Kingdom of Swaziland

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NATIONAL BIOSAFETY FRAMEWORK FOR THE KINGDOM OF SWAZILAND

Ministry of Tourism, Environment and Communication

March 2006

Project Description

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PREFACE

During the past centuries, Swaziland, like many developing nations, has benefited from conventional breeding techniques in the production of high yielding crops and animals. New F_1 maize hybrids have improved maize yields, stability of harvests and farm income. Improved animal breeding techniques has resulted in greater livestock and poultry yields. Despite such contributions of conventional breeding and improved health strategies to the performance of crops and animals, the country is still not sufficient in food supply. Recently, modern biotechnology has offered opportunities for improving food production, food processing and production of environmental friendly products. For this reason the government of Swaziland recognizes the potential benefits of modern biotechnology in the fields of agriculture, health and environment.

Despite this recognition, there are some legitimate concerns about the potential risks and side effects of modern biotechnology to the environment, human and animal health. Other serious threats particularly to this country include risks to our biological diversity, socio economic, cultural and ethical issues. The potential benefits and risks of modern biotechnology dictate the need to develop a policy, legal instruments as well as human and institutional resourses to regulate the technology in the country.

Conventional biotechnology is already making a significant contribution to the economy and environmental management of the country. However, research and development in modern biotechnology needs strengthening. Other factors that call for development of a regulatory regime include the globalization of trade and vulnerability of the country to natural disasters such as drought. This may expose the country to unregulated products of modern biotechnology particularly genetically modified food aid.

The government of Swaziland is very grateful to UNEP/GEF for the support in the development of the National Biosafety Framework (NBF). We greatly appreciate the developing of the framework, the draft biotechnology and biosafety policy and the draft biosafety bill.

The next demanding task is building human and infrastructural capacity to implement the NBF. Further cooperation and support in this respect will be greatly appreciated.

The framework has come out because of close cooperation and contributions from various stakeholders including government ministries, the private sector, NGOs and the public at large. This makes the document country owned and driven. The next step for its implementation calls for extensive cooperation amongst all Swazis, the donor community, Swazi institutions, the research fraternity and the rest of the world. I therefore welcome your further cooperation.

The Honourable Minister of Environment, Tourism and Communications

Thandi Shongwe

ACKNOWLEDGEMENT

The successful preparation of the National Biosafety Framework is as a result of the commitment and hard work of many individuals and institutions that deserve a vote of appreciation. Due to space limitation we cannot refer to all of them, but we assure them of our heartfelt appreciation and we value their cooperation and support.

We extend our thanks to the Principal Secretary for Agriculture and Cooperatives Mr. Noah Nkambule, the coordinators of the Projects Dr. Abednigo M. Dlamini and Similo Mavimbela for their guidance and valuable contributions during the entire period of the project.

We wish to express our gratitude to the drafting team for their input and commendable effort. The drafting team comprised of Dr. P.Z.E. Mabuza (University of Swaziland), Ms. Gcinaphi Mndzebele (Attorney-General Office), Dr. B. Dlamini (Department of Veterinary Services), Mr. E. Gwebu (late) - Cotton Board), Mrs. P. Mdziniso (Home Economics), Mr. S. Mavimbela (Malkerns Research Station - Plant Protection) and Dr. A.M. Dlamini (University of Swaziland - Agriculture)

We particularly thank Dr. A.M. Dlamini, National Project Coordinator-NBF for the facilitation and hard work during the entire period of this project.

Finally, we wish to express our thanks and appreciation to UNEP-GEF for providing the financial and administrative support to accomplish this task. We are particularly indebted to Mr. Charles Gbedemeh, Regional Coordinator for Africa, UNEP-GEF Global Biosafety Project, for his guidance and advice.

