Papua New Guinea Biosafety Framework

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Foreword

Modern biotechnology is a recent phenomenon in Papua New Guinea. This science has been in existence in the developing countries for 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, processes 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 that a small developing country such as Papua New Guinea faces in dealing with the issues of Living 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 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 Policy. The implementation of the policy will consequently require the combined effort of all the stakeholders to make it work.

By the Minister for DEC

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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 Inspections 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

Chapter 1 Introduction

1.1 The Biosafety Protocol

In 1992, Papua New Guinea sent a very strong delegation headed by the Governor-General to the United Nations Conference on Environment and Development (UNCED) in Rio De Janeiro in Brazil. This was the first time in the history of global politics that a large number of leaders from more than 170 countries gathered in a global meeting to discuss the issue of environment and development. The central agenda of the conference was to identify ways in which environmental protection and conservation would co-exist with development.

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 **Convention on Biological Diversity**. The CBD provides the international legal

framework for the conservation and sustainable use of biological resources. There are several commitments embodied in the treaty. These include:

To achieve the aims of the treaty, the CBD sets out a number of strategies in the form of obligations which member States are required to adopt. Some of the specific obligations mandated by the CBD are:

- **Creating a system of protected areas to conserve biological diversity (Article 8);**
- **Developing mechanisms to prevent the introduction of, control or eradicate alien species which threaten ecosystems (Article 8);**
- **Preserving and maintaining knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promoting their wider application through appropriate legal, policy and administrative arrangements (Article 8(j));**
- **Establishing and maintaining facilities for ex-situ conservation of components of biological diversity (Article 9);**
- **Protecting and encouraging customary use of biological resources in accordance with traditional and cultural practices (Article 10);**
- **Adopting economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity (Article 11);**
- **Establishing and maintaining programs for scientific and technical education and training measures for the conservation and sustainable use of biological diversity (Article 12);**

- **Promoting and encouraging public awareness on biological diversity protection and sustainable use through the media and educational institutions (Article 13);**
- **Introducing appropriate mechanisms for environmental impact assessment (EIA) of proposed projects which will have a significant impact on the biological diversity (Article 14);**
- **Developing rules and guidelines on access to biological diversity (Article 15);**
- **Introducing rules relating to the transfer of technology that promote biodiversity protection and sustainable use (Article 16);**
- **Facilitating the exchange of information between contracting parties (Article 17);**
- **Promoting scientific and technical cooperation between contracting parties (Article 18); and**
- **Developing legislative, administrative or policy measures to regulate and manage biotechnology research and benefit sharing (Article 19).**

The key areas of concern under the CBD are: (1) biodiversity policy and law reformation; (2) creation or strengthening of administrative or institutional capacity and (3) institutional facilities. Biodiversity protection and sustainable use requires a strong commitment by member States to implement these strategies. This will involve either, the transformation of the legal, policy and institutional structures or the introduction of new legal, policy and administrative regimes.

A specific biodiversity issue which was very contentious and thus was not resolved at the UNCED was living modified organisms (LMOs). 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 after ratification by the fiftieth country.

The **Biosafety Protocol on Biosafety** 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 LMOs 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 (GM) corn or tomato sauce from GM 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 LMOs. 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 principle espoused by Principle 15 of the *Rio Declaration*. The AIA procedure applies only to LMOs which will be introduced into the environment. Examples of such LMOs 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" LMOs 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 LMOs 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 that have been identified by the Bureau of Oceans and International Environmental and Scientific Affairs and on which there is a general consensus are:

1. 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.
2. The Protocol does not require segregation of commodities that may contain living modified organisms.
3. 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.
4. The Protocol does not require consumer product labeling. 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 will become legally binding in the international legal system and in the legal systems of States that have given consent to be bound by it. States must comply with and implement all the provisions of the Protocol. The Protocol is the only international instrument that deals exclusively with LMOs. 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 the domestic use and marketing of LMOs 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 Policy

The development of the draft biosafety policy emanated from a series of activities undertaken by the Department of Environment and Conservation (DEC) in close collaboration with the United Nations Global Environment Facility. The first step in the policy evolution process was the completion of several surveys conducted under the auspices of the DEC in late 2003. The findings of the surveys were presented and deliberated at the National Biosafety Consultative Workshop held in Port Moresby in March 2004.

