in Papua New Guinea	NAC, the Department of the Prime Minister and DOH	Current
Animals Act	• Legislation relates to the protection of cattle, sheep, horses, goats and dogs and cruelty to animals generally	DAL, Police	Current
Cocoa Act	• control and regulate the growing, processing, marketing and export of cacao, cacao beans, cocoa beans and cocoa products • promote the consumption of Papua New Guinea cocoa beans and cocoa products • promote research and development programs for the benefit of the cocoa	Cocoa Board, Coconut and Cocoa Research Institute and DAL	Current

	industry		
Copra Act	• Promote research into copra	Kokonas Industri Koporesen, Coconut and Cocoa Research Institute and DAL	Current
International Trade (Fauna and Flora) (Amendment) Act 2003	• Regulates the exportation and importation of specimen under Appendix I, II, and Schedule 1 of the CITES	DEC	Current
Medicines and Cosmetics Act 1999	• Regulates the importation of medicinal products, manufacture, sale and supply of medicinal product, device and cosmetic through the licensing process	DOH	Current
Dangerous Drugs Act (Consolidated to No 23 of 1990)	• Regulates the cultivation, production, and importation of dangerous drugs	National Narcotics Board and Police	Current
Environment Act 2000	• A key goal of the Act is to protect the environment, the ecological system, biodiversity and the control of impacts on the environment • Controlling the impacts of development activities on the environment	DEC	Current
National Agriculture, Quarantine and Inspection Authority Act	• Establishes the National Agriculture, Quarantine and Inspection Authority • Focus on biosecurity	NAQIA	Current
National Institute of Standards and Industrial Technology Act	• Establishes the National Institute of Standards and Industrial Technology (NISIT) • Two primary functions are: (1) setting of national standards for industrial production, trade and economic development and (2) conduct of scientific and technological research to support Papua New Guinean industries	NISIT	Current
Oil Palm Industry Corporation Act	• Act empowers the Oil Palm Industry Corporation to engage in research and development of oil palm	Oil Palm Industry Corporation and DAL	Current
Organic Law on Provincial and Local-level Governments 1995	• Establishes decentralized system of government • Promotes community and public participation in development including research and development	Department of Inter-Government Relations	Current
Plant Disease and Control Act	• The two aims of the legislation are: (1) regulating and controlling diseases of plants and (2) prohibit and restrict the keeping of certain plants. • Relates to biosecurity	NAQIA, DAL	Under Review

3.1.2 Export and Import Laws

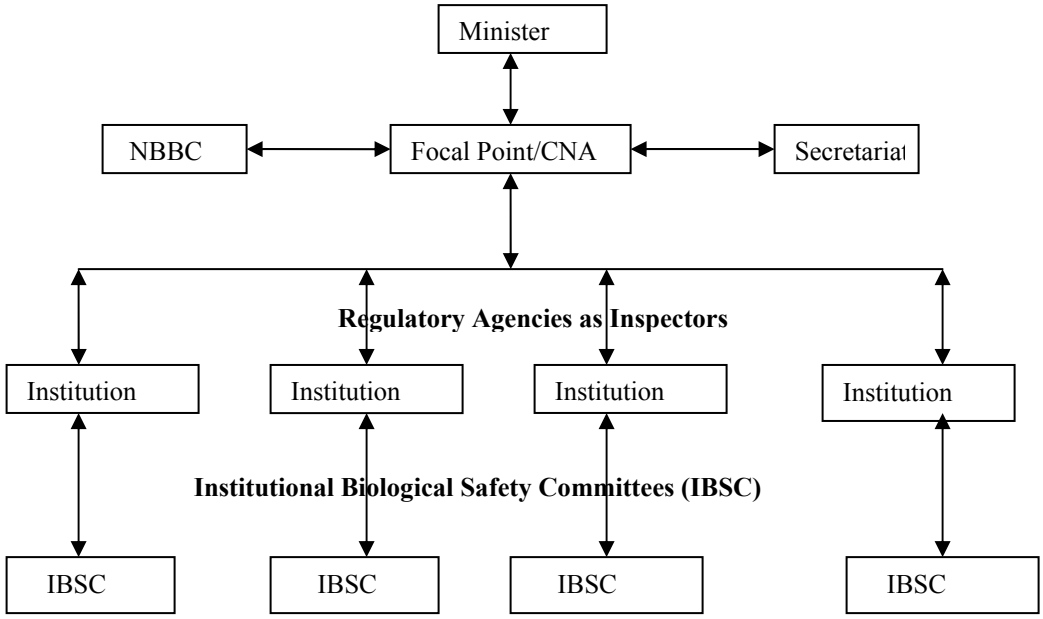
There are several pieces of legislation which have an impact on the exportation and importation of GMOs and genetically modified products. These are also tabulated below.

Name of Legislation	***Purpose and Objective***	***Responsible Agency***	***Status of Legislation***
Customs Act (Consolidated to No.44 of 2000)	• Provides for the control of exports, particularly of prohibited exports	Internal Revenue Commission (IRC)	Current
Customs (Prohibited Exports) Regulation (Consolidated to No. 23 of 1992)	• Contains a list of items which are restricted and prohibited from export	IRC	Current
Food Sanitation Act 1991	• Provides guidelines for the manufacture and handling of manufactured goods • Provides standards for food and food additives and labeling	Food Sanitation Council	Current
Customs Act (Consolidated to No.41 of 2000)	• Provides for the control of both imports and exports	IRC	Current
Customs Tariff Act	• Provides for the imposition of customs duties on imports and exports	IRC	Current
Independent Consumer and Competition Council Act	• Establishes the Independent Consumer and Competition Council (ICCC) • Empowers the ICCC to develop policies to protect the consumer and encourage trade and commerce	ICCC	Current
Quarantine Act	• Provides generally for the control of disease that may be caused by plants and animals • Together with NAQIA Act and the Plant Disease and Control Act provide the biosecurity framework	NAQIA, NARI and DAL	Under Review

4. SYSTEM TO HANDLE NOTIFICATION, REQUESTS AND LICENSING (ADMINISTRATIVE SYSTEMS)

4.1 Administrative Structure

The administrative structure under the Bill is set out in the Diagram below.



The key institutions are the CNA and the NBBC. The CNA is also the focal point. The Bill declares that the DEC is the CNA and the Focal Point. Under the Bill, institutional biological safety committees will be created in relevant regulatory agencies to promote the work of the CNA and the NBBC. It is anticipated that with the establishment of these institutional committees, there will be a transparent flow of information on biosafety and modern biotechnology issues between the CNA, NBBC and these institutions.

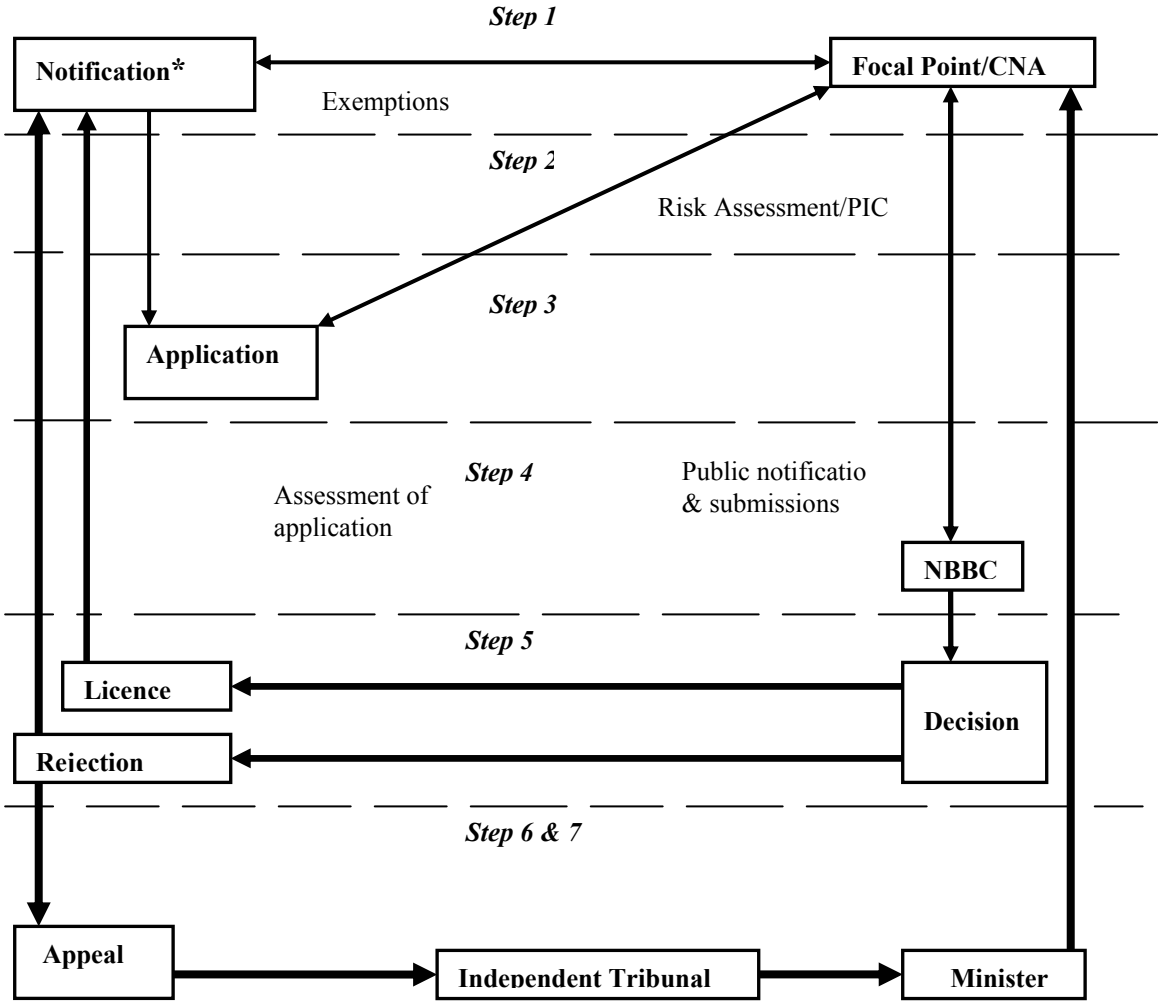
4.2 Notification

There are two levels of approval adopted by the Bill. The first involves the notifier lodging a notification with the DEC which is the focal point. The notifier must submit a request to the CNA seeking permission to engage in an activity involving genetically modified organisms.

The CNA has 30 days to make a decision on the request. If the CNA approves the request the notifier is required to move onto the second level. The Bill calls this process the Licensing System which involves a seven step process to obtain a licence to engage in the

activity. The steps are discussed in detail below. The seven steps are also shown in the Diagram below.

NOTIFICATION AND APPLICATION PROCESS



* R & D (in and outside contained structure)
Importation into containment
Exportation
Field Test (outside contained structure)
Release (with or without condition)

4.3 Licensing System

There are seven steps involved in the licensing system. These seven steps must be complied with under the Bill for the issuance of a genetically modified organism licence.

4.3.1 Step 1: Submission of Intent

A person who intends to undertake an activity or dealing involving GMO's or genetically modified products or research and development of a GMO must first lodge its intention with the CNA. The submission of intent is not an application for a GMO licence but an expression of intention to apply for a GMO licence.

The CNA must inform the potential applicant in writing within 30 days whether he or she is eligible to apply for a licence.

4.3.2 Step 2: Risk Assessment and PIC

Where a potential applicant receives a positive response to his or her request, he or she has 60 days in which to prepare a risk assessment and risk management plan. If the application will be for research and development of a GMO, the potential applicant must also initiate dialogue with local communities and governments and obtain their prior informed consent where the research and development project will either be situated on customary land or involve local communities.

4.3.3 Step 3: Application for a GMO Licence

After the 60 days period, the applicant can lodge a formal application with the CNA for a GMO licence. The application must contain a series of information set out in the Bill, the Regulation and any Guidelines issued by the CNA. The application must also be lodged with the relevant fee as specified by the NBBC.

4.3.4 Step 4: Processing of Application

A completed application lodged with the CNA, is then referred to the NBBC for determination. Where the CNA requires further information from the applicant, it may request such information from the applicant before referring the matter to the NBBC. The applicant has 30 days to furnish the CNA with the additional information.

When the NBBC receives the application from the CNA, it must cause the application to be published in the media for comments by the public. The Bill stipulates that the public have the right to have full access to all the relevant documents relating to the application.

The public has not less than 30 days and not more than 90 days to make submissions on the application.

The NBBC must then assess the application including the assessment of the risks. The NBBC can at this stage require the assistance of a technical expert or a technical expert panel to provide it with advice on the application.

4.3.5 Step 5: Decision

All applications for GMO licences are considered by the NBBC. The NBBC is required to make a decision on an application within 21 days of the closing date of public submissions. If more time is required by the NBBC, it must inform the applicant in writing of the extra time period it requires to consider and make a decision on the application.

Where the applicant fulfills all the requirements of the Bill, the NBBC will issue a licence to the applicant. The licence may contain a number of conditions which are clearly spelt out by the Bill. When the licence is obtained by the applicant he or she can engage in an activity involving a GMO.

The NBBC may reject an application for a GMO licence. The NBBC is required by the Bill to give reasons for rejecting the application. The decision of the NBBC is communicated to the applicant by the CNA.

4.3.6 Step 6: Appeal

Where an applicant or an objector is aggrieved by the decision of the NBBC, he or she can appeal the decision to the Biosafety and Biotechnology Tribunal. The appeal must be lodged within 21 days from the date of the NBBC decision. The Bill provides procedures for lodging an appeal and for determining an appeal. The principle of natural justice is paramount in the consideration of an appeal by the Tribunal.

4.3.7 Step 7: Final Decision

The Minister makes the final decision on an appeal. When the Minister receives a recommendation from the Biosafety and Biotechnology Tribunal he or she will either accept or reject the recommendation. If the decision is in favour of the appellant, the issue is resolved and a licence is issued to the appellant. If the Minister upholds the decision of the NBBC, he or she must give his or her reasons for rejecting the appeal. The decision of the Minister is communicated to the appellant by the CNA.

If the Minister decides against the appellant, the appellant can seek a judicial review in the National Court. This process will fall under the rules and procedures of the courts and is outside the scope of the Bill.

5. MONITORING AND ENFORCEMENT

5.1 Monitoring

The Bill sets out very clear procedures for monitoring of both the legislation and activities involving a GMO. The four essential elements of monitoring adopted by the Bill are: (1) risk assessment; (2) monitoring; (3) searching; and (4) auditing. These four tools are critical to the effective implementation of the Bill. Each of these elements is discussed below.

5.1.1 Risk Assessment

The precautionary approach plays a pivotal role in the assessment of risks and the management of potential risks posed by the use, handling, containment and management of GMOs and genetically modified products. It is a requirement of the Bill that an applicant for a licence under the Bill must provide all necessary information and a risk management plan before a licence is issued to the applicant. No licence will be issued by the CNA if a risk assessment and risk management plan are not put in place by the applicant for a licence under the Bill.

The CNA and the NBBC can use the risk assessment and risk management plan of the licence holder to scrutinize the activities of the licence holder.

5.1.2 Monitoring

The Bill provides wide powers to the CNA and its authorized agents to monitor the activities and dealings of licence holders. These powers include: (1) entry and search; (2) confiscation of materials to be used for prosecution and (3) regular visitations to sites of activity or dealing's involving a GMO.

5.1.3 Searching

The CNA and its authorized agents are empowered by the Bill to search and enter with a warrant, the premises of a licence holder. This power may be exercised where the licence holder is committing an offence or about to commit an offence against the Bill.

5.1.4 Auditing

The Bill makes it mandatory for the CNA to conduct an audit of the activity of a licence holder involving GMOs. The Bill also makes it mandatory for the licence holder to conduct his or her own audit and evaluation of its activities and make its report available to the CNA.

5.2 Enforcement

5.2.1 Prosecution

The Bill creates a series of offences which can result in either a fine or imprisonment or both. The most serious offence under the Bill is engaging in an activity with a GMO or a genetically modified product without a licence. The penalty for this offence is a fine of K500,000 or imprisonment for a period of 5 years.

Prosecution of offences under the Bill will be undertaken by the CNA with the assistance of the Office of the Public Prosecutor. There are two separate classes of action under the Bill. Where the offences carry a K50,000 penalty, the matters may be heard in the District Court. All other cases are heard by the National Court.

Two significant inroads are made by the Bill. First, the Bill requires that mediation must be exhausted before the matter is finally settled by the courts. The Bill promotes **alternative dispute resolution** as a way to minimize costs and also strengthen relationships between the CNA and the licence holders. Second, the public is given access to the courts by the Bill to enforce the legislation. Where the NCA fails to prosecute an offence under the Bill, a person or a class of persons can instigate the proceedings. This **public interest litigation** mechanism provides a check and balance on the CNA and the licence holders.

5.2.2 Penalties

The Bill provides a range of penalties for offences under the legislation. The most serious offence being, operation or dealing without a licence. This offence carries a fine of half a million Kina and a prison term of five years. The relevant provisions of the Bill, the offences they create and the penalties are shown in the Table below.

Provision of Bill	*Stipulation*	*Fine Amount (K)*	*Default (K)*	*Party*
7 and 75	General Duty	50,000		General
26	Code of Practice or Guidelines	50,000	5,000	General
51(1)	Cancellation and Suspension of licence	250,000	20,000	Corporation
		100,000		Human
61	Breach of Directions	125,000		Corporation
		50,000		Human
71	Dealings without Licence	500,000		Corporation
		200,000		Human
72	Breach of Licence	125,000		Corporation
		50,000		Human
	Obstruction	50,000		General
75	General Penalty	50,000		General
78	Confidentiality	20,000		Human

The amount of fines signals the grave concerns that PNG has about activities involving GMO and serve as a deterrent to potential law-breakers.

6. PUBLIC AWARENESS AND PARTICIPATION

6.1 Existing Mechanisms for Public Awareness and Participation

There exist in PNG a number of formal avenues which promote the participation of the public in important national issues. There are several pieces of legislation which make it mandatory for public participation in the development process beginning with the *Constitution*, the *Organic Law on Provincial Governments and Local-level Governments* 1995 and the *Environment Act* 2000. The Biosafety and Biotechnology Bill also contains several key provisions which strengthen the participation of the public in biosafety issues.

Biosafety and biotechnology issues are quite new in PNG. The challenge for the CNA, the NBBC and the government is to utilize existing mechanisms under the relevant laws to promote public awareness and active participation on biosafety issues. Some of the avenues that are immediately available are:

- Membership to the NBBC (representing various stakeholders);
- Public awareness at Universities and colleges;
- Public awareness at secondary and primary schools; and
- Collaboration with research and teaching institutions to utilize their channels for promoting awareness.

Several modes of communication also exist for dissemination of information to the public regarding biosafety issues. These include radio networks in the country; the national TV network and the daily and weekly newspapers. These modes of communication can be utilized by the CNA, NBBC and their partners in promoting public awareness on biosafety and biotechnology issues.

6.2 Public Participation and Awareness during the Development of the National Biosafety Framework

The development of the NBF has been utilized as a vital process by the project to disseminate information on biosafety and to promote and strengthen collaboration between relevant stakeholders. The participation of key stakeholders in the four national workshops is a testimony of the commitment of stakeholders to this important national project.

The consultative workshops have also provided an opportunity for the exchange of information and the learning of new ideas relevant to biosafety and biotechnology. The consultative process has generated a lot of interest among the stakeholders and certain sectors of the community. The public awareness activities which are planned for 2005 will result in wider and better community understanding of biosafety and biotechnology issues in PNG.

6.3 Proposed Activities to Promote Public Awareness and Participation

The Biosafety and Biotechnology Policy and Bill provides clear directives on future public awareness activities and participation of the public and particularly local communities in matters pertaining to biosafety and biotechnology. Public participation in the licensing process is a mandatory requirement of the Bill. Public awareness and participation are explicitly provided for in the Policy.

The CNA will need to develop a public awareness strategy to carry out public awareness in 2005 and beyond and will be implemented as part of the implementation phase. In the long term, the Bill makes it unequivocally clear that the NBBC and the CNA must conduct ongoing public awareness programs for the public so that Papua New Guinean's can actively and fully participate in biosafety and biotechnology activities in PNG.

7. IMPLEMENTATION

There are several important steps that must be undertaken to fully implement the NBF. These include:

- Ratification of the Cartagena Protocol by PNG;
- Presentation of the final Bill to the Parliament for approval;
- Presentation of the Biosafety and Biotechnology Policy to the National Executive Council for endorsement and approval by the Parliament;
- Establishment of the administrative system;
- Initiation of public awareness and capacity building programs;
- Monitoring and enforcement of the regulatory regime.

The successfully implementation of the NBF requires:

1. Sufficient financial resources;
2. Human and institutional capacity;
3. Effective collaboration between all relevant stakeholders;
4. Active and full participation of the public and local communities.

When these factors and steps are adequately addressed by the government, donors and stakeholders, GMO's will contribute to sustainable development of PNG.

8. ANNEXES

8.1 Summary of the Four National Biosafety Stakeholder Workshops

8.1.1 Summary of First Biosafety Stakeholder Workshop

Introduction

As one the first and important steps in building linkages with stakeholders to develop the National Biosafety Framework, the first National Biosafety stakeholder workshop was held between 27-29th April 2004 at the Lamana Hotel in Port Moresby. This was the first ever workshop organized under the auspices of the UNEP/GEF Biosafety Project since commencement of this Project. It was envisioned the workshop would enlighten stakeholders on the objectives and the outcome of the National Project as well as to learn more about the Cartagena Protocol on Biosafety. The workshop was seen as critical in highlighting issues PNG was faced with concerning the development and implementation of a National Biosafety Framework.

Stakeholders

The workshop was attended by 40 participants representing various Government Departments, State agencies and Research Institutions. The participants ranged from Departmental Heads to senior managers and technical officers of these organizations. The Government Departments, State agencies and research Institutions represented at this workshop included:

- Department of Environment and Conservation;
- Department of Trade and Industry;
- Department of Agriculture and Livestock;
- Department of Justice and Attorney General;
- Department of Health;
- National Fisheries Authority;
- Office of the Prime Minister;
- University of Vudal;
- University of Papua New Guinea;
- Papua New Guinea University of Technology;
- Food Sanitation Council;
- National Agriculture Research Institute;
- National Agriculture, Quarantine and Inspections Authority;
- Institute of Medical Research;
- National Institute for Standards and Industrial Technology;
- Independent Consumer and Competition Commission;
- Cocoa and Coconut Research Institute;

- Oil Palm Research Institute;
- Papua New Guinea Chamber of Commerce and Industry; and
- Papua New Guinea Institute of Biodiversity.

Objectives of Workshop

The main objectives of the 1st stakeholder workshop were to;

- To provide information on the Cartagena Protocol on Biosafety;
- Provide information and update on the status of the NBF project;
- Present information collected in the surveys for validation and to identify gaps, needs and to decide on the national priorities;
- Identify existing capacity building programs / activities relating to safe use of biotechnology available in different institutions in the country and identify gaps and needs in these institutions and suggest ways to rectify them;
- Provide insight on the current use of modern biotechnology including core national issues in Biosafety and biotechnology;
- Identify existing legislation, regulations etc. including the gaps and identify ways in which relevant legislation, regulations and guidelines would be drafted to address the issues on Biosafety within the context of PNG;
- Identify existing regional mechanisms aimed at ensuring synergy in risk assessment to meet the needs of the country in terms of biosafety; and
- Provide an overview of modern biotechnology.