J. D. VILAKATI
EXECUTIVE DIRECTOR -
SWAZILAND ENVIRONMENT AUTHORITY

ACRONYMS AND ABBREVIATIONS USED IN THE FRAMEWORK

CDB - Convention on Biodiversity

DNA – Deoxyribonucleic Acid

GEF – Global Environmental Facility

GMO – Genetically Modified Organism

LMO – Living Modified Organism

MEE – Ministry of Enterprise and Employment

MOAC – Ministry of Agriculture and Cooperatives

MOJ – Ministry of Justice

MTEC – Ministry of Tourism, Environment and Communication

NAB – National Advisory Committee on Biosafety

NBF – National Biosafety Framework

NCA – National Competent Authority

NCC – National Coordinating Committee

NGO – Non Governmental Organization

NPC – National Project Coordinator

SEA – Swaziland Environment Authority

SEAB - Swaziland Environment Authority Board

TCP – Technical Cooperation Program

UNEP – United Nation Environment Program

UNISWA – University of Swaziland.

WTO - World Trade and Organization.

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PART I

1.0 INTRODUCTION

1.1. Background

The kingdom of Swaziland is a land locked country of about 17,364 km^2 located in Southern Africa bordered by the Republic of Mozambique and the Republic of South Africa. Swaziland has a population of about 1 million people with an annual growth rate of 2.9%. The country has a varied climate and topography. There are four agro-climatic zones that run longitudinally West to East namely: the highveld, middleveld, lowveld and the lubombo plateau. The highveld has an average altitude of 1300 m, temperatures varying from 10 ^{0}C to 23 ^{0}C and rainfall ranging from 1016- 2285 mm. The middleveld has an average altitude of 700 m, temperatures varying between 14 ^{0}C and 26 ^{0}C and rainfall ranging between 762 mm and 1192 mm. The lowveld has an average altitude of 200 m, temperatures varying from 15 ^{0}C to 29 ^{0}C, and rainfall ranging between 508 mm – 890 mm. The lubombo plateau has an average altitude of 700 meters, temperatures varying from 14 ^{0}C to 26 ^{0}C, and rainfall ranging between 635 mm-1016 mm. Such variability in climate and topography has endowed the country with rich species diversity. The country's wealth in flora and fauna is distributed within variable ecological systems, ranging from mountain plains to lowland plains; from natural forests, rangelands and wetlands to cultivated areas. The rich biological diversity of Swaziland makes it one Africa's hot spots in biological wealth thus making vulnerability to biodiversity threats significant.

The economy of Swaziland is heavily dependent on agricultural production. Agriculture, forestry, and manufacturing contribute about 48% of the country's gross domestic product (GDP). Over 70% of the manufactured products are agricultural and forestry products. The agriculture sector is based on a coexistence of a dynamic commercial sector with a traditional semi subsistence sector. The major cash crops grown include cotton, sugarcane, tobacco and pineapples. Maize is the staple food crop grown by both

commercial and subsistence farmers. Beef production is the major foreign exchange earner from the livestock sector. Livestock and poultry feeds are processed from imported feed ingredients such as soybean meal, sunflower cakes and fishmeal. The seed industry is heavily depended on imports from neighbouring countries. In the past few years, parts of the country had been affected by drought resulting in an influx of food aid, mainly maize and legumes from international organizations. It is suspected that these conditions might have exposed the country to unregulated *trans* boundary movements of living modified organisms that could be a possible threat to the environment and public health.

1.2 Justification for developing a biosafety frame works for Swaziland.

Swaziland has great regards to the potential benefits of biotechnology on agriculture, environment management, animal and human health. Biotechnology can be used as a tool to improve crops and animals yields, thus ensuring food security. It can be used in the industry to produce environmental friendly products such as biofuel and biodegradable plastic materials. It can be used to produce disease diagnostic tools for human and animal health as well as being used for the production of antibiotics and special biopolymers such as enzymes; hormones and food ingredients. There are, however, serious concerns on the potential risks that are attributed to the application and use of products of modern biotechnology. Some of the potential risks to the environment may include the development of herbicide tolerant weeds and loss to natural biodiversity as a result of extensive mono cropping with transgenic crops. Potential risks to human health may include possible development of food allergens and development of antibiotics resistant gut pathogens. Since Swaziland gets imports or food aid that could be products of genetically modified organisms, and has interests in benefiting from the advantages of modern biotechnology as both research and production tools, measures should be taken to ensure that the technology is well regulated. The products of modern biotechnology should be adequately tested before release to the environment. They should also be adequately monitored once released to the environment. Such measures can be realised if a properly formulated management tool, a national biosafety framework, is in place.