There were several conclusions reached at the Biosafety Consultative Workshop, the most important being the formulation of a biosafety policy. The stakeholders at the Workshop agreed that there was a need to develop a policy framework on biosafety. A legal consultant was then engaged to develop a draft biosafety policy which would then be circulated amongst stakeholders for consideration and deliberation at the second Biosafety Consultative Workshop to be held in September 2004.

It is envisaged that at the second Biosafety Consultative Workshop, the draft policy will be debated and a final draft will be presented to DEC for endorsement. It is also envisioned that, after the adoption of the policy, a legal framework will be developed to implement the **Biosafety Protocol** in the country once Papua New Guinea ratifies the Protocol.

Chapter 2 Key Policy Issues

The formulation of the Biosafety Policy revolved around several key issues which are pertinent to Papua New Guinea. These policy issues are considered in the light of the overarching goal of the Biosafety Protocol – safety to human health, the environment and biodiversity. The key policy issues for Papua New Guinea are: (1) environment (biodiversity); (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 Policy** must promote and give effect to these five goals and directive principles. The five goals and directive principles are:

1. Integral human development.

We declare our first goal to be for every person to be dynamically involved in the process of freeing himself or herself from every form of domination or oppression so that each man or woman will have the opportunity to develop as a whole person in relationship with others.

WE ACCORDINGLY CALL FOR—

(1) everyone to be involved in our endeavors to achieve integral human development of the whole person for every person and to seek fulfillment through his or her contribution to the common good; and

(2) education to be based on mutual respect and dialogue, and to promote awareness of our human potential and motivation to achieve our National Goals through self-reliant effort; and

(3) all forms of beneficial creativity, including sciences and cultures, to be actively encouraged; and

(4) improvement in the level of nutrition and the standard of public health to enable our people to attain self fulfillment; and

(5) the family unit to be recognized as the fundamental basis of our society, and for every step to be taken to promote the moral, cultural, economic and social standing of the Melanesian family; and

(6) development to take place primarily through the use of Papua New Guinean forms of social and political organization.

2. Equality and participation.

We declare our second goal to be for all citizens to have an equal opportunity to participate in, and benefit from, the development of our country.

WE ACCORDINGLY CALL FOR—

(1) an equal opportunity for every citizen to take part in the political, economic, social, religious and cultural life of the country; and

(2) the creation of political structures that will enable effective, meaningful participation by our people in that life, and in view of the rich cultural and ethnic diversity of our people for those structures to provide for substantial decentralization of all forms of government activity; and

(3) every effort to be made to achieve an equitable distribution of incomes and other benefits of development among individuals and throughout the various parts of the country; and

(4) equalization of services in all parts of the country, and for every citizen to have equal access to legal processes and all services, governmental and otherwise, that are required for the fulfillment of his or her real needs and aspirations; and

(5) equal participation by women citizens in all political, economic, social and religious activities; and

(6) the maximization of the number of citizens participating in every aspect of development; and

(7) active steps to be taken to facilitate the organization and legal recognition of all groups engaging in development activities; and

(8) means to be provided to ensure that any citizen can exercise his personal creativity and enterprise in pursuit of fulfillment that is consistent with the common good, and for no citizen to be

deprived of this opportunity because of the predominant position of another; and

(9) every citizen to be able to participate, either directly or through a representative, in the consideration of any matter affecting his interests or the interests of his community; and

(10) all persons and governmental bodies of Papua New Guinea to ensure that, as far as possible, political and official bodies are so composed as to be broadly representative of citizens from the various areas of the country; and

(11) all persons and governmental bodies to endeavor to achieve universal literacy in Pisin, Hiri Motu or English, and in "tok ples" or "ita eda tano gado"; and

(12) recognition of the principles that a complete relationship in marriage rests on equality of rights and duties of the partners, and that responsible parenthood is based on that equality.

3. National sovereignty and self-reliance.

We declare our third goal to be for Papua New Guinea to be politically and economically independent and our economy basically self-reliant.