Presentations

The 1st stakeholder was opened on behalf of Minister for Environment and Conservation by Secretary for Environment and Conservation, Dr. Wari Iamo. The opening address was followed by a presentation, an overview of biotechnology and modern biotechnology by Professor Lance Hill. Several presentations also followed including one about how the Cartagena Protocol emerged and an overview on the Biosafety Project.

Overall, the first and second day focused on the Development of National Biosafety Frameworks both at the national and the international levels. Focus group discussions were held on various issues raised during presentations which also included reviews and survey results undertaken in phase 1 of the Project. These reviews covered issues such as:

- LMO's and environmental policy in PNG
- Overview of the Regulatory system in DEC
- Legislative review
- Risk assessment and management

- Review on current uses in biotechnology
- The Crop improvement program in PNG
- Public perception survey

The participants were again divided into groups to discuss issues that were raised from the surveys. The final day was devoted to formulating recommendations, action plans and conclusions.

Recommendations

A set of recommendations were made by stakeholders. These can be categorized under two headings – 'short term' and 'long term'. In the short term there were five recommendations. These were:

1. Ratification of the Cartagena Protocol on Biosafety;
2. Development of a national biosafety policy and synergizing of existing policies, regulations and guidelines on biosafety and biotechnology with regional and global policy and regulatory frameworks;
3. DEC to be appointed as Competent National Authority (CNA);
4. Promote education and public awareness on biosafety and biotechnology issues beginning with policy makers;
5. Promote exchange of information and ideas and create networking among stakeholders.

In the long term, a number of recommendations were put forward. These included:

1. Identify and develop capacity building programs especially on risk assessment and risk management;
2. Improve institutional infrastructure to handle and contain LMO's;
3. Develop standards and guidelines on risk assessment and risk management;
4. Establish an administrative system to handle notifications.

Comments / Outcomes

The first five recommendations have been adequately addressed by the draft Biosafety and Biotechnology Policy and the Biosafety and Biotechnology Bill. Recommendation 2 has been achieved with the development and adoption of the draft Biosafety Policy. Recommendations 3 and 4 are now covered by the Bill. In relation to Recommendation 1, the DEC has lodged the relevant documents for the ratification of the Cartagena Protocol with the National Executive Council for endorsement and final approval by Parliament. It is anticipated PNG should accede to the Cartagena Protocol on Biosafety before the project ends in 2005. As for the long-term recommendations, these concerns have now been covered by the draft policy and the Bill and will need to be addressed in the long term.

8.1.2 Summary of Second Biosafety Stakeholder Workshop

Introduction

The second national Biosafety stakeholder workshop was held at the Holiday Inn, in Port Moresby from 28-30th September 2004. The workshop was a follow-up from the first national Biosafety stakeholder workshop which was held in April 2004. At the first workshop, stakeholders had resolved that a biosafety policy be developed for presentation at the second workshop. The primary objective of this workshop was to deliberate on a draft Biosafety Policy as well as to address the element of public Awareness and Participation.

Stakeholders

The workshop was again attended by representatives of the stakeholders who had participated in the first workshop. The workshop was attended by 30 participants with several new stakeholders joining the process. These stakeholders included:

- Department of Inter-Government Relations;
- Milne Bay Provincial Government;
- Morobe Provincial Government;
- Central Provincial Government;
- Forest Research Institute;
- Coffee Industry Corporation;
- 4 Nature Limited.

An increase in stakeholders at the workshop was a reflection of the concerns stakeholders had about biosafety issues and showed their support and commitment towards development of the NBF.

Objectives of Workshop

There were three major objectives of the Workshop. These were:

- To present and discuss the draft Biosafety Policy;
- Discuss and make recommendations for development of the Biosafety and biotechnology regulatory framework; and
- To develop an administrative system to handle requests and notifications.

The Workshop was also designed to:

- Provide participants with further information on the Cartagena Protocol on Biosafety;
- Provide an update of the progress of the project;

- Provide an update on existing regulatory frameworks in the region with a view to developing a specific domestic regulatory regime on biosafety;
- To raise the issue of public awareness and participation in a national Biosafety Framework;
- Identify mechanisms available for public participation to be incorporated in the draft policy; and
- Formulate drafting instructions for the development of a regulatory framework.

Presentations

The 2nd stakeholder workshop was opened by Mr. John Genolagani, First Assistant Secretary for Conservation Division on behalf of DEC Minister. In the opening statement, the Minister urged stakeholders to make meaningful contributions to the draft Biosafety Policy to enable the project to move to the next stages for development of a regulatory regime on Biosafety.

In the first day, presentations were made on an overview of the draft policy, the Cartagena Protocol on Biosafety and an update on the Project by Mr. Veari Kula, Mr. Genolagani and Mr. G. Arigae. The participants were then divided into three groups to deliberate on the draft policy.

The second day focused on specific issues such as:

- Developing a Regulatory regime on Biosafety;
- An overview of the Advanced Informed Agreement Procedure;
- Regulatory regime for Living Modified Organisms;
- Public awareness and participation in a National Biosafety Framework;
- Role of traditional knowledge and Western science in environmental management;
- Developing administrative systems to handle requests and for follow up actions such as monitoring and enforcement;

Participants were again divided into three groups to discuss the above issues.

Recommendations

Several recommendations were made by stakeholders. These included:

1. To broaden the draft biosafety policy to encompass genetically modified organism's instead of being restricted to LMOs;
2. Policy must clearly state that PNG supports development of GMOs and genetically modified products while at the same time taking a precautionary approach;

3. A specific legislation on biosafety and biotechnology to be developed with amendments to relevant and existing legislations;
4. Development of genetically modified products be pursued by PNG as a tool for achieving sustainable development;
5. A future workshop on public awareness and participation be organized to enable stakeholders to further discuss and refine the element of public awareness and participation;
6. The capacity of DEC be strengthened to enable the Department to play a significant role in fulfilling PNG's obligations under the Cartagena Protocol on Biosafety.

Comments/Outcomes

Recommendations 1, 2 and 3 have now been implemented through the amendment of the draft Biosafety and Biotechnology Policy and the draft Biosafety and Biotechnology Bill. Recommendations 4, 5 and 6 are both short and long-term and will be key objective's of the NBF.

8.1.3 Summary of Third National Biosafety Stakeholder Workshop

Introduction

The third workshop was held at the Lamana Hotel in Port Moresby from 8-10th March 2005. The primary objective of the stakeholder workshop was to deliberate on the draft Biosafety and Biotechnology Bill which had been drafted by the consultant.

Stakeholders

Overall, 32 participants attended the third stakeholder workshop and again the attendance from stakeholders reflected the continued support for the project. Again to ensure continuity, stakeholders who had participated in the first and second stakeholder workshops were present at this workshop. New stakeholders who recently joined the process through the workshop included;

- Internal Revenue Commission
- Department of Agriculture, PNG University of Technology

Objectives of Workshop

The main objective's of the workshop was to deliberate on the draft Biosafety and Biotechnology Bill and make any relevant adjustments to the Bill. There were also two subsidiary objectives of the workshop. These were:

- To confirm the administrative system for requests and notifications;
- To identify mechanisms for public awareness and participation in the National Biosafety Framework.

It was envisioned that these two issues would also be resolved at the workshop.

Presentations

The third stakeholder workshop was opened by DEC Secretary, Dr. Wari Iamo. The opening presentations were made by Mr Veari Kula and Mr Barnabas Wilmot, First Assistant Secretary for Conservation Division and were facilitated by Mr John Genolagani. The presentations at the workshop were also made by Mr. Eric Kwa, the Policy and Legal Consultant to the project.

On the first day, participants were given an update of the project and an overview of the draft Bill.

The discussions on the draft Bill focused on three key issues:

- Administration of the Bill
- Enforcement
- Monitoring

The second half of the first day and the second day were devoted to discussions on the Bill. Much of the third day was spent identifying the mechanisms for public awareness and participation with discussions also centered on the administrative system.

Recommendations

The key recommendations from the 3rd stakeholder workshop included:

1. Having a provision in the Bill for exemptions;
2. Include provision's for appeal process in the draft Bill;
3. Include provision's in the Bill for mediation;
4. The need to remove Schedules and rename as Regulations;
5. Have in the draft Bill financial provisions.

Comments/Outcomes

The stakeholders also agreed on a draft administrative system which included stakeholders, a National Biosafety Biotechnology Council and a Secretariat within the National Competent Authority / Focal Point. It was agreed the Bill had strengthened the system. The stakeholders also agreed the Bill had also strengthened public participation and vested responsibilities on the CNA and the Biosafety Council to conduct public awareness programs.

8.1.4 Summary of Fourth Biosafety Stakeholder Workshop

Introduction

The fourth and final workshop was held at Lamana Hotel in Port Moresby from 5-7th July 2005. This workshop was the final stakeholder workshop under the UNEP/GEF Biosafety project.

Stakeholders

With the project in it's final stages to finalize the draft National Biosafety Framework, a smaller focus group of about 15 key stakeholders were invited to attend the workshop. Again, most stakeholders who had participated in the first, second and third workshops were present to finalize and endorse the draft document. The continued involvement of key stakeholders in the final stakeholder workshop was once more encouraging and showed their commitment and support for the Project.

Objectives of Workshop

The principal objectives of this workshop were to finalize the 5 components of the draft NBF, consider conclusions and findings from the Regional Review and to amend the draft NBF based on recommendations of the Regional Review. It was envisioned by the project team that at the end of the workshop, a final draft of the NBF would be agreed upon by stakeholders for submission to DEC Minister for approval.

Presentations

The workshop was opened on behalf of DEC Secretary, Dr. Wari Iamo by Mr. Barnabas. Wilmot, First Assistant Secretary, Conservation Division in the Department of Environment and Conservation. The presentations were made by Mr. Eric Kwa, the Policy and Legal Consultant to the Project, Mr. Douveri Henao of Department of Justice and Attorney-General, Mr Veari Kula and Mr Goro Arigae.

The first day of the workshop centered on an update of the project, the public consultation exercise carried out in the provinces followed by an overview of the Regional Review of the draft NBF.

The second half of the first day and the second day were devoted to the draft NBF, particularly-

- The draft Biosafety Policy;
- Administration of the Bill;
- Enforcement; and
- Monitoring.

The major outcomes and recommendations after the second day session included;

- The Public to instigate a review of a License and that decisions of the Council to be made public;
- A Review to be instigated in light of new scientific information;
- Labeling and handling of GM food products to be erased and inserted under provisions of the Food Sanitation Act. Provisions in the Bill to allow for labeling of a living modified organism for food, feed or for processing (LMO/FFP's) and product's such as biological control agents that are genetically modified;
- Revoke ownership of a GMO after a license was cancelled;
- Provision for a bioremediation agent to be held in a Bank and introduced in an emergency situation;
- Provision's for transboundary movement's of GMOs;
- Subordinate Instrument's include Regulations to address administration matters while Order's and Guideline's to address technical matters.

The third day was dedicated to discussions on the draft Regulations under the Bill. An important consensus reached at the workshop was the deletion of the word "product", "marketing" and "placing on the shelf" from the draft NBF and this replaced with the word 'commercialization. It was agreed that because of trade issues these terms should be removed from the draft Policy and Bill.

Recommendations

There were three main resolutions of the workshop. These were:

1. To endorse the Draft National Biosafety Framework document and enabling Policy and Bill together with the priority Regulations and recommend to DEC Secretary take to the CACC for it's endorsement and DEC Minister to take to NEC the same for carefully consideration and tabling of the NBF in Parliament for consideration and passage.

2. That the CNA be enabled to handle timely implementation of the NBF in 2006 under the auspices of DEC.

3. That the current stakeholders remain active to assist the CAN for the development of a full complement of subsidiary Regulations and Guidelines to guide implementation of the NBF.

After completion of the workshop, the consultant and the project team worked on the amendments to the draft NBF to enable the completion of the NBF in time. The consultant was also able to collapse the three draft regulations into a single Regulation based on the recommendation of the stakeholders. The draft Regulation now forms part of the NBF.

8.2 Draft Biosafety and Biotechnology Policy

Foreword

Modern biotechnology is a recent phenomenon in Papua New Guinea. This science had been in existence in the developing countries for over more than 20 years. Biotechnology has become a huge industry with more than $600 million in sales in 2003. The advances in science must however, be approached with caution given the inherent risks involved with the use, management and transfer of genetically modified organisms.

Papua New Guinea has a rich and unique biodiversity comprising of more than 700 000 biological species. The people of Papua New Guinea depend on these biological resources for their food, shelter and sustenance. It is incumbent on every Papua New Guinean to ensure that this diverse and unique biodiversity is protected and that Papua New Guineans are protected from all harm and danger from the introduction of foreign biological species into the country's fragile environment.

The impact of modern biotechnology is becoming increasingly evident. A wide range of products, process and services have been developed through biotechnology to enhance the health and well-being of people, agricultural production and environmental conservation. Papua New Guinea currently faces a food insecurity crisis. It is also prone to many natural disasters which destroy many of the food crops and the environment. The country also has a very limited capacity in modern applied biotechnology. A key issue for Papua New Guinea is: does the country support genetic engineering especially for food, feed, food processes and pharmaceuticals?.

The dilemma a small developing country such as Papua New Guinea faces in dealing with the issues of Genetically Modified Organisms is huge. There is evidence that genetically modified foods and pharmaceuticals have been brought into the country for some time now. There is also a growing use of tissue culture by national research and development institutions and organizations. Moreover, the country has a highly recognized biotechnology laboratory at the Papua New Guinea University of Technology capable of assessing genetically modified organisms and is also actively involved in developing genetically modified foods such as sugarcane, taro and vanilla.

Given these emerging trends and issues, it is timely that this draft Biosafety and Biotechnology Policy is introduced for review, discussion and possible adoption. The issues addressed in the draft policy are wide ranging and cross-sectoral and therefore, it is imperative that all stakeholders participate openly and actively in the development of the Biosafety and Biotechnology Policy. The implementation of the policy will consequently require the combined effort of all stakeholders to make it work.

HON. WILLIAM DUMA, LLB, LLM, MP
Minister for Environment and Conservation

Abbreviations

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CCRI	Coconut and Cocoa Research Institute
COP	Conference of Parties
CRI	Coffee Research Institute
DAL	Department of Agriculture and Livestock
DEC	Department of Environment and Conservation
DNA	Deoxyribonucleic acid
EIA	Environmental Impact Assessment
FFP	Food, Feed and Processes
FRI	Forest Research Institute
GE	Genetic Engineering
GMF	Genetically Modified Food
GMO	Genetically Modified Organism
IRC	Internal Revenue Commission
JICA	Japanese International Cooperation Agency
LMO	Living Modified Organism
MOP	Meeting of Parties
NARI	National Agriculture Research Institute
NAQIA	National Agriculture and Quarantine Inspection Authority
NBBC	National Biosafety/Biotechnology Committee
NISIT	National Institute for Standards and Industrial Technology
NRI	National Research Institute
UBC	Papua New Guinea University of Technology Biotechnology Centre
UPNG	University of Papua New Guinea
UNCED	United Nations Conference on Environment and Development
UNFCCC	United Nations Framework Convention on Climate Change

1. Introduction

1.1 The Biosafety Protocol

In 1992, at the United Nations Conference on Environment and Development (UNCED) in Rio De Janeiro in Brazil the leaders agreed to adopt a new development paradigm called "sustainable development". Sustainable development was defined by the World Commission on Environment and Development in 1987 as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." Sustainable development was to be achieved through a series of strategies contained in five documents adopted at the UNCED. These were: (1) the Rio Declaration on Environment and Development; (2) Agenda 21; (3) Statement of Principles for a Global Consensus on the Management, Conservation, and Sustainable Development of All Types of Forests **(**the Statement of Forest Principles**)**; (4) the Convention on Biological Diversity (CBD) and (5) the United Nations Framework Convention on Climate Change (UNFCCC).

Papua New Guinea adopted these documents in 1992 and ratified the two international treaties in March 1993. The adoption of these international documents by Papua New Guinea means that it is bound by the obligations contained in the documents, particularly the two treaties.

The principal treaty dealing with sustainable development and biological safety is the CBD. The CBD provides the international legal framework for the conservation and sustainable use of biological resources.

A specific biodiversity issue which was very contentious and thus, was not resolved at the UNCED was living modified organisms (LMO). The dispute was between developed countries on the one hand and developing countries on the other. Negotiators from the developed countries insisted that they should be allowed easy access to biological resources while the developing countries argued for greater and stronger controls over access to these resources which were largely located in their countries. After a lengthy and protracted negotiation, the Protocol to the CBD called the **Cartagena Protocol on Biosafety** or the **Biosafety Protocol**, was eventually adopted in 2000. On 11th September 2003, the Biosafety Protocol came into force.

The Biosafety Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms (LMO) created through the use of modern biotechnologies. The primary objective of the Protocol is to contribute to the safe transfer, handling and use of LMO that may have adverse effects on the conservation and sustainable use of biological diversity, specifically focusing on transboundary movements. The Protocol also deals with transboundary movement of LMOs that may have adverse effects on biodiversity, taking into account human health. The Protocol does not cover non-living products derived from LMOs, such as cooking oil from genetically modified corn or tomato sauce from genetically modified tomatoes.

There are several important things that the Biosafety Protocol does. First, it establishes an Internet-based "Biosafety Clearing-House" which is responsible for helping countries exchange scientific, technical, environmental, and legal information about LMO. Second, the Protocol creates an advance informed agreement (AIA) procedure which requires exporters to seek consent from an importing country before the first shipment of a LMO. The Protocol contains reference to the precautionary approach and reaffirms the precautionary approach espoused by Principle 15 of the *Rio Declaration*. The AIA procedure applies only to LMO which will be introduced into the environment. Examples of such LMO would include seeds for planting, fish for release, and microorganisms for bioremediation.

Third, the Protocol requires that shipments of LMO commodities, such as maize or soybeans that are intended for direct use as food, feed, or for processing must be accompanied by documentation stating that such shipments "may contain" LMO and that they are "not intended for intentional introduction into the environment". The Protocol establishes a process for considering more detailed identification and documentation of LMO commodities in international trade. Fourth, it sets out information to be included on documentation accompanying LMO destined for contained use, including any handling requirements and contact points for further information and for the consignee. Fifth, the Protocol includes a "savings clause", which states that the agreement shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement, including, for example, WTO agreements. And sixth, the Protocol calls on parties to cooperate with developing countries in building their capacity for managing modern biotechnology.

There are several issues that are not addressed by the Biosafety Protocol. These issues include:

- The Protocol does not address food safety issues. These issues are left to other international agreements or arrangements such as the Codex Alimentarius which addresses food safety. The Protocol also does not pertain to non-living products derived from genetically engineered plants or animals, such as milled maize or other processed food products.
- The Protocol does not require segregation of commodities that may contain living modified organisms.
- It does not subject commodities to the Protocol's AIA procedure, which would significantly disrupt trade and jeopardize food access, without commensurate benefit to the environment.
- The Protocol does not require consumer product labelling. The mandate of the Protocol is to address risks to biodiversity that may be presented by living modified organisms. Issues related to consumer preference were not part of the negotiation. The Protocol's requirement for documentation identifying commodity shipments as "may contain living modified organisms" and "not intended for direct introduction into the environment" can be accomplished through shipping documentation.

Now that the Protocol is in force, it is a legally binding document, in the international legal system and in the legal systems of States that ratify it. States must comply with and implement all the provisions of the Protocol. The Protocol is the only international instrument that deals exclusively with LMO. To become a party to the Protocol, a country or a regional economic integration organization must first be a party to the CBD. A member State that approves for domestic use and marketing of LMO intended for direct use as food, feed or processing that may be exported will be required to communicate this decision and details about the LMO to the world community via the Biosafety Clearing-House (BCH).

1.2 Developing the Biosafety and Biotechnology Policy

The draft Biosafety and Biotechnology Policy was developed under the auspices of the UNEP/GEF Biosafety Project. The aim of the project is to develop a National Biosafety Framework (NBF) for PNG. The first step in the evolution of the policy was the findings of the surveys conducted under the project in late 2003. The findings of the surveys were presented and deliberated at the National Biosafety Consultative Workshop held in Port Moresby in 27-29 April 2004.

Several conclusions were reached at the first Workshop. The most important being the recommendation for the formulation of a biosafety and biotechnology policy. The stakeholders at the Workshop agreed that there was a need to develop a policy framework on biosafety and biotechnology. A policy/legal consultant was then engaged to develop a draft biosafety policy which was presented for consideration by the stakeholders at the second National Biosafety Consultative Workshop held from 28-30 September 2004.

At the second Workshop, the stakeholders generally approved the draft Biosafety and Biotechnology Policy with a caveat that some minor adjustments be made to the policy. These have now been incorporated into this second draft of the policy.

Chapter 2. Key Policy Issues

The formulation of the draft Biosafety and Biosafety Policy revolved around several key issues which are pertinent to PNG. These policy issues are considered in the light of the overarching goal of the Biosafety Protocol – safety to human health and the environment and biodiversity. The key policy issues for Papua New Guinea are: (1) biodiversity protection; (2) trade; (3) research and development of biological species; (4) various stakeholders; (5) legal and institutional frameworks and (6) traditional knowledge and local communities. These are critical factors which have been taken into account in the development of this draft policy.

2.1 The Constitution

The Constitution of Papua New Guinea provides the constitutional mandate for the development of government policy. A national policy must find its basis in the Constitution. The Constitution embodies the goals and aspirations of the people of Papua

New Guinea. These goals and aspirations are contained in the five National Goals and Directive Principles of the Constitution. The development of the Biosafety and Biotechnology Policy must promote and give effect to these five goals and directive principles. The five National Goals and Directive Principles are:

1. Integral human development.
2. Equality and participation.
3. National sovereignty and self-reliance.
4. Natural resources and environment.
5. Papua New Guinean ways.

How can the Biosafety and Biotechnology Policy achieve the goals and aims of Papua New Guineans contained in the National Goals and Directive Principles? National development policies must aspire to promote the integral development of every Papua New Guinean; encourage and promote equality and, create and strengthen processes for full participation in development by Papua New Guineans; lead to economic and political self-reliance; promote the protection and sustainable use of natural and biological resources and enhance and promote the use of Papua New Guinean forms of social, political and economic processes.

The Biosafety and Biotechnology Policy is centered on people and protects, and promotes their rights and obligations, and provides opportunities for the expression of these rights. The expression of these rights and obligations in the social, economic and political processes will enhance the opportunities of future generations to also benefit from the socio-economic and political processes that are created to meet the needs of the present generation. The Biosafety and Biotechnology Policy will also promote and strengthen customary values and traditional knowledge systems which have sustained local communities for centuries.

The Biosafety and Biotechnology Policy take's a holistic approach to the handling and management of GMOs. It embodies the goals and aims of the people of Papua New Guinea as expressed in the five National Goals and Directive Principles. Specific components of the policy target the attainment of these Goals and aspirations of the people.

2.2 Biotechnology and GMO

Biotechnology has become a very important player in the developed world because of its significant economic impact on agricultural productivity through improved productivity, enhanced products and reduced input costs. In 2003, it was estimated that biotech products on the market was US$600 million and that it is expected to grow by 12-20% annually over the next decade. The products are mainly genetically engineered crop varieties with novel traits, new diagnostics for plant and animal diseases, and several new biopesticides. Novel vaccines against major animal diseases are in late stages of development.

Biotechnology has become an important tool in addressing food security issues. It has been described as the key to overcoming the problem of world hunger. Proponents of the technology argue that modern biotechnology has the potential to lead to increases in food security, decreased pressure on land use and sustainable yield increase in marginal lands or inhospitable environments and reduced use of water and agrochemicals in agriculture.