1.3 Developments leading to establishment of the National Biosafety Frameworks for Swaziland

During the earth summit on "Environment and Sustainable Development" held in Rio de Janeiro, Brazil in 1992, biosafety was adopted under agenda 21 as an international priority issue under the 'Convention on Biological Diversity' (CBD). Article 19 of The CDB states that "parties should consider the need for modalities of a Protocol setting out appropriate procedures, including in particular, advanced informed agreements in the field of safe transfer, handling and use of Living Modified Organisms (LMO) resulting from biotechnology that may have adverse effect on conservation and sustainable development. The CBD was mandated to initiate the biosafety protocol. Later, this protocol became known as the Cartagena Protocol on Biosafety (CPB). The CPB was adopted in Montreal, Canada on 29 January, 2000. It was adopted as a supplement to the CBD to address the safe transfer, handling and use of modified organisms. It entered into force on September 11, 2002. The major objective of the CPB is in accordance with the precautionary approach principle, principle 15 of the Rio Declaration on Environment Development. Swaziland acceded to the CPB on 13th January 2006.

In November, 2000, Global Environment Facility council approved the 'initial strategies for assisting countries to prepare for the entry into force of the Cartagena Protocol on biosafety'. One objective of the protocol was to 'assist countries in implementing the CPB through development of their national biosafety frameworks'. A UNEP/GEF project entitled 'Development of National Biosafety Frameworks' was approved at the same meeting. Swaziland was granted the privilege to participate in the project on February 17, 2003. The project started in September 2003, when the first funds were received and was completed in September 2005. The implementation of this project was aimed at assisting the country to develop a National Biosafety Framework, and it was undertaken in accordance with the overall objective of the UNEP/GEF programme for Development of National Biosafety Frameworks.

1.4. Composition of a National Biosafety Framework

According to UNEP/GEF 2003 guidelines, a National Biosafety Framework consists of:

- A Government **policy on biosafety,** often part often part of a broader policy on biotechnology.
- A **regulatory regime** set in place to address safety in the field of modern biotechnology. This includes laws, guidelines and regulations to guide practices in modern biotechnology.
- A **mechanism to handle applications for permits** for certain activities, such as releases of GMOs into the environment.
- A **mechanism for 'follow up' actions such as enforcement and monitoring for environmental effects.**
- A **mechanism for public awareness, education and participation**.

1.5 The development process for the NBF

The NBF project for Swaziland commenced in September 2003, and was completed in September 2005. Its main objective is to enable a safe responsible development and application of modern biotechnology while minimizing risks to the environment and human health. It is based on the precautionary approach principle as defined in the CPB. In Swaziland, the Ministry for Tourism, Environment and Communication is the focal point for biodiversity hence biosafety. It is also the Executing agency for the UNEP/GEF national biosafety framework project for Swaziland. The ministry appointed the National Coordinating Committee (NCC) for the project. The NCC recruited Dr. Abednego Dlamini from the Faculty of Agriculture at the University of Swaziland to work under the project as National Project Coordinator (NPC). He performed his duties under a contract signed with the UNDP resident office, Mbabane. The NBF process was as follows:

a. Surveys: Three teams were appointed to carry out surveys on behalf of the NCC under the following subjects: I) Status of biotechnology and inventory of experts and biotechnology facilities; II) Status of existing legislation and gaps on biotechnology and biosafety; III) Status of public awareness on biotechnology and biosafety and development educational and public awareness materials.