WE ACCORDINGLY CALL FOR—

(1) our leaders to be committed to these National Goals and Directive Principles, to ensure that their freedom to make decisions is not restricted by obligations to or relationship with others, and to make all of their decisions in the national interest; and

(2) all governmental bodies to base their planning for political, economic and social development on these Goals and Principles; and

(3) internal interdependence and solidarity among citizens, and between provinces, to be actively promoted; and

(4) citizens and governmental bodies to have control of the bulk of economic enterprise and production; and

(5) strict control of foreign investment capital and wise assessment of foreign ideas and values so that these will be subordinate to the goal of national sovereignty and self-reliance, and in particular for the entry of foreign capital to be geared to internal social and economic policies and to the integrity of the Nation and the People; and

(6) the State to take effective measures to control and actively participate in the national economy, and in particular to control major enterprises engaged in the exploitation of natural resources; and

(7) economic development to take place primarily by the use of skills and resources available in the country either from citizens or the State and not in dependence on imported skills and resources; and

(8) the constant recognition of our sovereignty, which must not be undermined by dependence on foreign assistance of any sort, and in particular for no investment, military or foreign-aid agreement or understanding to be entered into that imperils our self-reliance and self-respect, or our commitment to these National Goals and Directive Principles, or that may lead to substantial dependence upon or influence by any country, investor, lender or donor.

4. Natural resources and environment.

We declare our fourth goal to be for Papua New Guinea's natural resources and environment to be conserved and used for the collective benefit of us all, and be replenished for the benefit of future generations.

WE ACCORDINGLY CALL FOR—

(1) wise use to be made of our natural resources and the environment in and on the land or seabed, in the sea, under the land, and in the air, in the interests of our development and in trust for future generations; and

(2) the conservation and replenishment, for the benefit of ourselves and posterity, of the environment and its sacred, scenic, and historical qualities; and

(3) all necessary steps to be taken to give adequate protection to our valued birds, animals, fish, insects, plants and trees.

5. Papua New Guinean ways.

We declare our fifth goal to be to achieve development primarily through the use of Papua New Guinean forms of social, political and economic organization.

WE ACCORDINGLY CALL FOR—

(1) a fundamental re-orientation of our attitudes and the institutions of government, commerce, education and religion towards Papua New Guinean forms of participation, consultation, and

consensus, and a continuous renewal of the responsiveness of these institutions to the needs and attitudes of the people; and

(2) particular emphasis in our economic development to be placed on small-scale artisan, service and business activity; and

(3) recognition that the cultural, commercial and ethnic diversity of our people is a positive strength, and for the fostering of a respect for, and appreciation of, traditional ways of life and culture, including language, in all their richness and variety, as well as for a willingness to apply these ways dynamically and creatively for the tasks of development; and

(4) traditional villages and communities to remain as viable units of Papua New Guinean society, and for active steps to be taken to improve their cultural, social, economic and ethical quality.

How can the **Biosafety 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 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 Policy will also promote and strengthen customary values and traditional knowledge systems which have sustained local communities for centuries.

The **Biosafety Policy** takes a holistic approach to the handling and management of LMOs. 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 LMOs

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. It has been estimated that 2 million tonnes of genetically modified organisms in food are sent directly to developing countries as food aid by the United States annually. The World Food Program also distributes another 1.5 million tonnes of transgenic crops donated incidentally by the United States to developing countries annually. Genetic engineering promises remarkable advances in medicine, agriculture, and other fields. These may include new medical treatments and vaccines, new industrial products, and improved fibres and fuels. Proponents of the technology argue that 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.

Although final figures are not available, Professor Wagih estimated that there would be approximately 3.5 million acres of transgenic crop varieties grown in the United States in 2004. These crops include maize, cotton and potatoes with insect resistance, soybeans with herbicide resistance, and tomatoes with extended shelf-life. Other novel products which are close to market are: canola able to produce lauric oils, which would make it a direct competitor with coconut and palm kernel oils; and several biopesticides able to attack fungal diseases and insect pests. Most of these novel products in agriculture are coming from new biotechnology firms in the USA, or multinational seed and chemical companies which have either been merged, acquired, or entered into strategic alliances with major firms to enable the development and distribution of the new technologies. The products of the new technologies in agriculture will be distributed mainly through the seed of new crop varieties. Hence, the alliances established between new biotechnology firms and seed companies, often with their own plant breeding programs, are starting to have commercial returns.