While proponents of genetically engineered foods argue strongly that GMOs contribute to the alleviation of world hunger, their opponents contest that GMOs will reduce genetic diversity; that modern biotechnology is a very young and untested technology; genetically engineered technology is expensive for developing countries and that the problem of food shortage is a political and economic problem. Because it is a new field, much of the interaction of GMOs with various ecosystems is not yet known. Some of the concerns about the new technology include its potential adverse effects on biological diversity, and potential risks to human health. Some of these concerns include: unintended changes in the competitiveness, virulence, or other characteristics of the target species; the possibility of adverse impacts on non-target species (such as beneficial insects) and ecosystems; the potential for weediness in genetically modified crops (where a plant becomes more invasive than the original, perhaps by transferring its genes to wild relatives); and the stability of inserted genes (the possibilities that a gene will lose its effectiveness or will be re-transferred to another host). The opponents of GMOs also argue that the biotechnology industry is a niche industry and is controlled by a few rich industrialists who have a monopoly over GMOs.

These two competing views have permeated various international fora on the subject of biological diversity and genetic engineering. What is significant is that there are emerging technologies which will become increasingly important. These are: (1) the greater use of genome mapping in plant and livestock breeding, especially to identify specific genes which convey desirable characteristics; (2) improved transgenic plants with more specific promoters to enable improved control of genes inserted in target plants; (3) the combination of biotechnology with information technology to develop decision support systems for farmers applicable to practices such as integrated pest management; and (4) novel vaccines against human and animal diseases.

In the light of the scientific uncertainties of modern biotechnology and the need to ensure PNG obtains the benefits of this emerging technology, PNG will promote research and development of a GMO as food, food processes and pharmaceuticals for the benefit of Papua New Guineans. The Biosafety and Biotechnology Policy provide the framework for PNG to pursue this goal for the interest of the country and its people.

2.3 Biosafety and Biodiversity

Papua New Guinea's total land mass is 462 840 km^2. This land area consists of 0.5 percent beaches and ridges, 11 per cent swamps, 15 percent lowlands; 43 percent foothills, mountains to 1000m above sea level; 25 per cent mountains 1000-3000m and 4% above 3000m. Natural forest covers almost 77 percent of the total land area. PNG occupies half of the world's largest and highest tropical island and has 5,000 lakes,

extensive river systems, 5,000 miles of mangrove swamps (1.5 percent of land area), lagoons, wetlands, coral reefs and atolls plus island archipelagos. PNG's maritime jurisdiction extends over 8,000 km^2 of ocean, including 40,000 km^2 of coral reefs.

The country has been described as one of the four mega biodiversity area's of the world given that it contains about 5-7 percent of the world's species of plants and terrestrial live forms. In 2000, it was estimated that PNG has: 20,000 plant species; 90,000 fungi; 300,000 insects; 600 fish species; 800 species of corals; 304 mammals species; 733 species of birds; 298 species of reptiles; 228 amphibian species and 45 types of forest/wetlands. It is estimated that there is approximately 60 percent of plants which are endemic to PNG. There are about 500 species of food crops, 30 root and staple crops, 43 nut types, 100 fruits and 60 leafy green vegetables. This diverse biodiversity is unique and endemic to PNG.

One of the strongest argument that has been raised by developing countries in terms of the transfer, use and release of GMOs is the differential environmental conditions in the developing countries and developed countries where most of the biotechnology is being conducted. This issue hinges on three factors. First, there is a lot more biodiversity towards the equator which means that the variables and possible complications will increase with the release, use and transfer on a GMO in this condition. Second, is to do with the ambient temperature. In the tropics, the temperature outside is nearer to the temperature of containment in laboratories. This means that a transgenic organism that accidentally escapes into the environment will have a greater chance of survival and thus, have a much greater impact on human health and biodiversity. Third, there is a larger unadulterated gene pool in the tropical and sub-tropical regions of the world. The accidental release of a GMO into this environment will forever destroy the native gene pool including wild relatives of the crop.

PNG is one of the four mega diversity areas of the world. Given that it has about 700,000 biological species, the Biosafety and Biotechnology Policy enhances the protection and sustainable use of this unique and diverse biodiversity of the country. The policy also strengthens the status of the country as a mega biodiversity area which significantly contributes to the global ecosystem and the stability of the global environment.

2.4 Research and Development of GMO

The research and development of genetically modified organisms involves a number of stakeholders, facilities and funds. Investments in modern biotechnology have risen in many countries over the last two decades because of the benefits of genetic engineering for food, feed agriculture and medicines. In Papua New Guinea, biotechnology is still in its infancy. The Biotechnology Centre of the Papua New Guinea University of Technology is the first and only facility in the country that has potential for modern biotechnology research and development. It was developed to promote the interests of biotechnology throughout the country. The Centre's primary program is education and training on applied biotechnology. This includes an international post-graduate research program. It is the only institution in the country that has the capacity for advanced

scientific biotechnology research and development. The Biotechnology Centre has capability essential in the assessment of a GMO, genetically modified food and products.

The Biotechnology Centre hosts, but not limited to, transformation of sugarcane callus and protoplast, production of secondary metabolites from cell suspension culture of Stevia and Vanilla, and various tissue culture systems for numerous tropical crops, specially taro, sugarcane and kava. The Centre is participating in a number of regional projects, including research on DNA fingerprinting and virus indexing in taro and more recently forestry programs on molecular tree identification.

There are several other national institutions which are involved in some aspects of applied biotechnology. One of the key elements of applied biotechnology - tissue culture - is more widespread and is undertaken by most of the agricultural research institutions. These include the Coffee Research Institute (CRI), Cocoa and Coconut Research Institute (CCRI), Oil Palm Research Institute and the National Agricultural Research Institution (NARI). Some of these institutes are moving into more advanced research in biotechnology.

An important element of research and development is intellectual property rights. Issues of intellectual property rights arise at two critical points. The first is at the point of knowledge extraction. And the second is at the application of that knowledge. In the first instance, the critical issue is whether the knowledge involved in creating is original. If the knowledge is original, the holder of the knowledge has inherent rights to the use and management of that knowledge. The form that this knowledge takes varies from one place to the other. It may be in the form of oral tradition; sign language; designs; written formula; etc. The application of knowledge involves creativity. Thus, knowledge is applied, products are made.

In the field of modern biotechnology, the management of intellectual property rights is focused primarily on the products and the processes involved in developing the products. In the private sector, the patentability of products and processes are the driving force for investments in biotechnology. This leads to the situation where much of the intellectual property, patents, and knowledge and investment in the effective use of agricultural biotechnology, lie with a small number of firms world-wide. Successful access to these core technologies by other parties in order to evaluate their applicability to orphan commodities and global concerns will require critical negotiations, and knowledge of the available resources, including genetic resources and intellectual property.

On a global scale, Papua New Guinea fares poorly in investments in modern biotechnology. There is very little private sector engagement in modern biotechnology. Public sector research and development institutions are poorly funded by the government. This leaves the country vulnerable to domination by foreign interests in the research and development of new products through modern biotechnology. The Biosafety and Biotechnology Policy seeks to address this issue by providing for the roadmap for private and public sector funding for research and development of genetically modified products. The policy also seeks to provide strategies for institutional and human capacity building

which will promote and encourage PNG scientists and institutions to improve productivity.

2.5 Trade in GMO

The regulation of trade in GMOs under the rules specified by the Biosafety and Biotechnology Protocol must be considered against the rules and guidelines emanating from the World Trade Organization. The contention between the developed and developing countries centred on the issue of access to markets for GMO products. Papua New Guinea as a developing country must be mindful of its capacity to develop GMO and its ability to assess risks associated with the importation of GMOs.

The evidence strongly suggests that PNG lacks technical and institutional capacity to safely handle, transfer, manage and use GMOs. In fact, importation of GMO had already taken place in PNG. Some of these GMOs are known while some are not. The known imports include tilapia for human consumption under a DAL-JICA inland fisheries program. The Independent Consumer and Competition Commission is aware, of Bt-corn, which may be used for cultivation to provide food for human and animal consumption and as a market produce. The current PNG programs on applied biotechnology is already an integral element of' economic benefits. The Biosafety and Biotechnology Policy will encourage the provision of innovative and new economic incentives for PNG in the forestry, fisheries, environment (conservation) and health sectors.

The Biosafety and Biotechnology Policy seeks to strengthen capacity building programs to improve the skills and knowledge of Papua New Guineans involved in the assessment of genetically modified organisms and, research and development of genetically modified organisms. It is envisioned that the policy can be the catalyst for the upgrading of institutional facilities used for assessment, research and use of genetically modified organisms and where appropriate establish new facilities to enable proper scrutiny of genetically modified organisms before they are either released into the environment or used for beneficial purposes such as food and food processes.

2.6 Stakeholders and GMO

The handling, transfer, use and management of genetically modified organisms in PNG will involve many stakeholders. They include: the national government; the provincial governments; local-level governments; local communities; government departments and agencies; private sector; investors; non-governmental organizations; research and development institutions, and researchers and scientists.

Defining the role that each of these stakeholders play is critical to the successful implementation of the Biosafety and Biotechnology Policy. The role that these stakeholders assume in the assessment, research and development, transfer, use and management of genetically modified organisms must be commensurate with the degree of impact a genetically modified organism will have on their personnel and institutional well being, and their environment and biodiversity.

A key issue associated with stakeholder participation is human and institutional capacity. A stakeholder cannot participate in the decision-making process actively and fully if they lack the capacity. One of the priority concerns of the Biosafety Protocol is capacity building. A number of initiatives have been implemented at various levels to support countries to meet their capacity-building requirements under the Biosafety Protocol. The Action Plan for building capacities adopted by the first meeting of COP-MOP provides a framework to assist governments and organizations to better address priority capacity-building elements in a strategic, systematic and integrated manner. A Coordination Mechanism has been established to facilitate coherent and collaborative implementation of the Action Plan and to ensure mutual supportiveness among different initiatives.

By ratifying the Protocol, PNG can be able to access the various initiatives provided under the Protocol to adopt, establish and strengthen capacity building programs at the domestic level. The Biosafety and Biotechnology Policy is aimed at strengthening, promoting and coordinating capacity building programs to enable the different stakeholders to participate actively in the assessment, research and development, management and use of genetically modified organisms. It also provides the roadmap for stronger collaboration between the public sector and private sector.

Chapter 3. Definition and Scope of Policy

The Biosafety Protocol provides new and exciting challenges to both developing and developed countries in dealing with the issues of genetic engineering and particularly living modified organisms. The Protocol contains several key terms which require clarification to enable a proper understanding of the operations of the treaty.

3.1 Some Common Terms used in the Policy

Biotechnology: The term 'biotechnology' refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use. Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer. It has also been the basis of traditional animal and plant breeding techniques, such as hybridization and the selection of plants and animals with specific characteristics to create, for example, crops which produce higher yields of grain.

The difference with modern biotechnology is that researchers can now take a single gene from a plant or animal cell and insert it in another plant or animal cell to give it a desired characteristic, such as a plant that is resistant to a specific pest or disease. In the Biosafety Protocol, modern biotechnology means the application of: (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Biosafety: Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage. While developed countries that are at the center of the global biotechnology industry have established domestic biosafety regimes, many developing countries are only now starting to establish their own national systems.

Living Modified Organism: A LMO is defined in the **Biosafety Protocol** as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The Protocol also defines the terms 'living organism' and 'modern biotechnology'. In everyday usage LMO are usually considered to be the same as GMO, but definitions and interpretations of the term GMOs vary widely. Common LMO include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases. Examples of modified crops include tomatoes, cassava, corn, cotton and soybeans.

LMO Products: LMO's form the basis of a range of products and agricultural commodities. Processed products containing dead modified organisms or non-living GMO components include certain vaccines; drugs; food additives; and many processed, canned, and preserved foods. They can also include corn and soybean derivatives used in many foods and nonfoods, cornstarch used for cardboard and adhesives, fuel ethanol for gasoline, vitamins, vaccines and pharmaceuticals, and yeast-based foods such as beer and bread.

Advance Informed Agreement (AIA): The "Advance Informed Agreement" procedure applies to the first intentional transboundary movement of LMO for intentional introduction into the environment of the Party of import. It includes four components: notification by the Party of export or the exporter, acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import.

Specifically, the Party of export or the exporter must notify the Party of import by providing a detailed, written description of the LMO in advance of the first shipment. The Party of import is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the Party of import must communicate its decision: (1) approving the import, (2) prohibiting the import, (3) requesting additional relevant information, or (4) extending the 270 days by a defined period of time. Except in a case in which consent is unconditional, in other cases the Party of import must indicate the reasons on which its decisions are based.

A Party of import may, at any time, in light of new scientific information, review and change a decision. A Party of export or a notifier may also request the Party of import to

review its decisions. However, the Protocol's AIA procedure does not apply to certain categories of LMO. These are:

(1) LMO in transit;
(2) LMO destined for contained use; and
(3) LMO intended for direct use as food or feed or for processing.

It should be noted that, while the Protocol's AIA procedure does not apply to certain categories of living modified organisms, Parties have the right to regulate the importation on the basis of domestic legislation. In addition, the Party of import may also specify in advance to the Biosafety Clearing-House that it will exempt certain imports of living modified organisms from the AIA procedure. Also, the COP serving as the meeting of the Parties to the Protocol may in future decide to exempt additional living modified organisms from application of the AIA procedure.

LMOs intended for direct use as food or feed, or for processing: Living modified organisms intended for direct use as food or feed, or processing (LMO-FFP) represent a large category of agricultural commodities. The Protocol, instead of using the AIA procedure, establishes a more simplified procedure for the transboundary movement of LMO-FFP. Under this procedure, a Party must inform other Parties through the Biosafety Clearing-House, within 15 days, of its decision regarding domestic use of living modified organisms that may be subject to transboundary movement.

Decisions by the Party of import on whether or not to accept the import of LMO-FFP are taken under its domestic regulatory framework that is consistent with the objective of the Protocol. A developing country Party or a Party with an economy in transition may, in the absence of a domestic regulatory framework, declare through the Biosafety Clearing-House that its decisions on the first import of LMO-FFP will be taken in accordance with risk assessment as set out in the Protocol and timeframe for decision-making.

In case of insufficient relevant scientific information and knowledge, the Party of import may use precaution in making their decisions on the import of LMO-FFP.

Handling, transport, packaging and identification of living modified organisms: The Protocol provides for practical requirements that are deemed to contribute to the safe movement of living modified organisms. Parties are required to take measures for the safe handling, packaging and transportation of living modified organisms that are subject to transboundary movement. The Protocol specifies requirements on identification by setting out what information must be provided in documentation that should accompany transboundary shipments of living modified organisms. It also leaves room for possible future development of standards for handling, packaging, transportation and identification of living modified organisms by the meeting of the Parties to the Protocol. The first meeting of COP-MOP adopted decisions outlining identification requirements for different categories of living modified organisms.

Each Party is required to take measures ensuring that living modified organisms subject to intentional transboundary movement are accompanied by documentation identifying the living modified organisms and providing contact details of persons responsible for such movement. The details of these requirements vary according to the intended use of the living modified organisms, and, in the case of living modified organisms for food, feed or for processing, they should be further addressed by the governing body of the Protocol – the Conference of the Parties serving as the meeting of the Parties.

Risk Assessment: Risk assessment is the process of gathering diverse data to identify possible risks in research and development involving genetically modified micro-organisms, plants, and animals. Risk assessment focuses on the characteristics of the product itself rather than on the techniques used to produce it. The production of the living modified organisms must comply with standard safety measures.

One of the major issues relating to the role and application of modern biotechnology is the safety of organisms with novel traits and the appropriate regulatory measures for research and development, field testing, and marketing of beneficial organisms with novel traits. This is because uncontrolled introduction of organisms with novel traits might cause undesirable changes in ecological or genetic relationships in some communities. Hence careful design and review of organisms with novel traits, along with proper planning and regulation of environmental introductions, is advisable to ensure that organisms with novel traits do not pose unacceptable risks to the environment. In performing risk assessment and risk management a distinction would be made between evaluations of organisms intended for contained use and those for planned introduction into uncontained settings.

Risk Management: The type of risk management for contained use and planned introduction of organisms with novel traits depends on the organism involved and the intended application. The process involves reviewing alternatives and selecting the most appropriate regulatory actions based on the findings of the risk assessment. Measures to be taken to minimize risk include physical and biological containment.

Containment: The term containment is used to describe safe methods for maintaining control over the distribution of organisms with novel traits in the laboratory and in the environment into which they are introduced. The purpose of containment is to minimize unnecessary exposure of laboratory workers and the environment to potentially hazardous organisms. *Biological containment* of micro-organisms principally involves the use of specific combinations of vector and host in such a way that the probability of transfer of a vector to an unintended host and subsequent survival of the host-vector combination in the environment is limited. The growth of plants, which require special environmental conditions for their survival (for example, biological containment) can be achieved in either the greenhouse or field. Similar results can be obtained with studies using contained animal facilities. *Physical containment* involves physical constraints on the movement of organisms of uncertain risk or potential hazard. The aim of physical containment is to prevent inappropriate exposure of humans and the environment to organisms. Physical containment is achieved by following: (1) the principles of good

laboratory practice, occupational safety, and hygiene; (2) by involving well-qualified and competent personnel who follow safe, standard procedures and (3) by having a working environment designed to prevent the unintended spread to the environment of organisms with novel traits.

Biosafety Levels: Biosafety levels are described as a series of constraints on the handling and dissemination of organisms graduated according to the level of potential risk. Different biosafety levels are reached by different combinations of laboratory practice and techniques, safety equipment, laboratory facilities appropriate for the operations performed, and the hazards posed by different organisms. There are four biosafety levels or physical containment (PC) levels that have been defined based on the characteristics of the organisms involved.

1. *PC1* requires safety equipment and facilities as appropriate for undergraduate and secondary training laboratories and is suitable for work with strains of viable organisms not known to cause disease in humans, animals, or plants.
2. *PC2* is similar but includes specific personnel training, limited access to the laboratory and physical containment facilities, and is suitable for work involving moderate potential hazards to personnel and the environment.
3. *PC3* is suitable for work with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure.
4. *PC4* is required for work with those agents that pose a high individual risk of life-threatening disease.

The proposed safety levels for work with organisms with novel traits take into consideration the results of the risk assessment described above. For microorganisms these levels and conditions are summarized below. Similar levels and conditions have been established for transgenic plants and animals. Biosafety levels three and four are characterized by additional safety measures involving, among other things, further personnel training, strict working practices, qualified supervision, and strict physical containment in specially designed facilities and buildings.

3.2 Scope of the Policy

The objective of the Biosafety Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements. The Protocol applies to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity.

It must be clearly understood that the Biosafety Protocol applies to living modified organisms which are intended for intentional introduction into the environment. A major limitation to the Protocol is that the *AIA procedure applies only to living modified organisms which will be introduced into the environment*. These living modified

organisms include seeds for planting; fish for release and micro-organisms for bioremediation. The AIA procedure also does not apply to living modified organisms commodities which are intended for food, feed and food process.

The Protocol does not cover non-living products derived from living modified organisms. These would include food, food processes and pharmaceuticals for humans. These items are covered by other international agreements or arrangements. The Protocol also does not relate to issues of food safety; consumer product labelling and living modified organisms which are already available in the country of import.

The Biosafety and Biotechnology Policy takes a different approach to the Protocol. The policy takes a holistic approach to biosafety and biotechnology issues by embracing all genetically modified organisms and genetically modified products – thereby expanding the scope of the Protocol in PNG. The scheme of the policy has been designed to reflect this wider focus.

Chapter 3 Objectives

The Biosafety and Biotechnology Policy embraces nine key Policy Goals and adopts a series of strategies aimed at achieving these goals and ensuring human safety and biodiversity protection and conservation. The policy also acts as a signpost for government departments and agencies, private corporations and local communities engaged in modern biotechnology and biosafety and national development.

The primary objective of the Policy is to promote the safe use, management and transfer of genetically modified organisms to ensure that they do not adversely affect the safety of Papua New Guineans and their environment. The policy also promote research and development into genetically modified organisms and promotes the use of genetically modified organisms to increase food security for the people of PNG as expressed in the Food Security Policy 2000-2010; the National Agriculture and Livestock Policy 2001-2012 and the Medium Term Development Strategy 2005-2010. Research into genetically modified organisms for food and food processes will lead to increased access to food which promotes a healthy population, which is a key goal of the National Population Policy 2000-2010. The Biosafety and Biotechnology Policy has a cross-sectoral focus and is aimed at contributing to the attainment of many of the national goals and aims expressed in the other national policies.

2.1 Policy Goals

The Policy Goals are:

1. **To ensure the safe importation, exportation, development, field test, handling, use and management of genetically modified organisms for the safety of human health and biodiversity protection in Papua New Guinea.**

2. **To identify and strengthen institutional capacities for the assessment of risks associated with the handling, use and management of genetically modified organisms.**

3. **To strengthen national institutions engaged in the research and development of genetically modified organisms particularly for food, food processes and pharmaceuticals which contribute to the sustainable development of PNG.**

4. **To develop guidelines for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.**

5. **To regulate the trade in genetically modified organisms that may have harmful effects on the health of Papua New Guineans and their environment and biodiversity.**

6. **To actively promote the participation of all stakeholders in determining importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.**

7. **To facilitate the active participation of local communities in the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms that may have an impact on their biological resources and their communities.**

8. **To increase and promote the awareness of Papua New Guineans in biosafety and modern biotechnology issues.**

9. **To strengthen the capability for biosafety policy research, analysis and formulation for the modern biotechnology sector.**

2.2 Strategic Policy Objectives

2.2.1 To streamline and strengthen the processes and facilities to enable the efficient assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms, the following strategies will be initiated:

1. *Undertake a review to identify and streamline the current procedures and rules on assessing and reviewing of applications for the importation and exportation of genetically modified organisms.*
2. *Strengthen and promote the collaboration of relevant government agencies in their dealing with genetically modified organisms with a view to coordinating*

their programs and activities, and maximizing their financial and personnel resources to protect the safety of the people and their environment.