b. Training: Training and public awareness workshops on biotechnology and biosafety were held with the participation of the major stakeholders. Technical officers were specifically trained on methodology of risk assessment and management.

c. Process of drafting of the NBF: a drafting team that was appointed by the NCC drafted the NBF. The draft was presented to the NCC for comments and then it was discussed at a national workshop attended by 100 stakeholders representing: private sector (industry), non government organizations, the public sector, policy makers, farmers, research and educational institutions, consumers, and legislators. The composition of the drafting team was as follows: Dr. P.Z.E Mabuza from the Department of Biological Sciences, University of Swaziland, PhD, Molecular biology; Ms. G Mndzebele, Attorney's General Office, LLM drafting; Dr. B. Dlamini, Veterinary services, M.Sc. Veterinary science; Mr. E. Gwebu, Cotton Board, M.Sc. plant breeding; Mrs. P. Mdziniso, Home Economics, M.Sc. Food Science; Mr. S. Mavimbela, Malkerns Research station, M.Sc. plant protection; Dr. A.M. Dlamini, Department of Animal production and health, University of Swaziland, PhD, Dairy biotechnology.

1.6 Guiding principles of the NBF

Development of the NBF was guided by principles based on international and national regulatory regime. The major guiding principles were those of the convention on biological diversity through the Cartagena Protocol on biosafety. The major principles were:

a) *The precautionary principle*: This will be applied in accordance with the dictates of the Cartagena Protocol on Biosafety. It will be used during the decision making process of the NBF particularly in matters relating to risk assessment and management.

b) *Duty to protect the environment:* Every Swazi has the responsibility to protect the environment, safeguard it and ensure that it is maintained in a self sustainable manner. Swazis have a duty to inform relevant authorities about any activities or phenomena that may result in significant damage to the environment.

c) *Preventive principle:* Implementation of the NBF shall give priority to preventing any adverse effect of modern biotechnology to the environment, human and animal health.

d) *Advanced informed agreement:* Consent should be sought from the National Biosafety Competent Authority before any activity involving release of products of modern biotechnology to the environment is undertaken.

e) *Balanced informed decision:* Implementation of the NBF shall be guided by the balanced approach. Any decision on applications or activity on GMOs in particular shall be on case-by-case based on risk assessment. The balanced approach recognizes the potential benefits of modern biotechnology and potential risks to the environment, human and animal health.

f) *Public awareness, participation and transparency.* Under the NBF, decision shall be arrived at under transparency with participation from the public. All stakeholders shall have access to relevant information and be afforded the opportunity to participate in decision making.

g) *Socio economic and ethical consideration:* Socio economic aspects of the people of Swaziland and their ethical considerations shall be taken into consideration when biosafety decisions are made.

1.7 Objectives of the NBF

The principal objective of the NBF for Swaziland is to establish an environment that ensures safe development, deployment and application of modern biotechnology while ensuring protection of the environment, human and animal health from potential risks. The specific objectives of the NBF are:

- To provide a scientific based and transparent decision making system that will enable Swaziland benefit from the potential benefits of modern biotechnology

while ensuring maximum protection of the environment, humans and animals from potential risks.

- To ensure that research, release and handling of products from modern biotechnology are done in a manner that minimizes potential risks to the environment, human and animal health.
- To ensure safe handling and trans boundary movement of products derived from modern biotechnology

1.8 Introduction to the NBF

The UNEP-GEF sponsored project for development of the NBF for Swaziland began in September 2003 and completed in September 2005.

The National Executing Agency was the SwazilandEnvironment Authority (SEA).
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The National Project Coordinator (NPC) was Dr. Abednego Dlamini who was recruited from the University of Swaziland, Faculty of Agriculture for the duration of the project. His address was:

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The National Executing Agency appointed twenty-five (25) people from various stakeholders relevant to biotechnology and biosafety to form the National Coordinating Committee (NCC). The names of the NCC members and their institutions that they represent are shown below.