While proponents of genetically engineered foods argue strongly that LMOs contribute to the alleviation of world hunger, their opponents contest that LMOs will reduce genetic diversity; that 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 LMOs 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 LMOs also argue that the biotechnology industry is a niche industry and is controlled by a few rich industrialists who have a monopoly over LMOs.

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. The **Biosafety Policy** provides an opportunity for Papua New Guinea to fashion the manner in which these emerging technologies will be harnessed for the development of the country.

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 areas 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 LMOs 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 LMOs 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 LMO into this environment will forever destroy the native gene pool including wild relatives of the crop.

It is therefore, imperative for developing countries intent on importing LMOs from developed countries to provide strong safeguards through policy and regulatory frameworks to protect their people and the environment. Given that Papua New Guinea has about 700,000 biological species, it is incumbent on the government to design innovative strategies to protect this huge and diverse biodiversity. The **Biosafety Policy** enhances the protection and sustainable use of this unique and diverse biodiversity of Papua New Guinea. It 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 LMOs

The research and development of LMOs involves a number of stakeholders, facilities and funds. Investments in 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 in 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 GMOs, GMF 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 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 biotechnology. There is very little private sector engagement in 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 biotechnology. A strong and workable national policy and regulatory regime must protect the interests of the country, its people and its environment and biodiversity.

2.5 Trade in LMOs

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

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

Papua New Guinea needs to introduce and strengthen capacity building programs to improve the skills and knowledge of Papua New Guineans involved in the assessment of LMOs and, research and development of LMOs. Institutional facilities used for assessment, research and use of LMOs must also be upgraded and where appropriate established to enable proper scrutiny of LMOs before they are either released into the environment or used for beneficial purposes such as food and food processes.

2.6 Stakeholders and LMOs

The handling, transfer, use and management of LMOs in Papua New Guinea 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 Policy**. The role that these stakeholders assume in the assessment, research and development, transfer, use and management of LMOs must be commensurate with the degree of impact a LMO 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** 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.

When Papua New Guinea ratifies the Protocol, it 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 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 LMOs. 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. To avoid confusion, the definitions of the terms have been adopted from the biodiversity website which can be accessed at: www.biodiv.org/biosafety. Some of the writings by Professor Wagih are also adopted in this part of the Policy.

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 LMOs are usually considered to be the same as GMOs, but definitions and interpretations of the term GMO vary widely. Common LMOs 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: LMOs 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 LMOs 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 LMOs. These are:

(1) LMOs in transit;
(2) LMOs destined for contained use; and
(3) LMOs 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 LMOs, 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 LMOs from the AIA procedure. Also, the COP serving as the meeting of the Parties to the Protocol may in future decide to exempt additional LMOs from application of the AIA procedure.

LMOs intended for direct use as food or feed, or for processing: LMOs intended for direct use as food or feed, or processing (LMOs-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 LMOs-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 LMOs that may be subject to transboundary movement.

Decisions by the Party of import on whether or not to accept the import of LMOs-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 LMOs-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 LMOs-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 LMOs. Parties are required to take measures for the safe handling, packaging and transportation of LMOs 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 LMOs. It also leaves room for possible future development of standards for handling, packaging, transport and identification of LMOs by the meeting of the Parties to the Protocol. The first meeting of COP-MOP adopted decisions outlining identification requirements for different categories of LMOs.

Each Party is required to take measures ensuring that LMOs subject to intentional transboundary movement are accompanied by documentation identifying the LMOs and providing contact details of persons responsible for such movement. The details of these requirements vary according to the intended use of the LMOs, and, in the case of LMOs

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 microorganisms, 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 LMO must comply with standard safety measures. Following the framework put forward by the National Research Council of the US National Academy of Sciences, the following factors are recognized to be important in assessing risks of organisms with novel characteristics:

For the environment:

- Properties of the organism and of the environment into which it may be introduced
- Possibility of containing and controlling the organism
- Probable effect on the environment should the organism or genetic trait persists longer than intended or spread to non-target environments
- Risks to human health and the environment which are associated with introduction of organisms with novel traits.