3. *Review and synergize the policy and regulatory frameworks to ensure the assessment, handling, use, management and transfer of genetically modified organisms are coordinated and timely.*
4. *Devise procedures which expedite the assessment of applications for the importation, exportation, transfer, use and management of genetically modified organisms.*
5. *Identify and strengthen national competent authority with relevant skilled personnel and resources.*
6. *Identify human capacity needs and promote capacity building initiatives both at the national and international level through government and international donor funding.*
7. *Establish institutional biological safety committees to monitor institutional use, transfer, management, research and development of genetically modified organisms.*

2.2.2 To promote and strengthen human and institutional capacity building, these strategies will be implemented:

1. *Seek funding to undertake a review to identify human and institutional needs of government agencies which are responsible for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*
2. *Identify capacity building programs and ensure that relevant public officials involved with the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms undertake these programs to improve and enhance their capacities in dealing with genetically modified organisms.*
3. *Promote and strengthen in-country human capacity building programs relating to the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*

2.2.3 To promote and strengthen the research and development of genetically modified organisms as food and for food processing and pharmaceuticals, the following activities will be initiated:

1. *Seek funding to undertake an inventory of all research institutions, their programs and personnel, and create and manage a database on these items.*
2. *Promote institutional collaboration in genetically modified organism research for food and food processing, and pharmaceuticals through sufficient government and donor funding.*
3. *Promote stronger network between government agencies and the private sector and research organizations involved with genetically modified organisms research and development.*

4. *Review and strengthen the regulatory frameworks on genetically modified organism research and development.*
5. *Devise guidelines for research and development of genetically modified organisms as food and food processes, and pharmaceuticals to achieve the goals of the Food Security Policy 2000-2010, the National Health Plan 2001-2012, the Agriculture and Livestock Policy 2010-2010 and the Medium Term Development Strategy 2005-2010.*
6. *Develop codes of conduct for research and development relating to genetically modified organisms.*
7. *Upgrade and where appropriate provide adequate facilities for research and development of genetically modified organisms for food and food processing to improve food security.*
8. *Facilitate the production, marketing and utilization of genetically modified food to improve the nutritional status and standard of living of the people of Papua New Guinea.*
9. *Facilitate and promote capacity building programs for Papua New Guinean scientists and researchers.*
10. *Provide for the development of guidelines and codes of conduct relating to the use of genetically modified organisms destined for contained use.*

2.2.4 To design and promote the use of precautionary approaches in the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms, the following strategies will be applied:

1. *Undertake a review of the regulatory framework and devise a strategy to promote, develop and reinforce policy and regulatory frameworks for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*
2. *Ensure the application of the precautionary approach in the assessment of genetically modified organisms being imported into and exported from the country through the introduction of guidelines and codes of conduct rules.*
3. *Ensure the application of the precautionary approach into the research of genetically modified organisms and the release of genetically modified organisms into the environment to mitigate the risks to human health and the environment through the application of the risk assessment and risk assessment plan.*
4. *Devise guidelines and codes of conduct in the use, management and transfer of genetically modified organisms.*

2.2.5 To regulate the trade in genetically modified organisms so as to ensure the safety of Papua New Guineans, their environment and genetic resources, the following programs will be initiated:

1. *Undertake an inventory of all foods, food processes and pharmaceuticals containing genetically modified organisms and establish a database on this items which must be accessible to the public.*
2. *Undertake an inventory of all government agencies and private corporations engaged in the trade of genetically modified organisms and create a database on these institutions and organizations which must be accessible to the public.*
3. *Develop in close consultation with relevant government agencies guidelines for the labelling of tradable products containing genetically modified organisms.*
4. *Devise cross-sectoral policies to ensure the safe handling, use, transfer and management of genetically modified organisms by Papua New Guinean based industries engaged in genetically modified organism trade.*
5. *Promote collaboration in genetically modified organism research for food and food processes and pharmaceuticals between industry and national research organizations through funding, human capacity building programs and exchange of information and knowledge.*
6. *Promote collaboration in genetically modified organism research for food and feed and food processes and pharmaceuticals between international and national research organizations through funding, human capacity building programs and exchange of information and knowledge.*

2.2.6 To promote the full and active participation of stakeholders in the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms. This objective will be pursued by:

1. *Ensuring the formulation of simple procedures for the full and active participation of stakeholders in the assessment of proposals for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*
2. *Developing simple procedures for the receipt of oral submissions from the public in determining proposals for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*
3. *Promoting active participation of stakeholders at the provincial and local government levels in the assessment of proposals for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms.*
4. *Facilitating the full and active participation of local communities in the assessment of proposals for the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms which are likely to affect the local communities.*

2.2.7 To facilitate the involvement of local communities in the importation, exportation, assessment, use, management, transfer, field test, handling and research and

development of genetically modified organism, the following initiatives will be undertaken:

1. *Devise guidelines for the participation of local communities in the importation, exportation, assessment, use, management, transfer, field test, handling and research and development of genetically modified organisms which are likely to have an impact on the local people and their environment and biodiversity*
2. *Provide guidelines for the protection of local communities, their traditional knowledge and biological resources which will be used in the research and development of genetically modified organism.*
3. *Provide guidelines for the engagement of local communities, their land and other resources in the research and development of genetically modified organism.*

2.2.8 To increase the awareness of people on biosafety and biotechnology matters, these programs will be implemented:

1. *Facilitate the inclusion of programs on biosafety and biotechnology in school curriculums both at the primary and secondary school levels.*
2. *Identify and access sustainable funding for community awareness programs on the subject of biosafety and biotechnology.*
3. *Collaborate with relevant stakeholders to promote public awareness on biosafety and biotechnology.*

2.2.9 To promote and strengthen research in biosafety policy, the following strategies will be implemented:

1. *Facilitate the periodic assessment and review of the biosafety policy.*
2. *Promote and coordinate biosafety policy research, analysis and formulation.*

Chapter 4. Institutional Arrangements

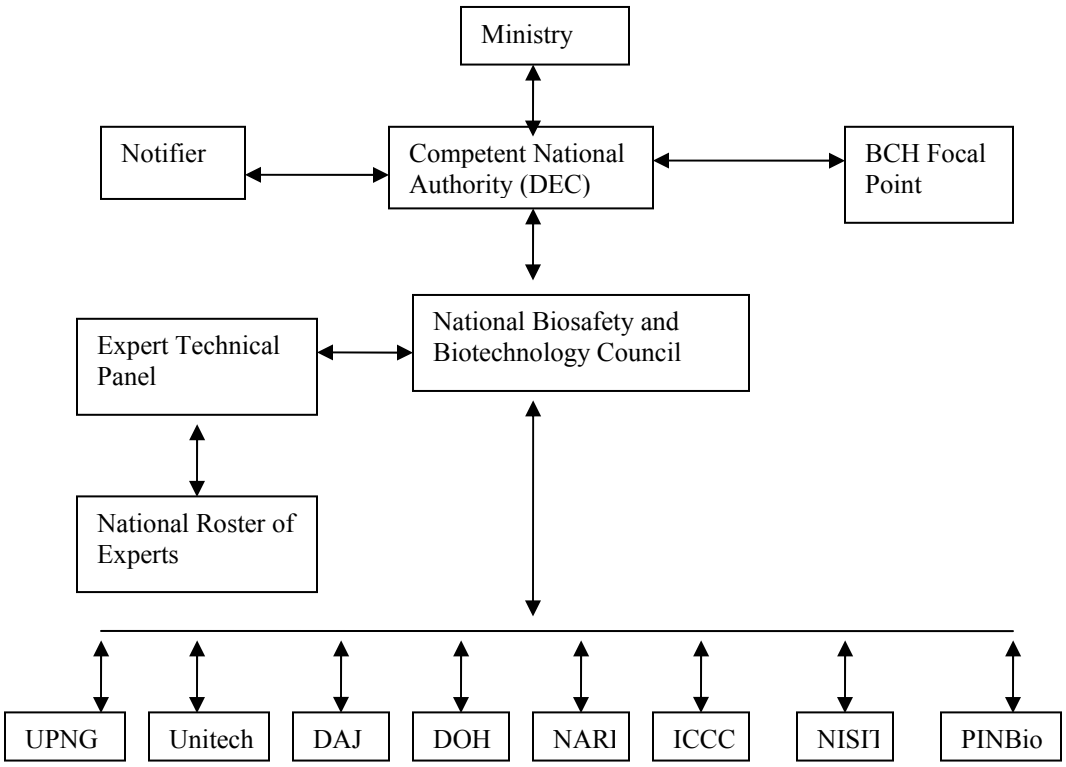
The Biosafety Protocol requires that a member Party must designate one national focal point which is responsible on its behalf for liaison with the Secretariat. The main role of the national focal point is to liaise with the Secretariat on matters relating to the Protocol.

The Protocol also requires Parties to designate one or more Competent National Authorities. The Competent National Authority may also perform the function of the National Focal Point. The main functions of the competent national authority are:

1. performing administrative functions stipulated by the Protocol; and
2. act on behalf of the government on matters relating to the Protocol

There are several national institutions whose roles and responsibilities impact on GMO. For instance, the Department of Trade and Industry has responsibilities over trade which includes trade in GMO products; the Internal Revenue Commission has power to monitor the import and exportation of GMO; the National Agriculture and Quarantine Inspections Authority monitors the importation and exportation of biological species which includes GMO; the National Institute for Standards and Industrial Technology has power to make rules and introduce guidelines relating to industrial standards. Such rules and guidelines will apply to the commercial development of GMO to be used for food, feed and food processes.

Administrative Framework



There was a general consensus that the DEC should be the Competent National Authority and also the national focal point. The CNA will work closely with the National Biosafety and Biotechnology Council. The members of the Council will be appointed on merit and will be drawn from the stakeholders. A technical panel can be utilized to provide advice to the Council and CNA. All notifications and requests will be handled by the CNA as the focal point.

The proposed structure envisages that DEC will act as the Secretariat for the NBBC. The formulation of rules, guidelines and codes of practice relating to the assessment, handling, use, management and transfer of GMOs will be developed by the NBBC in close consultation with the CNA.

Chapter 5. Biosafety and Biotechnology Policy and its Impact on other National Policies

The Biosafety and Biotechnology Policy has been developed against the backdrop of the various national policies which embody the goals and aspirations of the people of Papua New Guinea. The policy is aimed at creating a suitable environment for the realization of the potential of modern biotechnology, to improve conditions and services for Papua New Guineans and to mitigate concerns about potential adverse effects to human health and the environment and biodiversity.

The Biosafety and Biotechnology Policy complements several major national policies that have been adopted by the government. These include: (1) the Environment Policy 1976; (2) the Medium Term Development Strategy 2005-2010 (MTDS); (3) the National Agriculture and Livestock Policy 2001-2012; (4) National Food Security 2000-2010; (5) the National Health Policy 2001-2012; (6) Fisheries Policy; (7) the National Population Policy 2000-2010; (8) Forest Policy; (9) the Eco-Forestry Policy; (10) Education Policy and (11) Decentralization. Each of these policies is considered below.

5.1 Environment Policy

The Environment Policy was adopted by the government a year after Independence in 1976. The Policy is an expansion of Goal 4 of the National Goals and Directive Principles. The key element of the Policy is the promotion of the sustainable development concept captured by the term "wise use". The Environment Policy seeks to foster proper environmental management for the benefit of the present and future generations and the consideration of biodiversity protection and sustainable use in economic planning. Five key principles are articulated by the environment policy. These are:

1 Development must be economical, social and ecological;
2 Wise use of non-renewable natural resources;
3 Recognition of the ability of the environment to produce renewable resources;
4 Safeguarding and wisely managing the wildlife and their habitat in the development process; and
5 Planning to be applied to human settlement and urbanization.

The Biosafety and Biotechnology Policy embraces some of the principles promulgated by the Environment Policy. The main task of the stakeholders is to ensure that in the importation, research and development of GMO, safety of the country's environment and biodiversity must take precedence over other prevailing issues.

5.2 MTDS 2005-2010

The MTDS is the principal document outlining the government's key development goals and aspirations. The MTDS is the principal national development planning tool for the government. The last five year development program was the MTDS 1997 – 2002. When the MTDS 1997-2002 came to an end in 2002, the government introduced a new MTDS

covering the period 2005-2010. The primary vision of the new MTDS is to build a partnership between the government and the people. The MTDS outlines the government's key development goals and aspirations for the next 10 years. The MTDS 2003-2007 promote five national development goals. These are:

(1) Export-driven economic growth;
(2) Rural development;
(3) Poverty reduction;
(4) Good governance; and
(5) Promotion of agriculture, forestry, fisheries and tourism on a sustainable basis.

The MTDS 2005 – 2010 adopts these five goals as the pillars for the development of PNG over the next five years and beyond. The government aims to achieve these five goals through a series of intervention strategies which include:

- Strengthening political stability through political reforms.
- Greater transparency and accountability through institutional strengthening and public sector reforms.
- Stronger fiscal governance through improved expenditure management.
- Poverty reduction through greater emphasis on health, education and agricultural development.

The draft Biosafety and Biotechnology Policy establishes a framework for the scrutiny of imported genetically modified products and the research and development of GMOs and genetically modified products which can be used to improve food production for the people of PNG. The Policy also promotes the development of new pharmaceutical products which enhance the health of the people of Papua New Guinea. The use of genetically modified products can contribute to rural development, poverty reduction, improve health conditions and export-driven economic growth. Biosafety and modern biotechnology provide exciting opportunities to contribute to the attainment of the five goals of the government under the MTDS.

5.3 National Agriculture and Livestock Policy

Agriculture has been described as the backbone of the country's economy. It is estimated that more than 85% of Papua New Guineans live in rural areas of the country. These people live off their land, producing mostly subsistence crops. The main source of income for these rural dwellers is agricultural cash crops. The challenge for Papua New Guinea has and continues to be the development of strategies which will enable the 4, 412,169 people in the rural areas to harness their resources through agriculture production to enhance and improve their livelihoods.

Since independence in 1975, several agriculture policies had been developed by the government to address issues in agriculture. Most of these policies have not been able to solve the agriculture problems in the country. The new agriculture policy 2001-2012 has

been designed to achieve the goals of the Medium Term Development Strategy 1997 – 2002 and the National Charter on Reconstruction and Development 2000 – 2002.

The Agriculture and Livestock Policy targets four main issues. These are:

- Sectoral policies relating to economic and other policies specific to the sector;
- Commodity policies relating to policies focused on expanding production on a sustainable basis;
- Other development policy issues relating to inter-sectoral and interacting policies and compliance; and
- Monitoring and evaluation policies relating to performance requirements of the sector.

The underpinning of the Agriculture Policy is to increase sustainable production and productivity through improved research, extension and development. The government hopes to achieve this objective by promoting collaboration between those institutions engaged in agriculture research such as the National Agriculture Research Institute; Cocoa and Coconut Research Institute; Coffee Research Institute; PNG Oil Palm Research Association; Trukai Industries; Papua New Guinea University of Technology and Fresh Produce Development Company.

The Biosafety and Biosafety Policy affect's the Agriculture Policy in two main ways. The first is that the Biosafety and Biotechnology Policy articulates the government's position on the introduction of new food crops in the country and second it provides the framework for modern biotechnology. The Agriculture Policy promotes the introduction of new root and tuber crop varieties to boost household production. The introduction of these new food crops if genetically modified must meet the requirements set out in the Biosafety and Biotechnology Policy. If the root and tuber crop varieties are not genetically modified, they fall outside the scope of the Biosafety and Biotechnology Policy.

Biotechnology in the country is focused mostly on tissue culture. Most research and development institutions in the country concentrate their energies in this specific area of applied biotechnology. The only institution which has the capacity for advanced biotechnology research is the Papua New Guinea University of Technology Biotechnology Centre. It would seem that the Agriculture Policy encourages and promotes research and development of genetically modified food. In the area of research and development, the Agriculture Policy makes it unequivocally clear that the policy is to "strengthen the management and development of the genetic resources" and to "ensure research and development is diversified into both traditional and exotic food crops in high altitude areas aimed at identifying food crops resistant to frost attack".

5.4 National Food Security

Food security is a real concern for Papua New Guinea. It was estimated in 2001 that about 29 % of the population or 1,505,328 Papua New Guineans are food insecure. This can partly be attributed to the disparity in the rate of population and the rate of food production. In 2004, it was estimated that population was growing at 2.6 % while the rate of food production was 1.2 %. Given this dilemma, the National Food Security Policy 2000-2015 was formulated to "increase and diversify food production in Papua New Guinea in order to achieve greater self-sufficiency in food and attain food security at the national and household levels by the year 2015".

A number of strategies have been devised to achieve the goal of the Food Security Policy. These include: (1) diversification of food production and marketing; (2) improving food quality and safety; (3) adopting appropriate technology to sustainably intensify production systems and ensure sufficient supplies of food and (4) improve production, downstream processing, marketing and utilization of food.

The Biosafety and Biotechnology Policy has been fashioned to meet some of these objectives. Diversification of food production which entails GMO will fall within the ambit of the Policy.

5.5 National Health Policy

In 2001, the government adopted the first ever and most comprehensive 10 Year National Health Plan 2001-2010. The 10 year Health Policy is an ambitious action plan aimed at improving the delivery of health services to the people and strengthening the institutions responsible for the delivery of health services.

In 2003, the Health Department acknowledged that the effective implementation of the Health Policy was a difficult task. In line with the MTDS 2003-2007, the Department has reprioritized its goals and objectives. The Department has agreed to pursue five main goals in the short-term to provide the launching pad for the implementation of the Health Policy in the long-term. These reprioritized goals are:

1. Disease control – particularly malaria and TB.
2. Immunization.
3. Safe Motherhood and Family Planning.
4. HIV/AIDS and Sexually Transmitted Infections.
5. Maternal mortality- reduce by three quarters, maternal mortality by 2015.

It is envisaged that these five national health goals will enhance the health status of the country in the long term. The Health Department hopes that all its resources both internally and from external sources will be channeled towards achieving these five goals.

In the area of biosafety and biotechnology, the development of new medicines to control TB, cancer, HIV/AIDS and other sexually transmitted infections will be significant.

5.6 Fisheries Policy

There is presently no specific document which can be referred to as the fisheries policy. However, policy directives can be deduced from the various decisions of the government and especially the National Fisheries Authority and the regulatory framework. The major focus of the fisheries sector is the sustainable use and management of commercial fisheries resources. The sustainable use and management of non-commercial fisheries falls outside the scope of the National Fisheries Authority. Its research in marine organisms is limited to the identification of marine species. The National Fisheries Authority engages in this program through collaborative work with both national and international research organizations.

Genetic engineering in fisheries species by the fisheries sector is unknown in Papua New Guinea. Although there have been releases of new foreign aquatic fish species into the country, according to reports, none is genetically modified. The country does not have the capacity nor the facilities to conduct research into genetic engineering of fish species.

5.7 National Population Policy

The National Population Policy 2000-2010 is a very comprehensive document setting out in detail the population issues of Papua New Guinea and provides strategies to overcome some of these problems. The Policy is a key tool for decision-making for economic and social development.

An important component of the Population Policy is that it embraces sustainable development as a key principle for development planning. The Policy calls on the relevant government agencies to take into account environmental protection and conservation in the planning process because of the intricate linkage between Papua New Guineans and the environment. It also calls for the reduction in unsustainable production and consumption patterns as they have a significant impact on the health of the people and their environment.

The importation and research and development of GMO must be considered against the Population Policy. Where the GMO will not lead to sustainable production and does not substitute unsustainable consumption patterns, it must be prevented from entering the country and if it is being developed in Papua New Guinea, it must be prohibited from being released into the environment.

5.8 Forest Policy

The 1990 National Forest Policy 1990 is aimed at streamlining and strengthening access to forestry resources and their utilization and removing corruption in the sector. The Policy addresses these objectives through a number of strategies. These include: (1)

Forest Management; (2) Forest Industry; (3) Forest Research; (4) Forestry Training and Education and (5) Forestry Organization and Administration. These essential components of the National Forest Policy are designed to enhance the forestry sector and transform it into a viable sector. Each of these components is critical to the forestry sector.

The relevant component of the Policy is forest research. Forest research activities are promoted through the auspices of the National Forest Research Institute (FRI) which is based in Lae. An important aspect of the policy is forest conservation. The Policy expressly promotes the conservation of forests. If forests are unique because of their location, topographic constraints, ecological, or cultural or environmental considerations, they must be protected.

The Forest Policy does not expressly prohibit research into timber and other forest products for biotechnology purposes. The Policy promotes forest research activities such as: development of silviculture and new logging techniques for enhancing forest productivity; botanical research and protection of forests from biodegradation and fire. It may be argued that by giving a wide definition of forest research, genetic engineering into forest or botanical products may be permissible by the Forest Policy.

5.9 Eco-Forestry Policy

The objective of the draft Eco-Forestry Policy 2003 is to complement the National Forest Policy by strengthening the management and protection of the country's forest resources through the regulation of eco-forestry activities. Several key features of the draft Eco-Forestry Policy signal the shift in government thinking about the future of the country's forest resources. These are:

1. National Forest and Biodiversity Inventory.
2. Small and Medium-Scale Sawmills.
3. Biodiversity Conservation.
4. Support for Eco-Tourism.
5. Non Timber Forest Products.
6. Agroforestry.
7. Woodlots.
8. Community Tree Nurseries.

Under the draft policy, it is proposed that the national inventory will be undertaken jointly by several institutions ranging from universities to national government departments and non-governmental organizations. The inventory will cover all forestry resources including flora and fauna species. This national database will be updated every 20 years. The policy promotes institutional collaboration and seeks to strengthen institutional networking.

In so far as modern biotechnology is concerned, the Eco-Forestry Policy is unclear on the use of forest resources for GMO research and development. What is evident is that the Policy promotes the protection and trade in non-timber forest products and the concept of

protection forests. Under the draft policy, the National Forest Authority will promote the sustainable use of non-timber forest products and also establish a network of conservation forests throughout the country. Where an area has been declared a conservation forest, all commercial activities that by their nature would jeopardize the functions of the forest ecosystems will be banned.

5.10 Education Policy

In 1996 the government adopted the White Paper on Higher Education, Research, Science and Technology. The Policy had five broad objectives which are:

1. Creating a lively, just and self-reliant nation of forward and outward looking citizens.
2. Promoting peace with our neighbors at home and abroad.
3. Promoting pride in our rich cultural and environmental diversity.
4. Promoting and upholding Christian principles.
5. Equipping citizens with the best that higher education, research, science and technology can provide to improve and sustain the quality of life.

These higher education goals were to be achieved by the government through the creation of additional universities and other tertiary institutions. By 2000, there were 31 declared institutions of higher learning with six universities. Ironically, while the number of higher learning institutions was increased by the government, it began to cut funding to these same institutions. This is particularly evident in the universities. This funding cut has adversely affected the universities' ability to effectively perform their primary functions namely, teaching and research.

On the other hand, the government has placed a lot of emphasis on the provision of basic education through the elementary, primary and secondary schools. The new National Education Plan: Achieving a Better Future 2005-2014 sets out very strategic programs for the expansion of the education sector at the lower level. The government's plan through the MTDS 2005-2010 is to improve its budgetary allocation for basic education from K186 million in 2005 to K277 million in 2007. The aim of the government is to strengthen programs such as elementary teacher training; improvement of primary schools infrastructure; improvement of rural education facilities; teacher training; literacy and awareness, and technical and vocational training.

The National Education Plan: Achieving a Better Future 2005-2014 provides the roadmap for the implementation of the government's goals promulgated by the MTDS. In the light of the current review of the education policy, it would be useful to raise the issue of biosafety and biotechnology with the Department with a view to including the subject in the school curriculum.

5.11 Decentralization

In 1995 the government reformed the provincial government by replacing the old provincial governments with the new provincial and local-level governments. Two of the key reasons for reforming the decentralization process were: (1) to allow for greater accessibility to government by the people and (2) the efficient delivery of government goods and services to the people.

It was envisioned that people would easily access government through the local-level governments which was the face of government on the ground. Under the auspices of the Organic Law on Provincial Governments and Local-level Governments, 19 provinces and 297 local-level governments were created throughout the country. Papua New Guineans were required to participate in government through these new state institutions. The delivery of government goods and services were also meant to be achieved through the local-level governments.

There are three significant provisions of the Organic Law which will impact on modern biotechnology. These are sections 115, 116 and 98. Section 115 of the Organic Law states that it is mandatory for the participation of all the stakeholders in the development of natural resources located within their area. This provision is however, not in force because an enabling legislation required under section 116 has to be enacted to bring it into operation. Section 98 is concerned with benefit sharing from the development of natural resources. An essential term that has been clarified by the Organic Law is "natural resource". According to section 98(1) the term is defined as: minerals, petroleum, gas, marine products, water, timber (including forest products), fauna, flora and any other product determined by law to be a natural resource.

Modern biotechnology initially involves the use of living genetic resources. It can be argued that a biological resource obtained from a local community for GMO research and development will attract the provisions of the Organic Law. The Organic Law has provided the basic framework for the participation of local communities in the development of their natural resources for GMO purposes, the challenge is to provide the enabling regulations to implement the law.