Name	Institution
1. Mr. J.D. Vilakati	SEA, Ministry of Tourism, Environment and communication, Mbabane.
2. Dr. G.T. Masina	University of Swaziland, Faculty of Agriculture, CP Department, Luyengo.
3. Dr. A.M. Dlamini	University of Swaziland, Faculty of Agriculture, APH Department, Luyengo.
4. Mr. S.G. Mavimbela	MOAC, Malkerns Research station Crop protection division, Malkerns.
5. Mr. S.M. Zuke	SEA, Ministry of Tourism, Environment and communication, Mbabane.
6. Dr. P.E.Z. Mabuza	University of Swaziland, Faculty of Science, Biology Department, Kwaluseni.
7. Mrs. P. Mdziniso	MOAC, Department of Home Economics, Mbabane.
8. Mr. Ernest Gwebu	Swaziland Cotton Board, Breeding Division, Big Bend.
9. Dr. Mike Clowes	Swaziland sugar association, Simunye,
10. Dr. Bernard Dlamini	MOAC, Department of veterinary Services, Mbabane.
11. Ms. T. Lupupa	MOAC, Malkerns research station Gene bank unit, Malkerns.
12. Ms. D. Vilakati	MOAC Livestock breeding division, Mbabane.
13. Mr. S. Maphalala	SEA, Ministry of Tourism, Environment and communication, Mbabane.
14. Mr. Vuyile Dlamini	Ministry of Justice and Constitutional Affairs, Attorney's General Office.
15. Mr. Sipho Dlamini	National Maize Corporation, Technical Services, Matsapha.
16. Ms. N. Mashwama	Ministry of Foreign Affairs and Trade Mbabane.
17. Mr. N. Mavuso	MOAC, Seed Testing and Quality Control Division, Malkerns.
18. Mr. T. Mpanza	MOAC, Department of Agriculture Mbabane.
19. Dr. S. Gumbi	Swaziland Consumer Association Mbabane.
20. Mr. J. Ginindza	Deputy Prime Minister's Ministry National Disaster Task Force, Mbabane.
21. Mr. W. Nxumalo	Farmer R
22. Ms. B. Ndzinisa	UNDP Resident Office representative Mbabane.
23. Mr. S. Magagula	Ministry of Justice and Constitutional Affairs, Patents and Intellectual Rights, Mbabane.
24. Mr. E. Ndlangamandla	CANGO
25. Dr. C. Mabuza	Ministry of Health &Social Welfare, Public Health Services, Mbabane.

The NBF for Swaziland has the following components:

- Part 1: an introduction to the framework covering the description of the project, justifications, and objectives of the NBF.
- Part 2: The biotechnology and biosafety policy for Swaziland.
- Part 3. The Biosafety Act.
- Part 4. An administrative system to handle request for permits to undertake modern biotechnology works.
- Part 5. A post permit system covering monitoring for environmental effects, inspections to ensure applicants adhere to permit conditions, and enforcement, risk assessment and management.
- Part 6. A mechanism for public awareness, participation and information sharing.
- Part 7.Anexes
    c) Complete copy of the Draft Biotechnology and Biosafety Policy.
    d) Complete copy of the Draft Biosafety Bill.

PART II

2.0 DESCRIPTION OF THE BIOSAFETY POLICY FOR SWAZILAND

2.1 Introduction

Swaziland had no specific policy for Biosafety, hence it was decided that a national biotechnology and biosafety policy should be drafted. It was agreed that the policy will be based on the precautionary approach in compliance with the Cartagena Protocol on Biosafety. In this section the key points of the proposed biotechnology and biosafety policy are discussed. The complete policy is presented in Part VII as annex(a).

The main goal of the national biotechnology and biosafety policy is two folds:

- To promote the adoption and application of biotechnology in Swaziland;
- To ensure the highest possible level of biosafety in transfer, handling and use of products of modern biotechnology in congruous with the 'precautionary approach' principle.