For the organism with the novel trait, taking into account:

- The recipient host or parental organism that receives the new trait
- The donor organism from which the trait is derived
- The vector used to transfer the trait from donor to recipient
- The inserted or introduced trait, including potential toxicity of a gene product or its metabolises
- Empirical data on the novel organism
- The intended application, for example, contained use or planned production

- The potential receiving environment

Another way of looking at risk assessment is to distinguish the following two parameters, namely *hazard and exposure***.** *Hazard assessment* means evaluating whether an organism can be harmful and assessing whether it is a pest, a pathogen or if it will introduce new pests, pathogens or enhance existing ones. *Exposure assessment* involves evaluating the extent to which the environment or humans might be exposed to organisms with novel traits.

One of the major issues relating to the role and application of 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.

Questions to be posed include:

- What are the risks?

- How probable is it that they will occur?
- How serious is the damage if they occur?
- What can be done to minimize the risks and contain the damage?
- Do the benefits outweigh the risks?

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 microorganisms 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 that have been defined based on the characteristics of the organisms involved.

1. *Biosafety level **one*** 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. *Biosafety level **two*** 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. *Biosafety level **three*** is suitable for work with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure.
4. *Biosafety level **four*** 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 LMOs 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 LMOs which are intended for intentional introduction into the environment. A major limitation to the Protocol is that the **AIA procedure applies only to LMOs which will be introduced into the environment**. These LMOs include seeds for planting; fish for release and microorganisms for bioremediation. The AIA procedure also does not apply to LMO commodities which are intended for food, feed and food processes.

The Protocol does not cover non-living products derived from LMOs. 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 labeling and LMOs which are already available in the country of import.

The **Biosafety Policy** embraces these issues and provides specific strategies aimed at addressing these important issues. It has been designed to protect the interest of the people and the unique and diverse biodiversity of the country.

Chapter 4 Objectives

The **Biosafety Policy** embraces seven 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 biotechnology and biosafety and national development.

The primary objective of the policy is to promote the safe use, management and transfer of LMOs to ensure that they do not adversely affect the safety of Papua New Guineans

and their environment. The policy also seeks to promote research and development into LMOs and promotes the use of LMOs to increase food security for the people of Papua New Guinea as expressed in the Food Security Policy 2000-2010; the National Agriculture and Livestock Policy 2001-2012 and the Medium Term Development Strategy 2003-2007. Research into LMOs 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 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.

4.1 Policy Goals

1. **To ensure the safe handling, use and management of Living 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 Living Modified Organisms.**

3. **To strengthen national institutions engaged in the research and development of Living 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 Living Modified Organisms.**

5. **To regulate the trade in Living 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 the use, management and transfer of Living Modified Organisms.**

7. **To facilitate the active participation of local communities in the use, management and transfer of Living 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 biotechnology issues.**

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

4.2 Strategic Policy Objectives

4.2.1 To streamline and strengthen the processes and facilities to enable the efficient assessment of risks associated with the safe handling, use, transfer and management of LMOs

1. *To undertake a review to identify and streamline the current procedures and rules on assessing and reviewing of applications for the importation and exportation of LMOs*

2. *To strengthen and promote the collaboration of relevant government agencies in their dealing with LMOs 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. *To review and synergize the policy and regulatory frameworks to ensure the assessment, handling, use, management and transfer of LMOs are coordinated and timely*
4. *To devise procedures which expedite the assessment of applications for the importation, exportation, transfer, use and management of LMOs*
5. *To identify and strengthen national competent authority with relevant skilled personnel and resources*
6. *To identify human capacity needs and promote capacity building initiatives both at the national and international level through government and international donor funding*

4.2.3 To promote and strengthen human and institutional capacity building

1. *To seek funding to undertake a review to identify human and institutional needs of government agencies which are responsible for the assessment, handling, use, transfer and management of LMOs*
2. *To identify capacity building programs and ensure that relevant public officials involved with the assessment, handling, use, transfer and management of LMOs undertake these programs to improve and enhance their capacities in dealing with LMOs*
3. *To promote and strengthen in-country human capacity building programs relating to the assessment, handling, use, transfer and management of LMOs*