Chapter 6. Implementation

Modern biotechnology is in its infancy in Papua New Guinea, but efforts to promote rapid progress in both research and development have been initiated. Modern biotechnology consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology through to the novel techniques of modern biotechnology. Modern biotechnology enables the genetic manipulation of living organisms and provides modern immunology with a basis for new diagnostics and vaccines, and allows new cell and tissue culture techniques for the production of biological products.

The impact of modern biotechnology is becoming increasingly evident, as the substantial investments over the past two decades in research and development in modern biotechnology are now resulting in a wide range of new products, processes and services, which contribute to improvements in human health, agricultural production and environmental conservation.

The commitment and collaboration of all the stakeholders both in the public and private sector will lead to the successful implementation of the Biosafety and Biotechnology Policy. Building strong partnerships between the government through its agencies, non-governmental organizations, civil society and individual commitment will produce positive outcomes from the Policy. The government agencies whose functions and responsibilities will be affected by the Biosafety and Biotechnology Policy include:

- Department of Environment and Conservation
- Department of Agriculture and Livestock
- Department of Health
- Department of Education
- Department of Justice and Attorney-General
- Department of Trade and Industry
- Department of National Planning and Rural Development
- Provincial Governments
- Local-level Governments
- National Agriculture Research Institute
- Coconut and Cocoa Research Institute
- Coffee Research Institute
- Forest Research Institute
- Institute of Medical Research
- Food Sanitation Council
- Independent Consumer and Competition Commission
- Oil Palm Research Institute
- Internal Revenue Commission
- National Institute of Standards and Industrial Technology
- National Research Institute
- National Fisheries Authority
- Department of Inter-Government Relations
- National Agriculture and Quarantine Inspection Authority
- University of Papua New Guinea
- Papua New Guinea University of Technology
- Vudal University
- Papua New Guinea Chamber of Commerce and Industry
- Papua New Guinea Manufacturers Council

Most of these organizations have the mandate to assess, handle, use, manage, transfer and, research and develop GMO in the course of performing their duties and responsibilities. These institutions obtain their mandate from the enabling legislation

creating these institutions. These pieces of legislation did not envision modern biotechnology as an element of scientific research and development. However, when giving a liberal meaning to many of these legislative provisions, it is clear that modern biotechnology involving genetic engineering is encompassed by these laws.

Some of these organizations are involved in setting standards and guidelines for the handling, use, management and transfer of GMO. The organizations that fall under this category are the government departments and special institutions such as the IRC and NISIT.

It is imperative that whatever the contact point at which these organizations will engage in the assessment, use, management and transfer of GMO, they must all work together to protect the health and safety of the people and the unique biodiversity of Papua New Guinea. When balancing the interests of the global community in terms of access for GMO whether for food, food processes or pharmaceutical and the interest of the business community, the safety, health and welfare of the people of Papua New Guinea and their biological diversity must be paramount in the hearts and minds of the people making decisions on the handling, use, management and transfer and, research and development of genetically modified products.

8.3 Draft Biosafety and Biotechnology Bill

INDEPENDENT STATE OF PAPUA NEW GUINEA.

No. of 200….

Biosafety and Biotechnology Act 200….

ARRANGEMENT OF CLAUSES.

PART 1. – PRELIMINARY.

INDEPENDENT STATE OF PAPUA NEW GUINEA.

No. of 200….

A BILL

for

AN ACT

entitled

Biosafety and Biotechnology Act 200…,

Being an Act to-

(*a*) provide for the minimization of risks and avoid the negative impacts of genetically modified organisms that may cause harm to human and animal health, the environment and biological diversity; and

(*b*) protect and sustain the potential of natural and physical resources against threats posed by genetically modified organisms to meet the reasonably foreseeable needs of future generations; and

(*c*) safeguard the life-supporting capacity of air, water, land and eco-systems; and

(*d*) regulate the importation, export, research and development, transportation, storage, conservation, commercialization, use and release of genetically modified organisms obtained through modern biotechnology techniques; and

(*e*) to give effect in Papua New Guinea, as far as may be, the Cartagena Protocol on Biosafety,

and for related purpose.

MADE by the National Parliament to come into operation in accordance with a notice in the National Gazette by the Head of State, acting with, and in accordance with, the advice of the Minister.

PART 1. – PRELIMINARY.

1. COMPLIANCE WITH CONSTITUTIONAL REQUIREMENTS.

(1) This Act, to the extent that it regulates or restricts a right or freedom referred to in Subdivision III.3.C of the Constitution (Qualified Rights), namely-

(*a*) the right to freedom from arbitrary search and entry conferred by Section 44 of the Constitution; and

(*b*) the right to freedom of employment conferred by Section 48 of the Constitution; and
(*c*) the right to privacy conferred by Section 49 of the Constitution; and
(*d*) the right to freedom of information conferred by Section 51 of the Constitution; and
(*e*) the right to freedom of movement conferred by Section 52 of the Constitution,

is a law that is made for the purpose of giving effect to the national interest, public safety and public welfare, the purpose of protecting the exercise of rights and freedoms of other persons, and for public purposes that, in the considered opinion of the Parliament, are reasonably justified in a democratic society that has a proper regard for the rights and dignity of humans.

(2) For the purposes of Section 53 (*protection from unjust deprivation of property*) of the Constitution, the purpose of protecting, maintaining and strengthening the ecological integrity of the environment and biological diversity is a public purpose.

(3) For the purposes of Section 41 of the ***Organic Law on Provincial Governments and Local-level Governments***, it is hereby declared that this Act relates to a matter of national interest.

2. APPLICATION OF PROVISIONS OF THE ORGANIC LAW ON PROVINCIAL GOVERNMENTS AND LOCAL-LEVEL GOVERNMENTS.

(1) For the purpose of Section 98 of the ***Organic Law on Provincial Governments and Local-level Governments***, it is hereby declared that this Act—

(*a*) establishes the benefits which are payable pursuant to Subsection (2) of that section in respect of genetically modified organisms; and
(*b*) provides for the rates, management, sharing arrangement and application of such development benefits.

(2) For the purpose of Section 99 of the ***Organic Law on Provincial Governments and Local-level Governments***, it is hereby declared that this Act establishes the principles by which the National Government and its statutory agencies will share with applicable Provincial Governments and Local-level Governments the revenues of the National Government generated from the development of genetically modified organisms.

(3) For the purpose of Section 116 of the ***Organic Law on Provincial Governments and Local-level Governments***, it is hereby declared that this Act establishes—

(*a*) the consultation process amongst stakeholders, including the establishment and procedures for prior informed consent and access benefit sharing; and

(*b*) the extent to which the parties may participate in the development of genetically modified organisms and genetically modified products.

3. INTERPRETATION.

In this Act unless the contrary intention appears -

"accident" means any accident that implies a significant or involuntary release of genetically modified organisms during a specific activity that is carried out and that may imply a danger of immediate or retarded effect and risks for the human health, the environment, and the biological diversity;

"activities" involving modern biotechnology include the following-

(*a*) all applications and uses, including applications and uses on humans; and

(*b*) all development, experimentation, breeding, propagation, production, manufacture; and

(*c*) all deliberate releases into the environment; and

(*d*) commercialization; and

(*e*) every import and export,

of genetically modified organisms and products derived from genetically modified organisms and includes the possession, supply, use, transport, or disposal of genetically modified organisms derived from genetically modified organisms for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (*a*) to (*e*);

"biological diversity" means the natural variability of live organisms of any source, including the terrestrial, marine ecosystems and other aquatic ecosystems and the ecological complexes of which they form part, comprises the diversity within species, among the species and of the ecosystems;

"biosafety" means all the actions or safety measures required to minimize the risks derived from the handling of a genetically modified organism and the utilization and the technology of recombinant DNA (genetic engineering) and other modern molecular techniques;

"confidential commercial information" means information declared by the Competent National Authority to be confidential commercial information under Section 34(2);

"containment" means restricting an organism or a genetically modified organism to a secure location or facility to prevent escape;

"containment facility" means a facility which complies with guidelines imposed by the Competent National Authority on the advice of Council and includes field testing and large scale fermentation;

"containment level" in relation to a facility, means the degree of physical confinement of genetically modified organisms provided by the facility, having regard to the design of the facility, the equipment located or installed in the facility and the procedures generally used within the facility;

"containment structure" means a containment facility that is a vehicle, room, building, or other structures set aside and equipped for the development of genetically modified organisms;

"contained use" means any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical or biological barriers, to effectively limit their contact with, and their impact on, the general population, biological diversity and the external environment;

"Council" means the National Biosafety and Biotechnology Council established under Section 11;

"deliberate release" means any intentional introduction into the environment, including any production or use that is not contained use of genetically modified organisms and includes, releases for-

(*a*) commercial purposes, bioremediation, research purposes in field experiments; and

(*b*) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation; and

(*c*) disposal of waste containing genetically modified organisms; and

(*d*) transport of genetically modified organisms;

"Deoxy-Ribonucleic Acid" (DNA) includes Ribonucleic Acid and means the genetic material that contains determinant information of the heritable characters transmittable to lineage;

"develop" includes development and fermentation, and in relation to organisms means genetic modification of any organism but does not include-

(*a*) field testing; and

(*b*) low risk development of genetically modified organisms as determined by the Council of less than 10 litres;

"disposal" in relation to a genetically modified organism means rendering the organism biologically inactive in such a manner as to prevent the occurrence of future biological activity or exporting the organism from Papua New Guinea;

"ecological integrity" means the ecosystems' capacity to continue its ongoing change and development with limited restraint by human interferences and the abilities to regenerate themselves under normal stresses especially nonanthropogenic stress;

"environment" means the ecosystems and their constituent parts, and includes-

(*a*) all natural and physical resources; and

(*b*) human beings; and

(*c*) cultural values which are embedded in traditional knowledge and practices; and

(*d*) social, economic and aesthetic values;

"evaluation of risks" means estimation of possible damages and probability of occurrence in activities with genetically modified organisms;

"evidential material" means any of the following-

(*a*) an activity with respect to which an offence against this Act or a Regulation has been committed or is suspected, on reasonable grounds, to have been committed; or

(*b*) an activity that there are reasonable grounds for suspecting will afford evidence to the commission of any such offence; or

(*c*) a thing that there are reasonable grounds for suspecting is intended to be used for the purpose of committing any such offence;

"export" means the transboundary movement of genetically modified organisms from one country to another country;

"exporter" means any legal or natural person or his agent who arranges for genetically modified organisms to be exported pursuant to Section 58;

"facility" includes, but is not limited to, the following-

(*a*) a building or part of a building; or

(*b*) a laboratory; or

(*c*) an aviary; or

(*d*) a glasshouse; or

(*e*) an insectary; or

(*f*) an animal house; or

(*g*) an aquarium, tank, pond or sea cage;

"Fund" means the Biosafety and Biotechnology Fund established under Section 23;

"genetic material " means any material of plant, animal (excluding humans or a genetic structure derived from a human being), microbial or other origin containing functional units of heredity;

"genetic resources" means genetic material of actual or potential value;

"genetically modified organism" means any organism whose genetic material has been modified by any technique of modern biotechnology;

"handling of genetically modified organisms" means action that implies activities of research, manipulation, production, utilization, transportation, storage, conservation, commercialization, use and release of a genetically modified organism;

"importer" means any natural or legal person and includes an agent for an importer or consignee;

"laboratory" means a vehicle, room, building, or any other structure set aside and equipped for scientific experiments or research, for teaching science, or for the development of medicinal products;

"licence" means a licence issued under Section 36;

"licence holder" means the holder of a genetically modified organism licence;

"local communities" means a village, settlement or hamlets where Papua New Guineans usually reside;

"management of risks" means implementation of appropriate measures to minimize the identified risks and the ones that may arise during the process of carrying out of a determined activity with the genetically modified organism;

"medicinal purpose" has the same meaning as medicinal purpose under the *Medicines and Cosmetics Act* 1999;

"modern biotechnology" means the application of-

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

(*b*) fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"objector" is a person or class of persons, who is not an applicant or a licence holder under the Act, whose interest is or will be affected adversely by a decision made pursuant to this Act or Regulation;

"premises" includes the following-

(*a*) a building; or

(*b*) a place (including an area of land); or

(*c*) a vehicle; or

(*d*) a vessel; or

(*e*) an aircraft; or

(*f*) a facility; or

(*g*) any part of premises (including premises referred to in paragraphs (*a*) to (*f*));

"Register" means the Register mentioned in Section 21;

"release" means to allow a genetically modified organism to move freely in the country within the conditions specified under the Act;

"research and development" in relation to genetically modified organism, means systematic investigation or experimentation activities that involve innovation or technology transfer for the purpose of gaining knowledge about the properties or use of that organism;

"risk assessment" means the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic conditions and ethical values of the country and, the cultural and traditional values of local communities which may be posed by activities involving modern biotechnology, including the import, contained use, deliberate release or the commercialization of genetically modified organisms and this includes the evaluation of secondary and long-term effects;

"risk management" means the plans and methods adopted or to be applied to counter the direct or indirect risks whether secondary or long-term posed by activities involving modern biotechnology, including the import, contained use, deliberate release or commercialization of genetically modified organisms;

"socio-economic impact" means the direct or indirect effects to the economy, social or cultural practices, livelihoods, traditional knowledge systems, or indigenous technologies as a result of activities involving modern biotechnology, including the import, contained use, deliberate release or placing on the market of genetically modified organisms;

"sustainable development" under the Act means the wise use and management of the environment and natural resources for the collective benefit of the people and protecting and strengthening the capacity of the natural ecosystems to meet the needs of future generations;

"the principles of sustainable development" are-

(*a*) decision-making processes must effectively integrate both long-term and short-term economic, environmental, social and equitable considerations; and

(*b*) decision-making processes must be transparent and enable the people to have access to vital public information to ensure their full and active participation in development; and

(*c*) the protection and maintenance of ecological integrity should be a fundamental consideration in decision-making; and

(*d*) the precautionary approach to human health, natural resources and ecosystems is a vital element of decision-making processes and if there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation; and

(*e*) the principle of inter-generational equity - that the present generation should ensure that the health, diversity and productivity of the environment is maintained or enhanced for the benefit of future generations; and

(*f*) the traditional knowledge and values which support ecological integrity and the rights of local communities must be strengthened and improved;

"Tribunal" means the Biosafety and Biotechnology Tribunal established under Section 49;

"user" means any natural person or public or private institution in charge of the development, production, commissioning, commercialization and distribution of genetically modified organisms.

4. APPLICATION OF ACT.

(1) This Act applies to-

(*a*) the State; and

(*b*) all natural persons, whether resident in the country or not; and

(*c*) all corporations, whether incorporated in the country or not.

(2) The provisions of this Act shall apply to all matters relating to the introduction, research, manipulation, utilization, transportation, storage, conservation, commercialization, use and release of genetically modified organisms obtained through modern biotechnology techniques.

PART 2. – ADMINISTRATION.

Division 1. – Functions of the Minister.

5. FUNCTIONS OF THE MINISTER.

The Minister has the following powers and functions-

(*a*) to recommend to the National Executive Council in accordance with the advice of the government agency responsible for environment and conservation matters, the appointment of members of the Council under Section 11; and

(*b*) to recommend Biosafety and Biotechnology Regulations for approval by the National Executive Council in accordance with Part 9; and

(*c*) to issue a genetically modified organism licence in accordance with the recommendation of the Tribunal under Section 56; and

(*d*) such other functions as are provided for in this Act, or any other law.

6. EXEMPTIONS

(1) The Minister acting with and in accordance with the advice of the Council may exempt, by notice in the National Gazette, any genetically modified product or class of genetically modified products specified or described in the notice, from such of the provisions of this Act as are specified or described in the notice.

(2) The Council may exempt-

(*a*) any processes or organisms that will not be considered genetically modified organism; and

(*b*) any product or class of products containing genetically modified organisms that are used for a medicinal or any other purpose from any provision under Part 4 and 6 of this Act.

(3) An exemption under this section may be made unconditionally or subject to such conditions as are specified or described in the notice or by the Council.

Division 2. – The Competent National Authority.

7. COMPETENT NATIONAL AUTHORITY.

The government agency responsible for environment and conservation matters, for the time being, is the Competent National Authority and the National Focal Point.

8. FUNCTIONS OF THE COMPETENT NATIONAL AUTHORITY.

(1) The functions of the Competent National Authority shall be exercised by the head of the government agency responsible for environment and conservation matters.

(2) The Competent National Authority has the following functions-

(*a*) to administer this Act; and

(*b*) to establish arrangements for the exchange of information with other countries; and

(*c*) to maintain links with international organizations that deal with the regulation of modern biotechnology and with agencies that

regulate genetically modified organisms in countries outside Papua New Guinea; and

(*d*) to provide advice to other regulatory agencies about genetically modified organisms; and

(*e*) to monitor and where appropriate adopt and implement international best practice in relation to the regulation of genetically modified organisms; and

(*f*) to collaborate with relevant government agencies, private sector organisations, universities, research institutions and non-government organisations for the establishment of Institutional Biological Safety Committees; and

(*g*) to do all things that may be deemed necessary to implement the policy and provisions of this Act.

9. POWERS OF THE COMPETENT NATIONAL AUTHORITY.

(1) The Competent National Authority has the following powers-

(*a*) to appoint inspectors under this Act; and

(*b*) appoint an officer of the government agency responsible for environment and conservation matters, who is the head of the Division responsible for the administration of this Act, to be his alternate on the Council; and

(*c*) appoint such persons who are members of the National Public Service and who are officers of the government agency responsible for environment and conservation matters and furnish them with appropriate facilities and resources to act as the Secretariat to the Council; and

(*d*) on the advice of Council formulate, or adopt and implement appropriate guidelines for the implementation of an aspect or part of this Act.

10. DELEGATION.

In the event of the unavailability of the head of the agency to perform the functions and powers of the Competent National Authority under this Act, the alternate may exercise all the functions and powers under this Act accordingly.

Division 3. – The National Biosafety and Biotechnology Council.

11. ESTABLISHMENT AND APPOINTMENT OF MEMBERS OF THE NATIONAL BIOSAFETY AND BIOTECHNOLOGY COUNCIL.

(1) There shall be established a National Biosafety and Biotechnology Council consisting of 11 members.

(2) Subject to Subsection (3) a person appointed as a member of the Council must have a good standing in the community with tertiary qualifications and professional expertise in one or more of the following areas-

(*a*) modern biotechnology; or
(*b*) ecology; or
(*c*) virology; or
(*d*) entomology; or
(*e*) agricultural or aquaculture systems including quarantine; or
(*f*) public health and occupational health and safety; or
(*g*) biochemistry; or
(*h*) pharmacy; or
(*i*) financial accounting; or
(*j*) environmental policy and law; or
(k) community development or social science.

(3) A person appointed as a member of the Council must have worked in the relevant field for more than five years to be eligible for appointment.

(4) In appointing the members of the Council, the National Executive Council shall ensure that, as far as practicable, that among the members as a whole there is a broad range of skills and experience in the areas mentioned in Subsection (2).

(5) The members of the Council shall be appointed by the National Executive Council by notice in the National Gazette from a list of not less than 15 persons recommended by the Minister.

(6) The list referred to in Subsection (5) is to be prepared after applications have been publicly invited by the Competent National Authority from among residents of Papua New Guinea.

(7) The members of the Council-
(*a*) shall be appointed for a period of three years; and
(*b*) are eligible for re-appointment.

(8) The head of the government agency responsible for exercising the powers and functions of the Competent National Authority, who is ***ex-officio***, shall be the Chairperson of the Council.

12. FUNCTIONS OF THE COUNCIL.

(1) The Council has the following functions-
(*a*) carrying into effect the objects of this Act; and
(*b*) protect, manage and develop the nation's biological resources and the environment in such a way as to ensure the maintenance of the ecological integrity of the country's ecosystems for the benefit of present and future generations and the sustainable development of the country; and
(*c*) to advise the Minister on the importation, development, field test, release, usage, handling, administration, labelling, monitoring and

enforcement and awareness of genetically modified organisms in Papua New Guinea; and

(*d*) to develop regulations relating to the importation, development, field test, release, usage, handling, administration, labelling, awareness, monitoring and enforcement of genetically modified organisms; and

(*e*) to monitor, review and control negative impacts of genetically modified organisms on human health, the environment, ecosystems and biological diversity; and

(*f*) to periodically review any decision made in relation to a licence under the Act; and

(*g*) to publish statements, reports and guidelines relating to the performance of its functions; and

(*h*) to ensure that benefits of genetically modified organisms are maximized for the posterity and well being of the people of Papua New Guinea; and

(*i*) to ensure the maintenance of ecological integrity; and

(*j*) to promote and strengthen traditional knowledge and practices relating to the research and development and use of genetically modified organisms; and

(*k*) to promote and monitor research and development of genetically modified organisms; and

(*l*) maximizing Papua New Guinean participation in the sustainable use of genetically modified organisms; and

(*m*) to promote sustainable development through the development and use of genetically modified organisms.

(2) Subject to Subsection (3) the Council may delegate to any person a function of the Council.

(3) A delegation under Subsection (2) –

(*a*) shall be in writing; and

(*b*) may be subject to such conditions or restrictions as specified in the instrument of delegation; and

(*c*) revocable by the Council in writing.

(4) Subsection (3) shall not effect or prevent the performance of a function or the exercise of a power by the Council.

13. THE POWERS OF THE COUNCIL.

(1) The Council has the following powers -

(*a*) to approve licences relating to all activities, usage, importing, exporting, research and development, of genetically modified organism; and

(*b*) to regulate the import and export of genetically modified organisms; and

(*c*) to enforce labelling of genetically modified organisms and their use; and

(*d*) to protect the rights of local communities over their genetic resources where an activity relating to a genetically modified organism is directly or indirectly connected to customary land; and

(*e*) to exercise any power in a manner that is not inconsistent with the requirements of a regulatory contract; and

(*f*) to carry out any powers and duties vested on it by or under this Act.

(2) The Council has such other powers as are conferred by any other law and shall do all things necessary to be done in connection with the performance of its powers under the Act.

14. LEAVE OF ABSENCE OF MEMBERS.

(1) The Chairperson may grant leave of absence to a member of the Council on such terms and conditions as the Minister determines.

(2) The Minister may grant leave of absence to the Chairperson of the Council on such terms and conditions as the Minister determines.

15. VACATION OF OFFICE.

(1) A member of the Council may resign his office by writing signed by him and delivered to the Chairperson.

(2) If a member of the Council other than the Chairperson-

(*a*) becomes permanently incapable of performing his duties; or

(*b*) resigns his office in accordance with Subsection (1); or

(*c*) is absent, except with the written consent of the Chairperson, for three consecutive meetings of the Council; or

(*d*) fails to comply with Section 16; or

(*e*) becomes bankrupt, or applies to take the benefit of any law for the benefit of bankrupt or insolvent debtors, compounds with his creditors or makes an assignment for their benefit; or

(*f*) is convicted of an offence punishable under a law for a term of imprisonment of one year or longer or by death, and, as a result of that conviction, is sentenced to imprisonment or death; or

(*g*) ceases to be ordinarily resident in the country,

the Minister shall in principle terminate his appointment.

(3) The Minister, acting on advice, may, at any time, by written notice, advise a member that he intends to terminate his appointment on the grounds of inefficiency, incapacity or misbehavior.

(4) Within 14 days of the receipt of a notice under Subsection (3), the member may reply in writing to the Minister who shall consider the reply and, where appropriate, in principle terminate the appointment.

(5) Where the member does not reply in accordance with Subsection (4), his appointment is terminated.