The biotechnology and biosafety policy for Swaziland was drafted by a drafting team composed as described in section 1.5(c) above. The draft policy was distributed to members of the NCC for comments, and then presented to stakeholders in a national workshop. Comments of all stakeholders were incorporated.

2.2 Existing policies that may have a bearing on biotechnology and biosafety.

Although the country had no specific policy on biotechnology and biosafety, a survey of some closely related policies was done. It was found that some of these policies may impact on biotechnology but they mention very little about biosafety.

2.2.1 National Biodiversity Strategy and Action Plan (NBSAP), 2001.

The goal of the NBSAP with respect to biosafety is to minimise the risks associated with the use of LMOs in Swaziland. The NBSAP identifies some constraints in the area of biosafety as follows:

- Lack of an institutional structure to oversee all impacts of LMO use in Swaziland.
- Lack of a legal or policy framework in the area of biosafety.
- Limited human resources competent to deal with risk assessment.

The NBSAP further goes on to spell out strategic goals to address these constraints.

2.2.2 Forest Policy, 2001

The policy recognizes the potential benefits that may be obtained from use of genetically modified trees but advocates the precautionary principle to minimise potential adverse effects.

2.2.3 Draft Comprehensive Agricultural Sector Policy, 2003

The policy recognizes benefits that may be obtained from modern biotechnology applications in the agricultural sector and identifies some potential risks. It also calls for the formulation of a national policy in the area of biotechnology and biosafety.

2.2.4 Draft National Food Security Policy, 2005

The policy advocates adoption of appropriate and sustainable biotechnology innovations but also raises the following concerns:

- Limited capacity and knowledge of potential uses and benefits of biotechnology for food production.
- Lack of a regulatory environment to control and manage use of biotechnology.

2.3. The national biotechnology and biosafety policy

2.3.1. Why Swaziland needs a biotechnology and biosafety policy

As defined in the Convention on Biological Diversity (CBD), biotechnology refers to "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use". This definition covers a wide range of biotechnology applications ranging from traditional technologies such as fermentation, *in vitro* culture and other applications which have been practiced by mankind over long periods and are generally not controversial. More modern applications of biotechnology include recombinant DNA technology (rDNA) where the genetic make up of organisms is altered by inserting foreign DNA as well as fusion of cells beyond the taxonomic family. Organisms whose DNA has been altered in this manner are referred to as Genetically Modified Organisms (GMO) or Living Modified Organisms (LMO).

Modern biotechnology has found uses in many important applications including medicine and the pharmaceutical industry, food and beverage industry, environmental remediation, agriculture and other uses. In the food industry, enzymes and other biomolecules produced by modern biotechnology are routinely used in fruit juice

production, brewing, dairy industry etc. In agriculture, modern biotechnology has found uses in the following applications:

- Development of crop varieties that are tolerant of specific insect pests e.g. *bt* cotton (resistant to American bollworms)
- Development of crop varieties that are resistant to particular herbicides e.g. Glyphosate resistant cotton (Round-up-ready cotton)
- Development of disease resistant crops e.g. potato resistant to potato leaf-roll luteovirus (PLRV).
- Development of oil crops with altered oil profiles e.g. high oleic acid, low linolenic acid content in Argentine canola
- Biofortification of crops e.g. Golden rice- developed to contain high levels of β-carotene, a precursor to vitamin A
- Development of crops with improved shelf-life
- Development of saline tolerant crops
- Potential for development of drought tolerant crops.