4.2.4 To promote and strengthen research and development of LMOs as food and for food processing and pharmaceuticals

1. *To seek funding to undertake an inventory of all research institutions, their programs and personnel, and create and manage a database on these items*
2. *To promote institutional collaboration in LMO research for food and food processing, and pharmaceuticals through sufficient government and donor funding.*
3. *To promote stronger network between government agencies and the private sector and research organizations involved with LMO research and development*
4. *To review and strengthen the regulatory frameworks on LMO research and development*
5. *To devise guidelines for research and development of LMOs as food and food processes, and pharmaceuticals to achieve the goals of the Food Security Policy 2000-2010 and the National Health Plan 2001-2012*
6. *To upgrade and where appropriate provide adequate facilities for research and development of LMOs for food and food processing to improve food security*
7. *To 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*
8. *To facilitate and promote capacity building programs for Papua New Guinean scientists and researchers*
9. *To provide for the development of guidelines and codes of conduct relating to the use of LMOs destined for contained use*

4.2.5 To design and promote the use of precautionary approaches in the development, handling, use, management and transfer of LMOs

1. *To undertake a review of the regulatory framework and devise a strategy to promote, develop and reinforce policy and regulatory frameworks for the assessment, handling, use, management and transfer of LMOs*
2. *To ensure the application of the precautionary approach in the assessment of LMOs being imported into and exported from the country through the introduction of guidelines and codes of conduct rules*
3. *To ensure the application of the precautionary approach into the research of LMOs and the release of LMOs into the environment to mitigate the risks to human health and the environment through the application of an Environment Impact Assessment (EIA) under the Environment Act 2000*
4. *To devise guidelines and codes of conduct in the use, management and transfer of LMOs*

4.2.6 To regulate trade in LMOs so as to ensure the safety of Papua New Guineans, their environment and genetic resources

1. *To undertake an inventory of all foods, food processes and pharmaceuticals containing LMOs and establish a database on this items which must be accessible to the public*

2. *To undertake an inventory of all government agencies and private corporations engaged in the trade of LMOs and create a database on these institutions and organizations which must be accessible to the public*
3. *To devise cross-sectoral policies to ensure the safe handling, use, transfer and management of LMO products by Papua New Guinean based industries engaged in LMO trade*
4. *To develop guidelines for the labeling of products containing LMOs intended for human consumption and use*
5. *To promote collaboration in LMO research for food and food processes between industry and national research organizations through funding, human capacity building programs and exchange of information and knowledge*

4.2.7 To promote the full and active participation of stakeholders in the use, transfer and management of LMOs

1. *To ensure the formulation of simple procedures for the full and active participation of stakeholders in the assessment of proposals for the use, transfer and management of LMOs*
2. *To promote the active participation of stakeholders at the provincial and local government levels in the assessment of proposals for the use, transfer and management of LMOs*
3. *To facilitate the full and active participation of local communities in the assessment of proposals for the use, transfer and management of LMOs which are likely to affect the local communities*

4.2.8 To facilitate the involvement of local communities in the assessment, handling, use and management of LMOs

1. *To devise guidelines for the participation of local communities in the assessment, handling, use and management of LMOs which are likely to have an impact on the local people and their environment and biodiversity*
2. *To provide guidelines for the protection of local communities, their traditional knowledge and biological resources which will be used in the research and development of LMOs*
3. *To provide guidelines for the engagement of local communities, their land and other resources in the research and development of LMOs*

4.2.9 To increase the awareness of people on biosafety and biotechnology

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*

4.2.10 To promote and strengthen research in biosafety policy

1. *To facilitate the periodic assessment and review of the biosafety policy*
2. *To promote and coordinate biosafety policy research, analysis and formulation*

Chapter 5 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 national competent authority may also perform the function of the national focal point. The main functions of the competent national authority are:

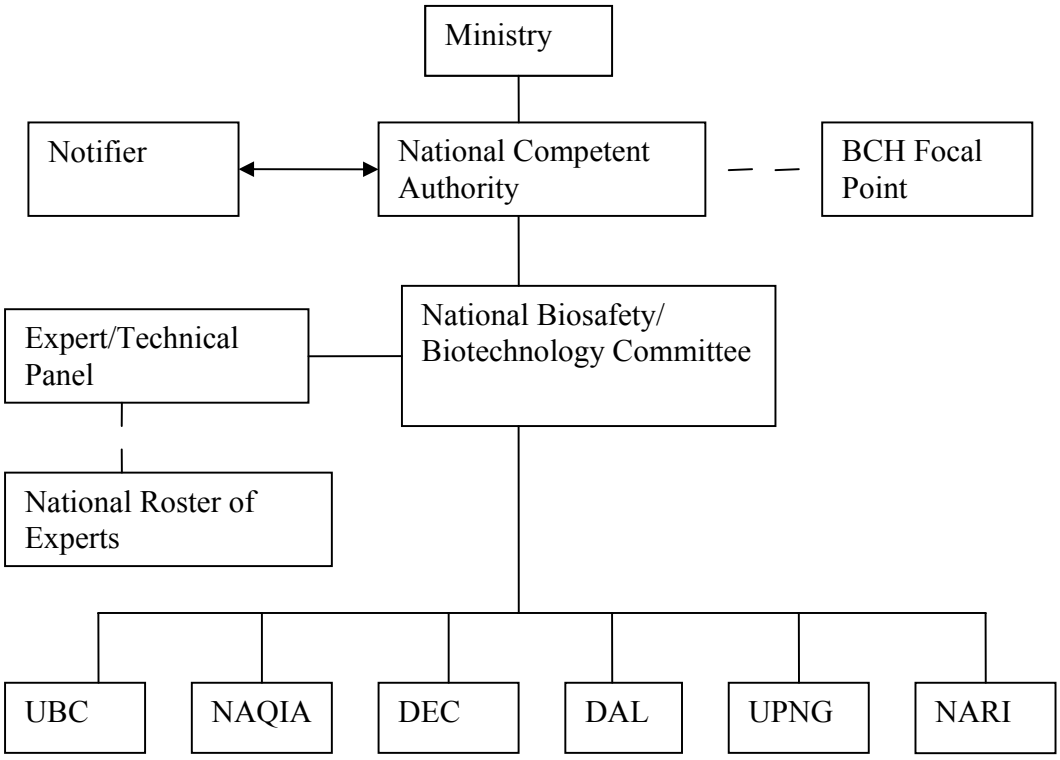
1. performing administrative functions stipulated by the Protocol; and
2. act on behalf of the government on matters relating to the Protocol

The Protocol stipulates that member Parties must inform the Secretariat no later than the date of entry into force in the country of the Protocol, the names and addresses of the national focal point and the competent national authority. The names and addresses of the individuals and organization are then entered into the database of the Secretariat.

In Papua New Guinea there are several national institutions whose roles and responsibilities impact on LMOs. For instance, the Department of Trade and Industry has responsibilities over trade which includes trade in LMO products; the Internal Revenue Commission has power to monitor the import and exportation of LMOs; the National Agriculture and Quarantine Inspection Authority monitors the importation and exportation of biological species which includes LMOs; 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 LMOs to be used for food, feed and food processes.

Figure 1: *Proposed Institutional Framework*



This proposed institutional framework was presented at the First National Biosafety Workshop in April 2004. There was a general consensus that the Department of Environment and Conservation (DEC) should be the National Competent Authority and also the national focal point. The Department will be supported by a team of experts who will comprise the National Biosafety/Biotechnology Committee (NBBC). The team of experts will be drawn from the various institutions that have an interest in biotechnology. The list provided above (UBC, NAQIA, DEC, DAL, UPNG and NARI) is not exhaustive. They have been listed for purposes of clarification.

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 LMOs should be done by DEC in close consultation with the NBBC. Applications for the importation of LMOs should be made to DEC which should then refer it to the NBBC. After considering the application, the NBBC can then advise DEC to either approve or reject the application.

For the proposed structure to operate successfully, it has to be supported by relevant legal framework. The National Competent Authority should also have the human, financial and other resources to function effectively. The task is on the government to firstly ratify the Protocol and then allocate the appropriate resources to ensure the successful implementation of the **Biosafety Policy**.