(6) Where the Minister makes a decision to terminate the appointment of a member, he shall make a recommendation to the National Executive Council to terminate the appointment, and the National Executive Council shall terminate the appointment.

16. DISCLOSURE OF INTEREST.

(1) A member who has a direct or indirect interest in a matter being considered or about to be considered by the Council shall, as soon as possible after the relevant facts have come to his knowledge, disclose the nature of his interest at a meeting of the Council.

(2) A disclosure under Subsection (1) shall be recorded in the minutes of the meeting of the Council and the member—

(*a*) shall not take part, after disclosure, in any deliberation or decision of the Council in relation to the matter; and

(*b*) shall be disregarded for the purpose of constituting a quorum of the Council for any such deliberation or decision.

17. COUNCIL'S QUORUM AND PROCEDURES.

(1) The Council shall meet as often as practicable and at such times and places as the Chairperson directs, but in any event not less frequently than three times in every year.

(2) At the meeting of the Council-

(*a*) half of the total number of members for the time being constitute a quorum; and

(*b*) the Chairperson, or in his absence the Deputy Chairperson, shall preside, and if both Chairperson and Deputy Chairperson are absent, the members present shall appoint, from their own number, a Chairperson for that meeting; and

(*c*) matters arising shall be decided by a majority of the votes of the members present and voting; and

(*d*) the Chairperson presiding has a deliberative, and in the event of an equality of votes on any matter, also a casting vote.

(3) Subject to this Act, the procedures of the meetings of the Council are as determined by the Council.

18. INSTITUTIONAL BIOLOGICAL SAFETY COMMITTEES.

(1) The National Competent Authority shall in close consultation with the Council liaise and establish within relevant government agencies, private sector organisations, universities, research institutions and non-government organisations Institutional Biological Safety Committees.

(2) The primary function of the Institutional Biological Safety Committee is to screen, monitor and supervise institutional activities relating to low risk development of genetically modified organism.

(3) The membership, functions and powers of the Institutional Biological Safety Committees shall be provided by Regulation.

19. TECHNICAL EXPERT PANEL.

(1) The Council shall maintain a register of technical experts whom the Council may engage where appropriate to assist the Council in the implementation of its powers and functions under the Act.

(2) Where the Minister or the Competent National Authority has referred a matter to the Council and the Council considers that the matter requires specialist advice, the Council may, engage technical experts from the register of experts to advise the Council on such matters as the Council considers necessary.

(3) In appointing experts under Subsection (2), the Council may—

(*a*) appoint such persons (including members) as it considers necessary; and

(*b*) specify in writing the terms and conditions of the engagement.

20. PROTECTION FROM PERSONAL LIABILITY.

A member of the Council, or an Institutional Biological Safety Committee, or technical expert panel, or a contractor, or an inspector is not personally liable for any act or default of himself done or omitted to be done in good faith.

21. PREPARING AND MAINTAINING THE REGISTER.

(1) The Competent National Authority shall keep a Register of all applications made to the Council.

(2) The Register shall specify-

(*a*) the name and address of the applicant; and

(*b*) a sufficient description of the genetically modified organism to uniquely identify that genetically modified organism; and

(*c*) the purpose and status of the application.

(3) The Register shall also record the details of any genetically modified organisms approved for use by the Council.

(4) Any decision by the Council to approve the importation for release or development of any genetically modified organism shall also be included in the Register.

22. REPORTS.

(1) The Council shall, by 31 March each year, furnish to the Minister a report on the progress and performance of the Council in relation to its functions for the year ending 31 December previously.

(2) The annual report shall include-

(*a*) the extent to which the Council has met the objects of the Act; and

(*b*) an assessment of the extent to which the Act has contributed to the health and safety of the people and the environment, including an assessment of any reduction in the likelihood that genetically modified organisms will adversely affect the people or the environment; and

(*c*) information showing the number of applications for genetically modified organism licences and approvals or rejections made by the Council in the year; and

(*d*) information showing the number and type of incidents caused by inadequate management of genetically modified organisms; and

(*e*) the strategies the Council has adopted or intends to adopt to achieve the objects of the Act in the succeeding year; and

(f) all financial statements; and

(*f*) any other matters that the Council may decide to incorporate in the report.

(3) As soon as practicable after he has received a report under Subsection (1), the Minister shall forward the report to the Speaker for presentation to the National Parliament.

PART 3. – FINANCES.

Division 1. – The Biosafety and Biotechnology Fund.

23. ESTABLISHMENT OF THE BIOSAFETY AND BIOTECHNOLOGY FUND.

(1) The Biosafety and Biotechnology Fund is hereby established.

(2) All monies received by or on behalf of the Council shall be paid into the Fund.

(3) The Council-

(*a*) shall be the trustee of the Fund; and

(*b*) shall invest the monies in the Fund in authorized trustee investments; and

(*c*) may dispose of the investments or any part of the investments and use the proceeds for the purposes of implementing the provisions of the Act.

(4) The Council may also use the Fund in the exercise and performance of the other objects of the Council.

(5) A person is not entitled to any interest in the Fund or to receive any payment or benefit from the Fund by reason only that he is liable to pay or has paid an amount specified under the Act.

(6) The provisions of the *Public Finance (Management) Act* 1995 shall apply to the control and management of the Fund.

Division 2. – Recovery of Costs.

24. RECOVERY OF COSTS FOR SERVICES.

(1) The Council may from time to time fix the charges-

(*a*) on a scale of charges for exercising or performing any power or function; and

(*b*) based on the time involved in exercising or performing any power or function; and

(*c*) specify the persons liable to pay the charges.

(2) Before any charges fixed by the Council pursuant to Subsection (1) come into force, the Council shall publicly notify the charges it has fixed-

(*a*) in the National Gazette; and

(*b*) in a national or local newspaper that is distributed regularly throughout the country; and

(*c*) through the radio networks; and

(*d*) in such other manner as the Council deems appropriate.

(3) Charges for expenses payable to the Competent National Authority under this Act may be recovered by the Competent National Authority as a debt.

Division 3. – Contracts.

25. TENDERS FOR PERSONS TO ASSIST THE COUNCIL

(1) The Council shall call public tenders for all works, supplies and services relating to the performance of any aspect of the powers and functions of the Council which exceed K100,000.00.

(2) The Council shall consider all applications relating to a tender under Subsection (1) and request the Minister for approval for the Council to enter into a contract with the approved contractor to under the works specified in the tender document and as directed by the Council.

(3) A person awarded a tender under Subsection (2) shall immediately enter into a contract with the Council.

(4) A contract under Subsection (3) shall specify the rights and duties and obligations of the Council and the person who has been awarded the contract.

PART 4. – LICENCES.

Division 1. – Notification.

26. NOTICE OF INTENTION TO APPLY FOR A LICENCE.

(1) A person who intends to engage in an activity involving genetically modified organisms, including importation, development, field test, or release, contained use, deliberate release, import, export or commercialization of genetically modified organisms shall notify the Competent National Authority in writing its request to apply for a licence.

(2) The notification must list the matters to be covered by the application.

(3) The Competent National Authority shall within 30 days of the lodgment of the notification-

(*a*) where it is satisfied that the notification lists all the relevant matters relating to the genetically modified organism including; importation, development, field test, or release, contained use, deliberate release, import, export or commercialization of the genetically modified organism – approve in principle the request; or

(*b*) refer the matter back to the potential applicant for amendment and re-lodgment.

(4) An interim approval given by the Competent National Authority under Subsection (3)(*a*) does not entitle a notifier to engage in activities relating to genetically modified organisms.

27. INVESTIGATIONS BY APPLICANT.

(1) A person whose notification has been considered and approved in principle shall within 60 days from the date of approval of his request proceed to-

(*a*) prepare a risk assessment and risk management plan; and
(*b*) if his activity or dealing will directly or indirectly affect local communities or where his activity will be located on customary land, liaise with the provincial and local-level governments and local communities.

(2) Where the proposed activity relates to the research and development of genetically modified organisms involving genetic materials to be taken from or involves the use of customary land and for deliberate release, commercialization, or export, the potential applicant shall-

(*a*) obtain the prior informed consent of the local communities in accordance with Section 63(1); and
(*b*) inform the provincial and local-level governments of the area concerned about his proposed activity in accordance with Section 63(2); and
(*c*) negotiate with the local communities, provincial and local-level governments and the Council, equitable benefit sharing arrangements pursuant to Section 65, for the distribution of financial and other benefits to be derived from the development of the genetically modified organisms.

Division 2. – Application for Licences.

28. APPLICATION FOR A LICENCE.

(1) A person whose notification had been considered and approved in principle under Section 26(3)(a) shall apply in writing to the Competent National Authority for a licence authorizing such an activity.

(2) The application must include-

(*a*) the information set out in the Regulation, in particular:-
(i) general information, including the details of the location or locations where the activity will be conducted; and
(ii) information relating to the genetically modified organism or organisms; and
(iii) information relating to the conditions of release, contained use or commercialization and where appropriate, the receiving environment; and
(iv) information on the interaction between the genetically modified organism and the environment; and
(v) information on monitoring, control, waste treatment and emergency response plans; and
(vi) in case of an application for contained use, an environmental impact assessment setting out the

consequences of unintentional release of genetically modified organism; and

(vii) a report on the impacts and risks posed by the genetically modified organism to human health and the ecosystem in accordance with the guidelines set out in the Regulation; and

(viii) information on results from deliberate releases in the country and other countries of the genetically modified organism previously or currently carried out by the applicant; and

(ix) information on previous approvals or rejections of the genetically modified organism by any other country, where approval was sought; and

(x) information on where and for what purposes the genetically modified organism will be commercialized, together with detailed instructions for use and the proposed labelling and packaging, fulfilling the requirements specified in the Regulation; and

(*b*) a risk assessment and risk management plan prepared in accordance with the Regulation; and

(*c*) a report on the benefit sharing arrangement with the provincial and local-level governments and local communities in accordance with Section 65; and

(*d*) a report to show that it has initiated negotiations or obtained the prior informed consent of the local communities under Section 63; and

(*e*) a report setting out in detail the financial implications of the activity involving modern biotechnology; and

(*f*) such other information as prescribed by Regulation; and

(*g*) such other information as is required by the Competent National Authority or the Council.

(3) The applicant may apply for a licence authorizing such activities by-

(*a*) a specified person or persons; or

(*b*) a specified class of persons; or

(*c*) all persons.

(4) The application must be submitted together with the prescribed amount.

29. REQUIREMENT FOR FURTHER INFORMATION.

(1) The Competent National Authority may, by notice in writing, require the applicant for a licence, to provide such further information in relation to the application as the Competent National Authority requires.

(2) The applicant for a licence is required to submit such further information to the Competent National Authority within 30 days upon the receipt of the notice.

30. REFERRAL OF THE APPLICATION TO THE COUNCIL.

(1) Subject to Subsection (2), the Competent National Authority shall upon receipt of an application for a genetically modified organism licence, refer the application with all the relevant documents to the Council for consideration.

(2) The Council shall not consider the application if-

(*a*) the application does not contain the information required by the Competent National Authority; or

(*b*) the application is not accompanied by the amount prescribed by the Council; or

(*c*) the applicant did not provide further information required by the Competent National Authority pursuant to Section 29; or

(*d*) the Competent National Authority is satisfied that to issue the licence would be inconsistent with an existing law or Regulation.

Division 3. – Risk Assessment and Risk Management.

31. RISK ASSESSMENT AND RISK MANAGEMENT.

(1) A person applying for a licence under Section 28 shall prepare a risk assessment and risk management plan in relation to the activities proposed to be authorized by the licence.

(2) A risk assessment and risk management plan must cover the matters set out in the Regulation.

(3) A risk assessment and risk management plan must be submitted together with the application for a licence to engage in an activity involving to genetically modified organism.

32. CONSIDERING RISK ASSESSMENT AND RISK MANAGEMENT.

(1) In considering the risk assessment, the Council must take into account the matters set out in the Regulation, in particular-

(*a*) the impacts and risks posed by the proposed activity or activities involving modern biotechnology to human, microorganisms, plant, and animal health, the environment and biological diversity; and

(*b*) whether the proposed activities involving modern biotechnology will contribute to and further promote the principles of sustainable development; and

(*c*) all socio-economic impacts; and

(*d*) whether the proposed activities involving modern biotechnology conforms with ethical, cultural and traditional values and norms of the people of Papua New Guinea; and

(*e*) any advice in relation to the risk assessment provided to the Council by a technical expert panel appointed for the purpose under Section 19; and

(*f*) any submission made under Section 33(3) in relation to such risks; and

(*g*) any advice the Council may request and receive from relevant governmental authorities.

(2) In assessing the risk management plan, the Council must take into account the following-

(*a*) the means of preventing, reducing and eliminating any risks posed by the proposed activities involving modern biotechnology so as to ensure the safety of:-

(i) humans, plants and animals; and

(ii) the environment; and

(iii) biological diversity; and

(*b*) any insurance taken by the applicant to cover the risks associated with the activities involving modern biotechnology; and

(*c*) any advice in relation to the risk management plan provided to the Council by a technical expert panel appointed for the purpose under Section 19; and

(*d*) any submission under Section 33(3) of the Act.

33. PUBLICATION OF APPLICATION.

(1) The Council shall upon receipt of an application for a genetically modified organism licence, publish a notice in respect of the application-

(*a*) in the National Gazette; and

(*b*) in a national or local newspaper that is distributed regularly throughout the country; or

(*c*) through the radio network; and

(*d*) in such other manner as the Council deems appropriate.

(2) The notice must-

(*a*) state that the application has been made with the risk assessment and risk management plan; and

(*b*) state that a person may request further information about the application in accordance with Section 34; and

(*c*) inform the public about proposed risk assessment and risk management plan; and

(*d*) invite written and oral submissions on whether the licence should be issued; and

(*e*) invite oral submissions and state the place, date and time where oral submissions can be made; and

(*f*) specify the closing date for submissions.

(3) The Council shall invite written and oral submissions from individuals, governmental authorities, provincial and local-level governments, holders of traditional knowledge, industry, interest groups and members of the public and stating a period of time (which shall not be less than 30 days and not more than three months) within which submissions may be made to the Council.

34. PUBLIC ACCESS TO CERTAIN DOCUMENTS.

(1) Subject to Subsection (2) a person may request the Competent National Authority to provide the person with a copy of the following documents-

(*a*) an application to which this Part applies; and

(*b*) a risk assessment and risk management plan prepared under Section 31 of the Act.

(2) Any confidential commercial information contained in the documents as determined by the Competent National Authority shall not be released to the public.

(3) A request made under Subsection (1) must be lodged with the prescribed amount.

(4) A request made under Subsection (1) without the accompaniment of the prescribed amount shall be rejected by the Competent National Authority.

35. ASSESSEMENT OF LICENCE APPLICATION.

(1) On receipt of an application under Section 28 the Council shall cause the application and risk assessment and risk management plan to be assessed.

(2) Subject to Subsection (3) the Council shall determine and make a decision on the application within 21 days after the close of submissions specified in the notice under Section 33.

(3) If the Council requires further period of time to consider and make a decision on the application it shall notify the applicant in writing stating the reasons necessitating such a period.

Division 4. – Approval and Conditions of Licences.

36. ISSUANCE OF LICENCE.

(1) Subject to Subsection (3), where the Council is satisfied that-

(*a*) the application satisfies all the requirements under this Act; and

(*b*) there is clear, convincing and sufficient evidence that the activities involving modern biotechnology that are sought to be licenced, pose no significant risk to the health and safety of the people, plants, animals, the environment and biological diversity; and

(*c*) the precautionary approach has been adequately covered in the risk assessment and risk management plan; and

(*d*) the activity involving genetically modified organism will promote and strengthen relevant national policies,

it shall approve and issue the licence and specify the conditions which will apply to the proposed activity.

(2) Where the activity involving modern biotechnology poses any significant risks or threats to the environment, the Council shall reject the application.

(3) In making a decision pursuant to Subsection (1), the Council shall have regard to-

(*a*) the objects of the Act; and
(*b*) the matters of national interest; and
(*c*) the general duty; and
(*d*) the biosafety and biotechnology policy; and
(*e*) any relevant risk assessment and risk management plan; and
(*f*) any submissions received from the public, a technical expert panel and relevant government authorities; and
(*g*) the public interest in the proposed activity; and
(*h*) any relevant obligations under any international treaty, convention or instrument to which Papua New Guinea is a party; and
(*i*) the suitability of the applicant to hold the licence.

(4) A decision by the Council under this section shall be in writing and specify the reasons for the decision.

37. CONDITIONS OF A LICENCE.

(1) The Council may impose such conditions it considers are necessary or desirable, including-

(*a*) the scope of activities authorized by the licence; and
(*b*) the purpose for which the activities may be undertaken; and
(*c*) variations to the scope or purposes of the activities; and
(*d*) documentation and record-keeping requirements; and
(*e*) the respect for cultural and traditional values of local communities; and
(*f*) the relevant ethical values to be observed; and
(*g*) the required level of containment in respect of the activities, including requirements relating to the certification of facilities to specified containment levels; and
(*h*) waste disposal requirements; and
(*i*) measures to manage risks posed to public health and safety or to the environment; and
(*j*) data collection, including studies to be conducted; and
(*k*) auditing and reporting; and
(*l*) actions to be taken in case of the release of a genetically modified organism from a contained environment; and

(*m*) the geographic area in which the activities authorized by the licence may occur; and
(*n*) conditions requiring compliance with the Regulation; and
(*o*) conditions relating to the supervision and monitoring by relevant government authorities.

(2) Notwithstanding Subsection (1) a licence is subject to the following conditions-

(*a*) the conditions set out in Sections 38, 39, 40 and 41; and
(*b*) any conditions prescribed by Regulation; and
(*c*) any conditions imposed by the Council at the time of issuing the licence; and
(*d*) any conditions imposed by the Competent National Authority under Section 45 after the licence is issued.

38. CONDITIONS ABOUT PUBLISHING OBLIGATIONS.

(1) It is a condition of the licence that the licence holder, inform any person covered by the licence of the following-

(*a*) any condition of the licence imposed by the Council that applies to the person, including variations; and
(*b*) the cancellation or suspension of the licence; and
(*c*) the surrender of the licence.

(2) The requirements in relation to the manner in which information is provided under Subsection (1) may be-

(*a*) prescribed by Regulation; or
(*b*) specified as a condition of the licence by the Council.

(3) The requirements in this section may include measures relating to-

(*a*) labelling; and
(*b*) packaging; and
(*c*) disposal; and
(*d*) conducting training; and
(*e*) providing information.

39. CONDITIONS ABOUT MONITORING AND AUDIT.

(1) It is a condition of a licence that any person authorized by the licence to engage in an activity involving a genetically modified organism to allow the Competent National Authority or a person authorized by the Competent National Authority to enter premises where the activity is being undertaken, for the purpose of auditing or monitoring the activity.

(2) Subsection (1) does not limit the monitoring powers under Section 70 and any conditions that may be imposed by the Council or prescribed by Regulation.

(3) It is a condition of a licence that a licence holder must-

(*a*) monitor and evaluate, on a continuing basis after the licence is issued, any risks associated with the activities involving biotechnology that are subject to the licence; and

(*b*) submit complete and accurate annual reports to the Competent National Authority in respect of monitoring and audits carried out under this section.

(4) All information gathered as a result of monitoring or audits shall be made available to the public and must be kept on a register of licences.

40. PERFORMANCE BONDS.

(1) A performance bond in the prescribed form shall be lodged with a bank approved by the Competent National Authority by a licednce holder and subject to Subsection (2), authorize the Council to draw directly on the bond in the event of a breach by the holder of the licence of any condition or requirement of the licence or of any provision of this Act.

(2) The Council may draw directly on a bond only—

(*a*) after following the procedures as prescribed by the Council; and

(*b*) to the extent of the prescribed scale of deductions for nominated breaches of conditions or requirements.

(3) Where the Council has drawn on a bond in accordance with this section, the holder of the licence shall, within 30 days of being so notified by the Council, deposit with the bank a sum equivalent to the amount drawn.

(4) A licence holder shall not engage in an activity involving genetically modified organisms, including contained use, deliberate release, import, export or commercialization of genetically modified organisms until the performance bond payable has been lodged with the Council.

(5) If such bond is not lodged within 21 days of the date of grant of a licence then the said approval shall be deemed void and shall be cancelled by the Council forthwith.

(6) The Council may, in its absolute and unfettered discretion, on being satisfied that extenuating circumstances exist, on application by the licence holder extend the time prescribed in Subsection (5) by which a person is required to lodge a performance bond.

(7) The amount of a bond for a licence shall be as determined by the Council.

41. CONDITIONS ABOUT EMERGENCY MEASURES.

(1) The Council shall ensure that before the release of a genetically modified organism is made or contained use is carried out, that the licence holder for such uses-

(*a*) prepare an emergency plan for the protection of human, plant and animal health, biologically diversity and the environment in the event of an accident and inform the relevant agencies of this plan in writing; and

(*b*) supply persons liable to be affected by the accident information on safety measures and procedures to adopt in the case of an accident; and

(*c*) ensure that the emergency measures are made available to the general public.

(2) Where a genetically modified organism is required to remedy an emergency situation, the licence holder shall inform the Competent National Authority and obtain approval from the Council for the use of the genetically modified organism for bioremediation.

42. PERIOD OF LICENCE.

(1) A licence continues in force-

(*a*) if the licence is expressed to be in force for a particular period – until the end of that period; or

(*b*) until it is cancelled or suspended or surrendered.

(2) A licence is not in force throughout any period of suspension.

(3) A licence is valid for five years beginning from the date of issue and may be renewed every five years thereafter.

(4) The Council is required to review each licence at intervals not exceeding five years after the issue of the licences.

(5) The Council must give public notice of the licences that are to be reviewed as follows:

(*a*) a notice of the review is to be published:-

(i) in the National Gazette; and

(ii) in a national or local newspaper that is distributed regularly throughout the country; or

(iii) through the radio networks; and

(iv) in such other manner as the Council deems appropriate; and

(*b*) a notice of the review is to be published not less than one month, and not more than six months, before the review of the licence is to be undertaken; and

(*c*) the notice is to specify the activities to which the licence relates and the location of the premises (if any) at which the activities are to be carried out.

(6) The Council may, after considering submissions from the public and a technical expert panel, renew or cancel the licence.

43. RESTRAINT ON APPROVAL BY OTHER GOVERNMENT AUTHORITIES.

(1) Other governmental authorities shall be restrained from issuing permits or licences for activities involving genetically modified organisms (other than existing activities) which would authorize the holder to carry out an activity which would cause harm to humans, microorganisms, plants, and animals, ecosystems and the environment where to do so would be a breach of this Act until a licence in relation to the activity has been granted according to this Act.

(2) Subsection (1) does not apply to approvals under the ***Investment Promotion Act*** 1992.

(3) Where a person applies for another kind of approval in respect of an activity relating to a genetically modified organism under the provisions of other legislation, the other governmental authority shall refer the application to the Competent National Authority.

Division 5. – Administration of Licences.

44. PROCEDURES FOR THE ADMINISTRATION OF LICENCES.

A Regulation shall prescribe-

(*a*) procedures for renewal of licences; and
(*b*) procedures for transfer and surrender of licences; and
(*c*) procedures for amendments of licences; and
(*d*) annual charges in relation to licences; and
(*e*) reporting by licence holders; and
(*f*) procedure for review of a licence; and
(*d*) the effect on the validity of a licence for failure to lodge an annual return or pay annual charges.

45. AMENDMENT OF LICENCE.

(1) Subject to Subsection (3) the Competent National Authority acting with and in accordance with the advice of the Council may at any time, by notice in writing to the licence holder vary the licence.