Environmental and health concerns that have been raised about the use of modern biotechnology applications in agriculture in particular include:

- Potential for build up of resistance to *bt* in insects and thus implications for control of pests
- Potential negative effects of *bt* on non-target and possibly beneficial organisms
- Genetic erosion due to uptake of GM crops and thus increase tendency towards monoculture
- Potential for transgenic crops to escape thus becoming problematic weeds due to resistance genes
- Potential transfer of transgenes to wild crop relatives and landraces
- Use of antibiotics as marker genes in the transformation process and implications thereof in treatment of diseases

- Potential toxicity of GM foods
- Potential allergenicity of GM foods

Some socio-economic concerns of biotechnology include:

- Multinational control of agriculture thus compromising the ability of small scale farmers to control their business
- Globalisation and resulting inequality of accruing benefits
- Intellectual property rights and the right of farmers to reuse and freely exchange farm-saved seed
- The use of Genetic Use Restriction Technologies (GURTS) and possible implications to rights of farmers already stated
- Food safety and the rights of consumers to make their own choices
- Ethical issues

These concerns cannot be ignored, therefore it is of prime importance that a national policy on biosafety is established, that will set an overall framework in which safety measures can be developed and implemented so that the country can minimize any risks to the environment, human and animal health.

2.3.2 Policy principles

The Biotechnology and biosafety policy shall be based on the following principles:

- ❖ Swaziland has sovereign rights over all resources in her area of jurisdiction and as such reserves the authority to regulate any activities which either exploit or might have negative impact on such resources
- ❖ Swaziland shall as far as possible endeavour to create a suitable environment for the adoption of modern biotechnology applications and or products which can contribute to the socioeconomic development of the country whilst taking measures to prevent or, at least minimize the adverse

effects such applications may have on human and animal health as well as the environment in line with the requirements of the precautionary principle.

- The use, import, export, transit and sale of all modern biotechnology applications, products and products derived from them must be in full compliance with national legislation, present and future.
- Risk assessment will be carried out on a case-by-case basis taking into account structures and mechanisms for regional cooperation in this area
- Swaziland shall as far as possible, cooperate with other states to ensure the safe application of biotechnology within her borders and to prevent illegal transboundary movement of GMOs.
- The Kingdom of Swaziland reserves the right to make her own decisions about appropriate biotechnology applications, processes and products to adopt as perceived by her people and will neither be made a dumping ground nor a testing ground for products and applications that have been banned elsewhere.
- The applicant shall bear all costs relating to the decision-making process including containment and field trials.
- In the event of any adverse effects resulting from the application of a modern biotechnology application, product or product thereof, the applicant shall be held responsible and shall be liable to a fine as well as any costs related to remediation etc.

2.3.3 Policy objectives

The vision of the Kingdom of Swaziland is to be in the top 10% of the medium human development group of countries founded on sustainable development, social justice and political stability by the year 2022.

Key activities in line with this vision include;

- Eradication of poverty
- Creation of employment

- ❖ Practicing gender equality
- ❖ Social integration
- ❖ Protection of the environment

Biotechnology is one of a number of technologies that can contribute towards implementation of these activities. However, it is important that safeguards are put in place to minimise adverse effects that may result the practicing of biotechnology.

The specific objectives of the national biotechnology and biosafety policy are as follows:

- To support the safe application of biotechnology and its products to enhance the socio-economic development of the country whilst minimising, as far as possible, any adverse effects on human and animal health as well as the environment
- To ensure effective control of the trans-boundary movement of genetically modified organisms and products thereof resulting from modern biotechnology

- To help ensue an adequate level of biotechnology development within the country

2.3.4 Scope of the national biotechnology and biosafety policy

The national biotechnology and biosafety policy shall cover all modern biotechnology processes, applications, products and all products derived from them. This includes all living modified organisms including plants, animals and micro-organisms:

In particular, the policy covers:

- Applications of modern biotechnology in the food industry, agriculture, medicine, veterinary medicine, environmental applications as well as any future applications in the mining industry and other sectors.
- Regulatory and administrative procedures including applications and their processing, risk assessment and monitoring, review processes, contained use, environmental release and placing of GMOs on the market.
- Human capacity building and infrastructure development in biotechnology and biosafety.
- Occupational safety at workplaces where modern biotechnology procedures may be used or products thereof might be handled.
- Any other measures necessary to ensure human and animal health as well as environmental health in the country.