Chapter 6 Biosafety Policy and its Impact on other National Policies

The **Biosafety 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 **Biosafety Policy** seeks to create a suitable environment for the realization of the potential of 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 Policy** complements several major national policies have been adopted by the government. These include: (1) the Environment Policy 1976; (2) the Medium Term Development Strategy 2003-2007 (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.

6.1 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. That development must be economical, social and ecological;
2. That non-renewable natural resources must be used wisely;
3. The ability of the environment to produce renewable resources must be recognized;
4. That wildlife and their habitat must be protected and wisely managed in the development process; and
5. That planning to be applied to human settlement and urbanization.

The **Biosafety Policy** clearly 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 LMOs, safety of the country's environment and biodiversity must take precedence over other prevailing issues.

6.2 MTDS 2003-2007

The MTDS is the principal document outlining the government's key development goals and aspirations. 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 2003-2007. The primary vision of that MTDS was to build a partnership between the government and the people. The MTDS 2003-2007 promote five national development goals. These are:

- Good Governance;
- Export-driven Economic Growth;
- Rural Development;
- Poverty Reduction and
- Human Resource Development.

The draft MTDS 2003 – 2007 adopts these six objectives as the pillars for the development of PNG over the next five years and beyond. The government aims to achieve these objectives through a number 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; and
- Poverty reduction through greater emphasis on health, education and agricultural development.

Is there a relationship between the MTDS and the **Biosafety Policy**? The **Biosafety Policy** establishes a framework for the scrutiny of imported LMOs which may be used to improve food production for the people of Papua New Guinea. The **Biosafety Policy** also

promotes the development of new pharmaceutical products which enhance the health of the people of Papua New Guinea.

6.3 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 been 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 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; Coca 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 Agriculture Policy affects the **Biosafety 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 **Biosafety Policy**. If the root and tuber crop varieties are not genetically modified, they fall outside the scope of the Biosafety 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 does encourage research and development into LMOs. In the area of research and development the 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".

6.4 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) improvement of food quality and safety; (3) adoption of appropriate technology to sustainably intensify production, systems and ensure sufficient supplies of food and (4) improvement of production, downstream processing, marketing and utilization of food.

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

6.5 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, the development of new medicines to control TB, cancer, HIV/AIDS and other sexually transmitted infections will be significant. The release of LMOs into the environment without any strong safeguards will also impact on the health of the people and thus must be controlled.

6.6 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 biology 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.

6.7 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 taken 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 LMOs must be considered against this Policy. Where the LMO 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.

6.8 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 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 Policy.

6.9 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; and
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 biotechnology is concerned, the Policy is unclear on the use of forest resources for LMO 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.

6.10 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; and
5. Equipping citizens with the best that higher education, research, science and technology can provide to improve and sustain the quality of life.

These 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 government's plan through the MTDS 2003-2007 is to improve its budgetary allocation for basic

education from K101.8 million in 2003 to K103.2 in 2006. 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 Education Department is currently working on a new education policy which will hopefully provide 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.

6.11 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 are 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 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.

Biotechnology initially involves the use of living genetic resources. It can be argued that a biological resource obtained from a local community for LMO 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 LMO purposes. The challenge is to provide the enabling regulations to implement the law.

Chapter 7 Implementation

Biotechnology is in its infancy in Papua New Guinea, but efforts to promote rapid progress in both research and development have been initiated. 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 **Biosafety Policy** requires commitment and collaboration by various government departments and agencies to make it successful. 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 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
- National Agriculture Research Institute
- Coconut and Cocoa Research Institute
- Coffee Research Institute
- Forest Research Institute
- Institute of Medical Research
- Internal Revenue Commission
- National Institute of Standards and Industrial Technology
- National Research Institute
- National Agriculture and Quarantine Inspection Authority
- University of Papua New Guinea
- Papua New Guinea University of Technology
- Vudal University

NARI; NAQIA; Papua New Guinea University of Technology; University of Papua New Guinea; Vudal University; IMR; CCRI; CRI and FRI have the mandate to assess, handle, use, manage and transfer LMOs in the course of performing their duties and responsibilities. These institutions base their mandate on 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 the 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 LMOs. 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 LMOs, 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 LMOs whether for food, food processes or pharmaceuticals, 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 of LMOs.