(2) The Competent National Authority acting with and in accordance with the advice of the Council may-

(*a*) impose additional licence conditions; or
(*b*) remove or vary licence conditions that were originally imposed by the Council; or
(*c*) extend or reduce the authority granted by the licence.

(3) A licence shall not be varied for the deliberate release of a genetically modified organism into the environment if the original application for the licence did not seek authorization for the deliberate release.

(4) Subject to Subsection (5), where a licence holder intends to transfer out of a specifically approved location to conduct his activity, the licence holder shall apply to the Council to vary the licence.

(5) The Council shall, prior to varying a licence, notify the public in accordance with the procedures in Section 33 and invite written submissions on whether the licence should be varied.

46. SUSPENSION AND CANCELLATION OF LICENCE.

(1) The Competent National Authority acting with and in accordance with the advice of the Council, may by notice in writing, suspend or cancel a licence where-

(*a*) the Competent National Authority believes on reasonable grounds that a condition of the licence has been breached, whether by the licence holder or a person covered by the licence; or

(*b*) the Competent National Authority believes on reasonable grounds that the licence holder or a person covered by the licence has committed an offence against this Act or Regulation; or

(*c*) the licence was issued because of a materially false or misleading representation or declaration in writing; or

(*d*) the licence holder has failed to perform an obligation required under this Act in relation to an activity carried out pursuant to the licence; or

(*e*) the Competent National Authority becomes aware of risks associated with the continuation of the activity authorized by the licence and is satisfied that the licence holder is not capable of implementing adequate measures to deal with those risks.

(2) The Competent National Authority shall serve a notice on the licence holder requiring him to show cause within 30 days why the licence should not be suspended or cancelled.

(3) Where-

(*a*) a notice under Subsection (2) has been served on the licence holder; and

(*b*) the licence holder has failed to satisfy the Competent National Authority that there are good reasons for the failure,

the Competent National Authority shall advise the Council to suspend the licence for a specified period or cancel the licence.

(4) The Competent National Authority shall inform the licence holder of the decision of the Council by written notice and state the reasons for the decision.

(5) In the event that the licence is suspended or cancelled the Competent National Authority shall take full possession of the facility, premises or laboratory and take necessary steps to contain, destroy or dispose of the genetically modified organism.

47. OFFENCES IN RELATION TO LICENCES.

(1) A person who carries out an activity to which a licence has been issued while that licence is suspended or cancelled, is guilty of an offence.

Penalty: Where the person convicted of an offence is-

(*a*) corporation – a fine not exceeding K250,000.00; and

(*b*) other than a corporation – a fine not exceeding K100,000.00 or imprisonment for a term not exceeding five years, or both.

Default penalty: A fine not exceeding K20,000.00

(2) A person who breaches a condition of a licence, is guilty of an offence.

Penalty: Where the person convicted of an offence is-

(*a*) corporation – a fine not exceeding K150,000.00; and

(*b*) other than a corporation – a fine not exceeding K50,000.00 or imprisonment for a term not exceeding five years, or both.

Default penalty: A fine not exceeding K10,000.00

48. REVIEW OF LICENCES.

(1) Where the Competent National Authority becomes aware or receives credible new scientific information relating to a genetically modified organism which the Council has approved, the Competent National Authority shall immediately inform the licence holder in writing that the licence will be reviewed and provide the licence holder copies of the new scientific information and require him to make submissions to the Council.

(2) The Council shall consider the new scientific information and the views of the licence holder and may vary, suspend or cancel the licence.

(3) The Council shall inform the public of its decision by notice in the National Gazette and where appropriate in a national or local newspaper that is distributed regularly throughout the country.

PART 5. – APPEALS.

49. THE BIOSAFETY AND BIOTECHNOLOGY APPEALS TRIBUNAL.

(1) A Biosafety and Biotechnology Appeals Tribunal is established for the purpose of hearing appeals and giving rulings as to whether a decision of the Council is contrary to the objectives of the Act or not.

(2) The Tribunal shall consist of three members-

(*a*) a lawyer as defined in the *Lawyers Act* 1986; and
(*b*) either a biochemist or a pharmacist or a ecologist or a virologist or an entomologist or a food safety specialist or a public health and occupational health and safety specialist; and
(*c*) a member nominated by the Minister to represent a National Government viewpoint.

(3) The members of the Tribunal shall—
(*a*) be appointed by the Head of State, acting on advice, by notice in the National Gazette; and
(*b*) be appointed for a period not exceeding three years; and
(*c*) be appointed on such terms and conditions as the National Executive Council shall determine; and
(*d*) are eligible for reappointment.

50. CHAIRPERSON.

The Chairmanship of the Tribunal shall rotate among the members from meeting to meeting.

51. RESIGNATION.

A member of the Tribunal may resign his office by written notice to the Minister.

52. VACATION OF OFFICE BY TRIBUNAL MEMBER.

(1) If a member of the Tribunal—
(*a*) becomes permanently incapable of performing his duties; or
(*b*) resigns his office under Section 51; or
(*c*) is absent from three consecutive meetings of the Tribunal; or
(*d*) becomes bankrupt, or applies to take the benefit of any law for the relief of bankrupt or insolvent debtors, compounds with his creditors or makes an assignment of his remuneration for their benefit; or
(*e*) is convicted of an offence punishable under a law by a term of imprisonment for one year or longer and as a result is sentenced to imprisonment,

the Head of State, acting on advice, shall terminate his appointment.

(2) The Head of State, acting on advice, may at any time by written notice advise a member that he intends to terminate his appointment on the grounds of inefficiency, incapacity or misbehavior.

(3) Within 14 days of the receipt of a notice under Subsection (2), the member may reply in writing to the Head of State who shall consider the reply, and, where appropriate, terminate the appointment.

(4) Where the member referred to in Subsection (2) does not reply in accordance with Subsection (3), his appointment is terminated.

53. CONDUCT OF TRIBUNAL.

(1) The Tribunal shall meet not less than four times in each year but shall not meet if there are no appeals to be heard.

(2) All three members of the Tribunal must be present in a meeting for the appeal to be heard.

(3) All decisions of the Tribunal shall be reached by consensus.

(4) The procedure at a meeting of the Tribunal is as prescribed and until it is prescribed is as determined by the Tribunal.

54. APPEAL AGAINST A COUNCIL DECISION.

(1) An applicant, or a licence holder or an objector who is aggrieved by a decision of the Council, may appeal to the Tribunal within 21 days from the date of the decision.

(2) An appeal under Subsection (1) may only be against—

(*a*) a decision on a licence application; or
(*b*) non determination within the prescribed time under Section 36; or
(*c*) the amendment of a licence under Section 45; or
(*d*) the suspension or cancellation of a licence under Section 46.
(*e*) a condition imposed on the approval of a licence; or
(*f*) a decision under Section 48; or
(*g*) a direction issued by the Competent National Authority under Section 66; or

55. REPRESENTATIONS AT THE TRIBUNAL.

(1) The Tribunal shall afford the appellant and the Council and any person who has a significant interest in the appeal an opportunity to make representations concerning the appeal if they so wish.

(2) At the discretion of the Tribunal the above representations may be made in writing or may be at a hearing.

(3) Where representations are made at a hearing, a party may be represented by an agent and may call such evidence and produce such documents as are relevant and material in support of those representations.

(4) In the absence of any or all of the interested parties or their representatives at a hearing, the Tribunal may proceed to determine the appeal on the basis of such

representations as are before it but in such a situation the Tribunal shall satisfy itself that there is sufficient information to make a considered decision.

56. CONSIDERATION OF APPEALS.

(1) The Tribunal shall consider an appeal in the prescribed manner and shall make a recommendation to the Minister to—

(*a*) allow the appeal; or

(*b*) dismiss the appeal and allow the decision of the Council to stand; or

(*c*) refer the matter back to the Council as it thinks just in the particular circumstances of the case.

(2) On receipt of a recommendation under Subsection (1), the Minister shall consider the matter and shall—

(*a*) accept the recommendation of the Tribunal; or

(*b*) refer the matter back to the Tribunal for further consideration; or

(*c*) reject the recommendation of the Tribunal and—

(i) allow the appeal; or

(ii) reject the appeal; or

(iii) refer the matter back to the Council with such direction as he thinks just in the particular circumstances of the case,

and his decision is final except on a point of law.

(3) Where the Minister makes a reference back to the Council, the Council shall comply with any direction within one month or such other time as is specified in the reference back.

(4) Where the Minister allows an appeal he shall publish the result of the appeal in the National Gazette.

(5) The Tribunal shall make its recommendation on any appeal within any prescribed time limit.

PART 6.– LABELLING, IMPORT, EXPORT AND TRANSSHIPMENT OF GENETICALLY MODIFIED ORGANISMS.

Division 1.- Labelling

57. IDENTIFICATION AND LABELLING.

A genetically modified organism shall be clearly identified and labeled as such, and such identification shall specify the relevant traits and characteristics in sufficient detail for purposes of traceability.

Division 2.- Export and Import

58. EXPORT.

(1) A person who intends to export genetically modified organism must apply for and obtain approval for such export.

(2) There shall be no authorization for the export of genetically modified organism that does not have a licence under this Act or that are prohibited from use by any other law.

59. IMPORT.

(1) A person who intends to import genetically modified organism for use in the country must apply for and obtain approval for such import.

(2) There shall be no authorization for the import of genetically modified organism that does not have a licence under this Act or that are prohibited from use by any other law.

(3) Where a licence to import a genetically modified organism has been approved by the Council, the Competent National Authority may issue an advance informed agreement to the applicant at the request of the applicant.

(4) Where a genetically modified organism has received approval for importation into containment, then no further approval shall be required for any subsequent importation into containment of the same genetically modified organism.

60. ADVANCE INFORMED AGREEMENT.

(1) A person who intends to export genetically modified organism shall provide the Competent National Authority a written advance informed agreement from the competent authority of the importing country.

(2) The presentation of the advance informed agreement by an exporter shall in no way absolve the exporter from complying with any other law governing foreign trade.

Division 3.- Genetically Modified Organisms in Transit

61. TRANSSHIPMENT OF GENETICALLY MODIFIED ORGANISMS.

(1) The Competent National Authority shall upon the advice of the Council issue guidelines specifying the manner in which a genetically modified organism shall be handled while in transit in the country.

(2) A person who intends to bring into the country for the transshipment of a genetically modified organism shall notify the Competent National Authority in writing 28 days prior to the transshipment of the genetically modified organism.

(3) The Competent National Authority on receipt of the notification shall consult the relevant government agencies and based on advice consider the notification and where the genetically modified organism does not pose any potential risk to human health, biological and environmental health, he may approve the transshipment of the genetically modified organism.

(4) Where a genetically modified organism has been approved for transit then no further approval shall be required for any subsequent transshipment of the same genetically modified organism.

(5) The Competent National Authority shall provide to the Council at its next meeting a report containing information on all notifications and the decisions made in relation to the transshipment of genetically modified organisms.

PART 7.– ACCESS TO GENETIC RESOURCES FOR RESEARCH AND DEVELOPMENT.

62. ACCESS TO GENETIC RESOURCES.

(1) A person who intends to access the country's genetic resources to conduct scientific research for the discovery of genetic material for the development of genetically modified organism shall obtain a licence for such purpose from the Council.

(2) The application for a biodiscovery licence shall be in accordance with Section 28 of this Act.

(3) Where the research activity will be conducted on customary land the applicant shall set out in full the manner in which traditional knowledge of the local communities will be applied and the rights of the holders of traditional knowledge will be protected if the research leads to the development of genetically modified organisms.

(4) Where the applicant for research and development is a foreign individual or organization, the applicant shall provide clear and strong guarantees for technology transfer and capacity building in that-

(*a*) it will work together with relevant tertiary or research institutions in Papua New Guinea on the proposed research and development project; and

(*b*) it will fund, train and engage Papua New Guinean scientists in the research and development of the genetically modified organisms.

(5) In addition to the matters contained in Section 36(3) and this section, the Council shall give paramount consideration to the protection and conservation of the

cultural values and traditional knowledge and biological diversity of the local communities.

(6) Subject to Section 24, the Council shall fix charges for access-

(*a*) to be paid by an applicant under this Part; and

(*b*) remitted to the local-level government to be shared equally by the local-level government and local communities.

63. PRIOR INFORMED CONSENT.

(1) Where local communities will be directly affected by the biodiscovery project, the prior informed consent of local communities must be obtained by the applicant and Council before a licence is granted under this Act.

(2) The provincial and local-level governments shall be fully informed of the negotiations between the applicant, the Council and the local communities.

(3) Subject to Subsection (5), the Council may formulate regulations specifying the manner in which consent of local communities would be obtained for the purposes of this Act.

(4) The process by which the prior informed consent of the local communities is obtained must be simple, transparent and allow the greatest opportunity for participation by the local communities particularly women and the youths.

(5) The absence of an appropriate Regulation under Subsection (3), does not absolve the Council and the applicant of their duty to seek and obtain the prior informed consent of the local communities before the issuance of a licence under this Act.

64. REGISTER OF CONSULTANTS.

(1) In order to assist local communities participate meaningfully in the negotiations on access and benefit sharing, the Council shall keep a register of consultants who may be called upon to provide social, financial, legal or environmental advice to local communities.

(2) The costs of the consultants shall be covered by the applicant and the Council.

(3) The appointment and the terms of references of consultants shall be by mutual agreement between the Council, the applicant and the local communities.

65. BENEFIT SHARING.

(1) The Council shall, before issuing a licence for an activity relating to this Part, ensure that a valid benefit sharing arrangement in the form of a contract is executed between the local communities, the relevant local-level governments, provincial government, the applicant and the Council.

(2) The following principles shall be taken into account by the parties when negotiating benefit sharing agreements-

(*a*) the percentage of royalties negotiated as payments might vary depending on the relationship of the marketed genetically modified product to the original isolated material; and

(*b*) it is understood that the eventual development of a product to the marketing stage is a long term process which may require 10 to15 or more years; and

(*c*) benefit sharing must be on an equitable basis, whether the genetically modified organism is based on synthetic or semi-synthetic variations of compounds or structurally based natural products; and

(*d*) all scientists and individuals who contribute to the identification and discovery of new genetically modified organisms for products such as chemotherapeutics, pharmaceuticals, industrial products or molecular probes or genetic constructs should be compensated in terms of royalties arising from patent agreements; and

(*e*) compensation will include milestone payments at key stages of clinical development; and

(*f*) if a genetic material, isolated from a Papua New Guinea source material is developed as a commercial agent, and is required for semi-synthesis of such, then Papua New Guinea should be the first source of the raw material, unless the quality and quantity of material is insufficient for such use; and

(*g*) if prior indigenous knowledge is involved in the collection of samples or development of genetically modified organisms, then suitable recognition should be given to this intellectual property in terms of appropriate compensation and patent inventorship status; and

(*h*) should any genetically modified organism eventually be licensed to a commercial enterprise for further development or commercialization, the interests of Papua New Guinea and the local communities must be adequately taken into account.

(3) In determining the distribution of benefits, the following criteria shall be used as a guide-

(*a*) fifteen percent of the benefits shall be allocated to the local communities; and

(*b*) five percent of the benefits shall be allocated to the local-level government; and

(*c*) three percent of the benefits shall be allocated to the provincial government; and

(*d*) ten percent of the benefit shall be allocated to the State; and

(e) sixty seven percent of the benefits shall be allocated to the applicant.

(4) To ensure that benefits to local communities are equitable and sustainable, the following method of disbursement shall be used as a guide to manage the benefits provided to local communities under Subsection (3)(a)-

(*a*) thirty percent of the benefits will be set aside for future generations to be held in trust and managed by the State; and

(*b*) thirty percent of the benefits shall be allocated for sustainable development projects for the community; and

(*c*) twenty percent of the benefits shall be used for investments; and

(*d*) twenty percent of the benefits may be distributed in cash equitably amongst the members of the local communities.

(5) The benefit sharing agreement shall be executed by the parties whether or not the biodiscovery and the use of modern biotechnology will result in the development of genetically modified organisms or in the commercialization of genetically modified organisms.

(6) Where there are disputes as to ownership of land or other related disputes, the disputing parties must in principle give their consent for the biodiscovery activity to proceed, and in the event that the dispute is procrastinated, the State shall manage the benefits of the local communities until such time as those disputes have been resolved.

PART 8.- ENFORCEMENT.

Division 1. – Directions and Injunctions.

66. COMPETENT NATIONAL AUTHORITY TO GIVE DIRECTIONS.

(1) The Competent National Authority may-

(*a*) give written directions to the licence holder, or to the person covered by the licence, requiring the licence holder or the person to take such steps in relation to the activity as the Competent National Authority considers necessary for the person to comply with the Act or Regulation; or

(*b*) if the Competent National Authority considers it necessary in order to avoid an imminent risk of death, serious illness, serious injury or to protect the environment from serious damage—take such steps in relation to the activity as the Competent National Authority considers appropriate.

(2) A person commits an offence if he does not take the steps specified in a notice under Subsection (1)(*a*) within the time specified in the notice.

Penalty: Where the person convicted of an offence is-

(*a*) a corporation – a fine not exceeding K125,000.00; and

(*b*) other than a corporation – a fine not exceeding K50,000.00 or imprisonment for a term not exceeding five years, or both.

(3) If the licence holder or the person does not take the steps specified in the notice within the time specified in the notice, the Competent National Authority may arrange for those steps to be taken.

(4) If the Competent National Authority incurs costs because of-

(*a*) steps taken under Subsection (2)(*b*); or

(*b*) arrangements made by the Competent National Authority under Subsection (3),

the licence holder or the person is liable to pay to the Competent National Authority an amount equal to the cost, and the amount may be recovered by the Competent National Authority as a debt due to the Competent National Authority in a court of competent jurisdiction.

67. INJUNCTIONS.

(1) The Competent National Authority or any other person, may apply to the National Court to obtain an injunction restraining a person who has engaged, is engaging, or is about to engage in any conduct that is or would be an offence against this Act or Regulation.

(2) Where-

(*a*) a person has refused or failed, is refusing or failing, or is about to refuse or fail, to do a thing; and

(*b*) the refusal or failure is, or would be, an offence against this Act,

the Court may, on the application of the Competent National Authority or any other person, grant an injunction requiring the person to do the thing.

(3) The Court shall grant an injunction-

(*a*) whether or not it appears to the Court that the person intends to engage, or to continue to engage, in a conduct of that kind; and

(*b*) whether or not the person has previously engaged in a conduct of that kind.

(4) The Court may discharge or vary an injunction granted under this section.

(5) The Court may grant an interim injunction pending a determination of an application under Subsection (1).

(6) The powers granted by this section are in addition to, and not in derogation of, any other powers of the Court.

Division 2. – Inspections and Monitoring.

68. INSPECTORS.

(1) The Competent National Authority may, by instrument in writing, designate a person or persons employed in the government agency responsible for environment and conservation matters as biosafety officers for the purposes of this Act.

(2) The Competent National Authority may, by instrument in writing, designate a person or body or body of persons separate and independent from the Competent National Authority as inspectors for the purposes of this Act.

(3) In exercising powers or performing functions as an inspector, an inspector must comply with any directions of the Competent National Authority.

69. MONITORING.

(1) For the purpose of enforcing this Act or Regulation, an inspector may-

(*a*) enter any premises; and

(*b*) exercise the monitoring powers set out in Section 70.

(2) An inspector is not authorized to enter a premises under Subsection (1) unless-

(*a*) the occupier of the premises has consented to the entry; or

(*b*) the entry is made under a warrant issued by a court of competent jurisdiction; or

(*c*) the occupier of the premises is a licence holder, or a person covered by a licence, and the entry is at a reasonable time; or

(*d*) exigent circumstances warrant the immediate entry.

70. MONITORING POWERS.

(1) The monitoring powers that an inspector may exercise under Section 69(1)(*b*) are as follows-

(*a*) to search the premises and any thing on the premises; and

(*b*) to inspect, examine, take measurements of, conduct tests on, or take samples of, any thing on the premises that relates to a genetically modified organism; and

(*c*) to take photographs, make video or audio recordings or make sketches of the premises or any thing on the premises; and

(*d*) if the inspector was authorized to enter the premises by a warrant - to require any person in or on the premises to:-

(i) answer any questions put by the inspector; and

(ii) produce any book, record or document requested by the inspector; and

(*e*) to inspect any book, record or document on the premises; and

(*f*) to take extracts from or make copies of any such book, record or document; and

(*g*) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises; and

(*h*) to secure a thing:-

(i) that the inspector finds during the exercise of monitoring powers on the premises; and

(ii) that the inspector believes on reasonable grounds is evidential material,

until a warrant is obtained to seize the thing.

(2) For the purposes of this Part, monitoring powers include the power to operate equipment at premises to see whether-

(*a*) the equipment; or

(*b*) a disk, tape or other storage device that:-

(i) is at the premises; and

(ii) can be used with the equipment or is associated with it,

contains information that is relevant to determining whether there has been compliance with the Act.

(3) If the inspector, after operating the equipment at the premises, finds that the equipment, or that a tape, disk or other storage device at the premises, contains information of that kind, the inspector may-

(*a*) operate facilities at the premises to put the information in documentary form and copy the document so produced; or

(*b*) if the information can be transferred to a tape, disk or other storage device that:-

(i) is brought to the premises; or

(ii) is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises,

operate the equipment or other facilities to copy the information to the storage device, and remove the storage device from the premises.

71. SEARCH AND ENTRY.

(1) This section applies if an inspector has reasonable grounds for suspecting that there may be evidential material on any premises.

(2) The inspector may-

(*a*) enter the premises, with the consent of the occupier or under a warrant; and

(*b*) exercise the powers set out in Subsection (3) and Section 72; and

(*c*) if the entry is under a warrant—seize the evidential material, if the inspector finds it on the premises.

(3) Where-

(*a*) in the course of searching, in accordance with a warrant, for a particular thing, an inspector finds another thing that the inspector believes on reasonable grounds to be evidential material; and

(*b*) the inspector believes, on reasonable grounds, that it is necessary to seize that other thing in order to prevent its concealment, loss or destruction, or its use in committing, continuing or repeating an offence against this Act or Regulations,

the warrant is taken to authorize the inspector to seize that other thing.

72. SEARCHING POWERS.

The powers an inspector may exercise under Section 71(2)(*b*) are as follows-

(*a*) to search the premises and any thing on the premises for the evidential material; and

(*b*) to inspect, examine, take measurements of, conduct tests on, or take samples of the evidential material; and

(*c*) to take photographs, make video or audio recordings or make sketches of the premises or the evidential material; and

(*d*) to take onto the premises such equipment and materials as the inspector requires for the purpose of exercising powers in relation to the premises.

73. EMERGENCY POWERS.

(1) Subject to Subsection (3) where-

(*a*) an inspector has reasonable grounds for suspecting that there may be on any premises an activity in respect of which this Act or Regulation have not been complied with; or

(*b*) the inspector considers that it is necessary in the interests of public health to exercise powers under this section in order to avoid an imminent risk of death, serious illness, serious injury, or to protect the environment,

the inspector shall immediately inform the Competent National Authority and may do any of the following-

(*c*) enter the premises; and

(*d*) search the premises for the thing; and

(*e*) secure the thing, if the inspector finds it on the premises, until a warrant is obtained to seize the thing; and

(*f*) if the inspector has reasonable grounds for suspecting that a person has not complied with this Act or Regulation in respect of the thing—require the person to take such steps that the inspector considers necessary for the person to comply with this Act or Regulation.

(2) The inspector may exercise the powers in Subsection (1) only to the extent that it is necessary for the purpose of avoiding an imminent risk of death, serious illness, serious injury or serious damage to the environment.

(3) Where, in the opinion of the Competent National Authority, an emergency has arisen that requires action to be taken not otherwise authorized by this Act, the Competent National Authority shall immediately inform the relevant government agencies and cooperate with the government agencies to prevent, contain or remedy the situation.

74. ASSISTANCE OF EXPERTS.

Where an inspector believes on reasonable grounds that-

(*a*) evidential material may be accessible by operating electronic equipment at the premises; and

(*b*) expert assistance is required to operate the equipment; and

(*c*) if he or she does not take action under this section, the material may be destroyed, altered or otherwise interfered with,

he may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise and seek the assistance of an expert to examine the equipment.

75. OBSTRUCTION.

A person who-

(*a*) hinders or obstructs an inspector in the execution of his duties; or

(*b*) fails to comply with a lawful requirement made by an inspector; or

(*c*) refuses an inspector entry to premises which the inspector may lawfully enter; or

(*d*) impersonates an inspector,

is guilty of an offence.

Penalty: A fine not exceeding K50,000.00 or imprisonment for a term not exceeding two years, or both.

Division 3. – Offences.

76. ENGAGING IN OR DEALING WITH GENETICALLY MODIFIED ORGANISM WITHOUT A LICENCE.

(1) No genetically modified organism shall be imported, developed, field tested or released otherwise than in accordance with an approval under this Act.

(2) A person who engages in an activity involving a genetically modified organism without a licence is guilty of an offence.

Penalty: Where the person convicted of an offence is-

(*a*) a corporation – a fine not exceeding K500,000.00; and

(*b*) other than a corporation – a fine not exceeding K200,000.00 or imprisonment for a term not exceeding five years, or both.

77. LIABILITY OF LICENCE HOLDERS.

A licence holder or a person covered by the licence who takes an action or omits to take an action and the action or omission contravenes the licence is guilty of an offence.

Penalty: Where the person convicted of an offence is-

(*a*) corporation – a fine not exceeding K125,000.00; and

(*b*) other than a corporation – a fine not exceeding K50,000.00 or imprisonment for a term not exceeding five years, or both.

78. CIVIL LIABILITY.

(1) A person who carries out any activity in relation to genetically modified organisms shall be strictly liable for any harm, injury or loss caused directly or indirectly by such genetically modified organism or any activity in relation to them.

(2) The harm, injury or loss referred to in Subsection (1) includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity.

(3) Civil liability shall attach to the licence holder, the person responsible for the activity which results in the damage, injury or loss, as well as to the provider, supplier or developer of the genetically modified organism.

(4) Where liability under this section is incurred by a body corporate, any director, manager, secretary or similar officer of the body corporate shall be similarly liable unless he can show that he did everything in his power to prevent the import, deliberate release, commercialization or contained use which caused the damage in question.

(5) If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.

(6) Where proceedings are brought against more than one person it shall not be a requirement for the person bringing the proceedings to identify the person who caused the damage in question, provided that he can prove that one or more of the persons so proceeded against could have caused the damage.

(7) In the case of harm to the environment or to biological diversity, redress shall include the costs of reinstatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable, the costs of preventive measures and any loss or damage caused by the taking of the preventive measures, provided that the person responsible may be required to carry out the reinstatement or rehabilitation at its own cost and to the satisfaction of the Competent National Authority.

(8) Liability shall also extend to harm or damage caused directly or indirectly by the genetically modified organism to the economy, social or cultural practices, livelihoods, traditional knowledge systems, or traditional technologies and such harm includes the following-

(*a*) disruption or damage to production systems; and
(*b*) damage to agricultural systems; and
(*c*) reduction in yields; and
(*d*) damage to the economy of an area or local community.

(9) A licence holder shall indemnify-

(*a*) any other person who deliberately releases or commercializes genetically modified organism; and
(*b*) any person who manufactures or processes genetically modified organisms,

against any civil liability where the genetically modified organism in question was first imported, deliberately released, used in contained conditions, or commercialized by the applicant.

(10) A licence holder shall indemnify against any civil liability any person who fails to label genetically modified organisms, but where the licence holder can show that he took all reasonable steps under the Act to prevent such failure the indemnity shall not apply.

(11) The right to bring any action to redress the harm caused by the genetically modified organism shall lapse only after a reasonable period from the date on which the affected person or local community could reasonably be expected to have learnt of the harm, taking due account of-

(*a*) the time the harm may take to manifest itself; and
(*b*) the time that it may reasonably take to co-relate the harm with the genetically modified organism, having regard to the situation or circumstance of the person or local community affected.

(12) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the Council or the Competent National Authority.

79. CONDUCT OF DIRECTORS, EMPLOYEES AND AGENTS IN THE COMMISSION OF AN OFFENCE.

(1) If, in proceedings for an offence against this Act or Regulation, or an ancillary offence in relation to this Act or Regulation, it is necessary to establish the state of mind of a body corporate in relation to a particular conduct, it is sufficient to show-

(*a*) that the conduct was engaged in by a director, employee or agent of the body corporate within the scope of his actual or apparent authority; and
(*b*) that the director, employee or agent had the state of mind.

(2) Any conduct engaged in on behalf of a body corporate by a director, employee or agent of the body corporate within the scope of his actual or apparent authority is taken, for the purposes of a prosecution for-

(*a*) an offence against this Act or Regulation; or

(*b*) an ancillary offence relating to this Act or Regulation,

to have been engaged in also by the body corporate, unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) If, in proceedings for an ancillary offence relating to this Act or Regulation, it is necessary to establish the state of mind of a person other than a body corporate in relation to a particular conduct, it is sufficient to show-

(*a*) that the conduct was engaged in by an employee or agent of the person within the scope of his actual or apparent authority; and

(*b*) that the employee or agent had the state of mind.

80. GENERAL PENALTY.

A person who fails to comply with a requirement under this Act applicable to him in respect of which a specific penalty is not provided, is guilty of an offence.

Penalty: A fine not exceeding K50,000.00.

Division 4. – Proceedings.

81. MEDIATION.

Before hearing an action under this Act, a court shall endeavor to have the matter settled by mediation.

82. INSTITUTION OF PROCEEDINGS.

(1) Subject to Section 81, an offence against this Act shall be prosecuted-

(*a*) before a District Court where the offence provides for a maximum monetary penalty of K50,000.00 or less in the case of a person other than a corporation; or

(*b*) in the National Court in any other case.

(2) The Competent National Authority may, after consultation with the Public Prosecutor, lay information and institute prosecution for offences under the Act.

(3) Subject to Subsection (4), a person may, on his own behalf or on behalf of a group or class of persons representing that group or class or the public as a whole, take proceedings—

(*a*) where an alleged offence against this Act or Regulation has occurred or is likely to occur; or

(*b*) where there is an alleged failure to perform an act or duty under this Act or Regulation that is not discretionary,

in a court against—

(*c*) the State; or

(*d*) a government body; or

(*e*) a holder of a licence issued under the Act; or

(*f*) another person,

or all or any of them jointly.

(4) Proceedings under Subsection (3) shall not be commenced—

(*a*) where the State or a government body is proceeding in an action in a court for the same offence or failure to perform an act or duty; or

(*b*) in any other case, before the expiry of 60 days, from the service of written notice of the alleged offence or failure to perform an act or duty to—

(i) the Council; and

(ii) the Competent National Authority; and

(iii) the party responsible for the alleged offence or failure to perform an act or duty.

(5) Where an action is commenced under Subsection (4)(*a*), any person may intervene as a matter of right.

(6) In an action under this section, the court may, in making any order—

(*a)* award such costs; and

(*b*) make an order as to the lodging of a bond or equivalent security,

as it thinks fit.

(7) This section does not restrict any right that a person or class of persons may have under any other law.

(8) No costs shall be awarded against a person under Subsection (3) who fails in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

83. FORFEITURE.

(1) Where a court convicts a person of an offence against this Act or a Regulation, the court may order forfeiture to the State of any substance or thing used or otherwise involved in the commission of the offence.

(2) A substance or thing ordered by a court to be forfeited under this section becomes the property of the State and may be sold or otherwise dealt with in accordance with the directions of the Council.

PART 9. – GENETICALLY MODIFIED ORGANISMS REGULATIONS.

84. PREPARATION OF REGULATIONS.

(1) The Minister, acting on the recommendation of the Council, may recommend regulations relating to an activity involving genetically modified organisms to the National Executive Council, in accordance with the procedures set out in this Part.

(2) The National Executive Council, after considering the recommendation of the Minister, may approve regulations relating to an activity involving genetically modified organisms in accordance with the procedures set out in this Part.

85. NATURE OF REGULATIONS.

(1) A regulation may be made in relation to an activity relating to genetically modified organisms or an aspect of genetically modified organism, in accordance with this Part.

(2) Without limiting the generality of Subsection (1), a regulation may apply to all activities with genetically modified organisms or an aspect or element of a genetically modified organism and may be made in respect of the following matters-

(*a*) research and development of genetically modified organisms; or
(*b*) containment of genetically modified organisms; or
(*c*) importation of genetically modified organisms; or
(*d*) exportation of genetically modified organisms; or
(*e*) handling of genetically modified organisms; or
(*f*) field testing of genetically modified organisms; or
(*g*) risk assessment of genetically modified organisms; or
(*h*) labelling of genetically modified organisms; or
(*i*) criteria for determining what is or is not a genetically modified organism; or
(*j*) charges for recovery of costs relating to research and development, importation, exportation, handling and use of genetically modified organisms; or
(*k*) participation of local communities in the research and development, handling and use of genetically modified organisms and related activities; or
(*l*) equitable distribution of benefits arising from the development and use of genetically modified organisms derived from the country's biological resources; or
(*m*) establishment of Institutional Biological Safety Committees, membership, powers and functions and criteria for appointment.

86. CONTENTS OF REGULATION.

(1) A regulation shall-

(*a*) state whether the regulation applies generally to genetically modified organisms, or to a matter referred to in Section 85; and

(*b*) specify the persons to whom the Regulation applies.

(2) A regulation may-

(*a*) state the objectives to be achieved and maintained under the regulation; and

(*b*) provide the criteria to be applied to achieve the stated objectives including:-

(i) the measures to be adopted to minimize or eliminate risks associated with the release of genetically modified organism to human health and the ecosystems; and

(ii) the measures designed to remedy any harm caused to a person or the ecosystem as a result of the release of a genetically modified organism; and

(*c*) state the indicators for monitoring the use of genetically modified organisms; and

(*d*) specify the extent to which the regulation will or may affect existing licence holders; and

(*e*) fixing the means for enforcement of the regulation including declaration of all or some of the provisions of the regulation as mandatory provisions.

87. PROCEDURE FOR MAKING A REGULATION.

(1) The Council may cause a draft of regulation to be prepared.

(2) The Council shall give-

(*a*) public notice of the draft regulation:-

(i) in the National Gazette; and

(ii) in a national or local newspaper that is distributed regularly throughout the country; or

(iii) through the radio networks; and

(iv) in such other manner as the Council deems appropriate.

(*b*) written notice to existing licence holders who would be affected by the approval of the draft Regulation and whether they are required to submit a revised risk assessment and risk management plan or otherwise; and

(*c*) in any such manner as the Council determines, and

stating where copies may be obtained or inspected.

(3) The Council shall invite written and oral submissions from governmental authorities, provincial and local-level governments, holders of traditional knowledge, industry, interest groups and members of the public and stating a period of time (which shall not be less than 60 days and not more than eight months) within which submissions may be made to the Council.

(4) Before making a recommendation to the Minister, the Council shall refer the draft regulation to a technical expert panel for its comments.

(5) Without limiting the rights of persons to make submissions under Subsection (3), an existing licence holder may within the period provided for submissions under Subsection (3), notify the Council that in the licence holder's opinion, the new requirements or standards are likely to affect the viability of the activities of the licence holder.

(6) Where the regulation relating to a genetically modified organism or an aspect of a genetically modified organism will have a direct effect on local communities and their cultural values and their environment, the Council shall make every effort to enable the full and active participation of the local communities to enable them to make submissions on the draft regulation.

(7) The Council shall maintain a register containing names and addresses of agencies and persons who made submissions to the Council on a draft regulation.

(8) The Council shall consider any comments received and all submissions made to it under Subsections (3) to (6) inclusive.

(9) The Council shall, prior to making a recommendation to the Minister, provide a further draft of the regulation, as revised by the Council, to each person who made a submission to the Council under Subsection (3) to (6) inclusive.

(10) The Council shall allow a period of 60 days, after providing a further draft of the regulation under Subsection (9) for the making of submissions by any of those persons who received such draft.

(11) The Council shall consider any comments received and all submissions made to it under Subsection (10) in preparing a recommendation to the Minister for a final regulation.

(12) The Minister, acting on the recommendation of the Council, may recommend the final regulation to the National Executive Council.

(13) The National Executive Council, after considering the recommendation of the Minister, may approve the final regulation.

(14) The Minister shall, within 30 days after the National Executive Council has approved the regulation-

(*a*) cause a copy of the regulation to be published in the National Gazette declaring that the regulation to be an authorized regulation; and

(*b*) give public notice of the approved regulation in the national or local newspapers that are distributed regularly throughout the country; and

(*c*) table the regulation in Parliament as a subordinate legislative enactment; and

(*d*) give written notice to existing licence holders who would or may be affected by the approval of the regulation and whether or not they are required to submit a revised risk assessment and risk management plan.

88. SIMPLIFIED PROCEDURE FOR MAKING CERTAIN REGULATIONS.

(1) Subject to Subsection (3), where the Minister, acting on the advice of the Council, and after consultation with persons and bodies likely to be affected, is satisfied that a draft regulation refers to or incorporates, without substantial modification of the whole or part of a standard of other documents prepared by a government authority or a body recognized by the Council for the purposes of this section and the draft regulation will not require existing licence holders to submit a revised risk assessment and risk management plan–

(*a*) the procedure set out in Section 87 will not apply in relation to the draft regulation; and

(*b*) the National Executive Council may approve the regulation on the recommendation of the Minister.

(2) The Minister shall, within 30 days after the National Executive Council has approved the regulation-

(*a*) cause a copy of the regulation to be published in the National Gazette declaring that the regulation to be an authorized regulation; and

(*b*) give public notice of the approved regulation in the national or local newspapers that are distributed regularly throughout the country; and

(*c*) table the regulation in Parliament as a subordinate legislative enactment.

(3) Where the draft regulation will directly affect local communities and their cultural values and their environment, they shall be consulted and their views taken into account before a recommendation under Subsection (1) is made to the National Executive Council.

89. EFFECT OF REGULATIONS.

On approval of a regulation, all governmental authorities which may be required to issue approvals relating to the importation, exportation, research and development, use and handling of genetically modified organisms must give effect to the regulation.

PART 10. - MISCELLANEOUS.

90. CONFIDENTIALITY.

(1) Information disclosed under this Act to the Minister, to a member of the Council or Institutional Biological Safety Committee or a technical expert panel or a contractor or an inspector or to any employee of the Competent National Authority shall not be disclosed to any person who is not a member of the Council or Institutional Biological Safety Committee or a technical expert panel or a contractor or an inspector or an employee of the Competent National Authority without the prior written approval of the person who provided that information, except—

(*a*) to the extent that disclosure is authorized or required under this Act or any other law; and

(*b*) to the extent that the person providing the information authorized its disclosure at the time of providing the information; or

(*c*) to the extent necessary to enable the Competent National Authority to publish statistical information concerning the subject matter of the functions of the Council; or

(*d*) to the extent necessary to enable the Council or the Minister to give advice to the National Executive Council, Departments, or the Central Bank.

(2) A member of the Council or Institutional Biological Safety Committee or a technical expert panel or a contractor or an inspector or an employee of the Competent National Authority who uses, for the purpose of his personal gain, any information disclosed under this Act that comes to his knowledge in the course of, or by reason of, his membership of the Council or an Institutional Biological Safety Committee, or technical expert panel or a contractor or an inspector or his employment an employee of the National Competent Authority, is guilty of an offence.

Penalty: A fine not exceeding K20,000.00 or imprisonment for a term not exceeding two years, or both.

91. PROTECTION OF WHISTLEBLOWER.

(1) An employee or an agent of a licence holder who discloses information or material leading to the prosecution of the licence holder under this Act shall not be liable for any act or default of himself done or omitted to be done in good faith.

(2) An employee or an agent of a licence holder who discloses information or material leading to the prosecution of the licence holder under this Act shall not be terminated, suspended or discriminated in any manner by the licence holder or his agent for the reason that he provided information or material leading to the prosecution of the licence holder.

92. TRANSITIONAL PROVISION.

(1) Where, on the commencement date, a person has obtained approval for an activity relating to genetically modified organisms, including importation, development, field test, fermentation as noted before, contained use, deliberate release, commercialization, import or export of genetically modified organisms, that licence shall continue in force and shall be deemed for all purposes under this Act to be a licence approved under this Act, as applicable, commencing on the date on which such licence was issued under another Act.

(2) The Competent National Authority shall, within twelve months after the commencement of this Act, give written direction to a licence holder referred to in Subsection (1) to take measures to comply with the requirements of the Act.

(3) The licence holder referred to Subsection (1) shall comply with the requirements of the Act within 12 months from the date of receipt of the requisition from the Competent National Authority.

8.4 Draft Biosafety and Biotechnology Regulation

INDEPENDENT STATE OF PAPUA NEW GUINEA.

STATUTORY INSTRUMENT.

No. of 200…

Biosafety and Biotechnology (Information Required for a Genetically Modified Organism Licence, Risk Assessment Plan and Field Testing) Regulation 200…

Being a Regulation,

MADE by the Head of State, acting with, and in accordance with, the advice of the National Executive Council under the Biosafety and Biotechnology Act 200….

1. INTERPRETATION.

In these Regulations, unless the contrary intention appears—

"Act" means the *Biosafety and Biotechnology Act* 200…;

"Competent National Authority" means the Competent National Authority established under the Biosafety and Biotechnology Act;

"Council" means the National Biosafety and Biotechnology Council;

"genetically modified organism licence" is a licence issued under the Biosafety and Biotechnology Act 200…;

"organism" in relation to this Regulation means any biological entity that is viable, or capable of reproduction, or capable of transferring genetic material, but does not include a human being or a genetic structure derived from a human being; and

"Regulations" means these Regulations.

2. APPLICATION.

This Regulation applies to and in relation to information required for a genetically modified organism licence, risk assessement plan and field testing of genetically modified organisms.

3. GENERAL INFORMATION.

An applicant for a genetically modified organism licence shall include in his application-

(*a*) his name and address; and

(*a*) name of person(s) responsible for planning and carrying out the containment or release, including those responsible for supervision, monitoring and safety, in particular the name and qualification(s) of the responsible scientist(s); and

(*b*) information on training and qualification(s) of personnel involved in carrying out the release; and

(d) any other information required by the Council or Competent National Authority under this Regulation.

4. INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISMS AND CONDITIONS OF RELEASE.

The Competent National Authority, may, from time to time, by notice in the National Gazette-

(*a*) determine the information required of a genetically modified organism; and

(*b*) the conditions of release of the genetically modified organism and the receiving environment.

5. IMPACTS OF GENETICALLY MODIFIED ORGANISM ON THE ENVIRONMENT.

The Competent National Authority, may, from time to time, by notice in the National Gazette determine the information relating to-

(*a*) the characteristics and factors affecting survival, multiplication, gene expression and dissemination of a genetically modified organism; and

(*b*) the interactions of the genetically modified organism with the environment; and

(*c*) the potential environmental impacts of the genetically modified organism; and

(*d*) any other information that is necessary to make a proper assessment of the impact of the genetically modified organism on the environment.

6. INFORMATION RELATING TO MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS.

The Competent National Authority, may, from time to time, by notice in the National Gazette determine the information relating to-

(*a*) the monitoring techniques relating to a genetically modified organism; and

(*b*) the control of release of a genetically modified organism; and

(*c*) the waste treatment plan of a genetically modified organism; and

(*d*) the emergency response plan relating to a genetically modified organism; and

(*e*) measures put in place to compensate aggrieved and injured persons; and

(*f*) any other information relating to the monitoring, control, waste and management and emergency response plan relating to a genetically modified organism.

7. INFORMATION RELATING TO A RISK ASSESSMENT PLAN.

(1) Subject to Subsection (2) the Competent National Authority, may, from time to time, by notice in the National Gazette determine the information relating to a risk assessment plan and the matters that must be considered in the assessment of a risk assessment plan.

(2) The information required for risk assessment shall include the following-

(*a*) the characteristics of donor and recipient organisms or parental organisms; and

(*b*) the characteristics of the vector; and

(*c*) the characteristics of the genetically modified organism; and

(*d*) the characteristics of resuscitated organisms and gene(s) and fossil DNA sequences; and

(*e*) all material information on the genetically modified organism and information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled; and

(*f*) the socio-economic considerations; and

(*g*) the effects of the genetically modified organism on the cultural, ethical and ecosystem of the local communities.

(3) When reviewing a risk assessment plan the following general principles shall be taken into account-

(*a*) the precautionary approach; and

(*b*) all relevant scientific theory, evidence and experience relating to the genetically modified organism; and

(*c*) ecological integrity; and

(*d*) that every transgenic line is different because of random insertion.

8. CONTAINMENT AND FIELD TESTING OF GENETICALLY MODIFIED ORGANISM .

(1) Subject to Subsection (2) the Competent National Authority may, from time to time, by notice in the National Gazette-

(*a*) determine the conditions under which facilities are to be used for the contained use of genetically modified organisms; and

(*b*) determine the conditions under which facilities are to be used for the release of genetically modified organisms; and

(*c*) determine the procedures and mechanisms for the prevention, control and monitoring of genetically modified organism; and

(*d*) the interests of local communities which will be affected either directly or indirectly by the release of genetically modified organism; and

(*e*) where appropriate the prior informed consent of local communities.

(2) Where the site of a field test-

(*a*) is within close proximity to a local community-

(*i*) a risk assessment and risk management plan shall be completed by the licence holder before field tests are conducted; and

(*ii*) the residents of the local community and the local-level government shall be informed of the purpose and likely effects of the genetically modified organism prior to field testing; and

(*iii*) the licence holder shall inform the local community and the local-level government on the progress of the field test; and

(*iv*) the licence holder shall monitor the field test site two years after the experiment to ensure that the impacts of the field test does not adversely affect the social, cultural and ethical values of the community and their ecosystems and

(*v*) in the event that an accidental release of the genetically modified organism adversely affects the social, cultural and ethical values and the ecosystems of the local community, the licence holder shall compensate the local community and the local-level government for the contamination.

(*b*) is located on customary land-

(*i*) a risk assessment and risk management plan must be completed before field tests are conducted; and

(*ii*) the licence holder shall negotiate with the landowners to lease the land for the purpose of field testing of a genetically modified organism under agreed terms and conditions;

(*ii*) the residents of the local community and the local-level government must be informed of the purpose and likely effects of the genetically modified organism prior to field testing; and

(*iii*) the licence holder shall inform the local community and the local-level government on the progress of the field test; and

(*iv*) the licence holder shall take all necessary steps to ensure that the field test is conducted in a safe and reasonable manner; and

(*v*) the licence holder shall monitor the field test site two years after the experiment to ensure that the impacts of the field test does not adversely affect the social, cultural and ethical values of the community and their ecosystems and

(*vi*) in the event that an accidental release of the genetically modified organism adversely affects the social, cultural and ethical values and the ecosystems of the local community, the licence holder shall compensate the customary landowners, local community and local-level government for the contamination.

MADE this day of , 200…

GOVERNOR-GENERAL.