2.3.5 Policy statements

Swaziland shall make it her policy to continue:

- Recognizing the importance of protecting her people, environment and biological diversity while promoting sustainable social and economical development through the adoption of biosafety measures;
- Recognizing the environmental, human and animal health risks that could be incurred when unregulated modern biotechnology practices are a norm.
- Recognizing the need to develop her own human and infrastructural capabilities in biosafety and biotechnology.
- Reaffirming her commitment to the obligations of the CBD and CPB

2.3.6 The specific policy statements

The Biotechnology and Biosafety policy for Swaziland emphasizes the following statements:

- The National Focal Point for Biosafety shall be at the Ministry of Tourism, Environment and Communication, in the Swaziland Environment Authority. The policy shall be implemented by the Focal Point through the National Biosafety Advisory Committee (NBAC). Activities of the NBAC shall be coordinated by the decision-making body, the Swaziland Environment Authority Board (SEAB) that shall be the National Competent Authority (NCA).

- Where GM maize is allowed into the country as food aid, it will be milled prior to distribution. A written declaration shall be required that all events involved in all GM food aid donations have been approved in the country of origin for use as food and further, that such donations have not been contaminated by unapproved events, edible vaccines or any other such contaminants. A database of all such donations received and distributed will be maintained and made available to the biosafety office and the NBAC.

- Labelling of genetically modified products shall be made mandatory. This shall include all products resulting from modern biotechnology at all stages of the production process from raw to final product in order that the demands of consumers for a free and informed choice regarding food are fulfilled.

- Where GMOs destined for use as animal feed, food and processing have the potential to be released into the environment, they shall be treated as GMOs to be introduced into the environment and subjected and thus subject to the AIA procedure.

- National safety guidelines and implementation practices shall be adopted by all systems using modern biotechnology including industry, research and academic institutes and NGOs. The guidelines shall cover all related aspects including material handling, equipment, storage, waste disposal, distribution and laboratory safety.

- Any approved events on modern biotechnology will be subject to periodic inspection and monitoring. The Government of Swaziland reserves the right to terminate any applications that are found to be in contravention of the conditions upon which approval may have been granted.

- In addition to monitoring of approved biotechnology applications, inspectors shall have the authority to enter and collect samples for testing to ensure that no applications are being run illegally.

- In the event that any illegal applications are being run, inspectors shall have the authority to cease and destroy all such material, working closely with law enforcement agencies.

- Research into development of modern biotechnology, biotechnology risk to the environment, human health, and animal health, shall be supported. Adequate funding shall be sourced and allocated.

- The government of Swaziland recognizes the urgent need to build up its capacity for biotechnology research and risk assessment with a view to creating a critical mass of skilled scientists and to enable her to meaningfully participate in regional networking activities in this area. In this regards the government will commit herself:

    - To training a number of locals in the key areas already identified to MSc level within the region or if be beyond the region;
    - To creating an environment that will be conducive to encouraging individuals with relevant expertise in stakeholder institutions to seek PhD training in fields related to biotechnology and risk assessment.

- In the absence of an adequate intellectual property rights regime, there is a risk that local communities can be cheated out of benefits accruing from the exploitation of their genetic resources and indigenous knowledge. The government of Swaziland shall not recognise or permit the patenting of genes and life forms but shall develop a *sui generic* to protect such innovations. The government of Swaziland shall strive to protect the rights of her farmers and local communities to freely save, use and exchange farm saved seeds. Guidelines for fair and equitable sharing of benefits accruing from biotechnology will be developed in line with the requirements of the CBD.

- The government of Swaziland shall commit herself to the establishment of at least one facility, to international standards for: *In vitro* culture; GMO testing; Genetic transformation; Contained trials.

- Public awareness of modern biotechnology including potential risks, potential benefits, risk assessment and management techniques shall be enhanced. This shall involve the community at large, policy makers, legislators, administrators, farmers, extension officers, private sector and boarder post control custom officers.
- Appropriate knowledge bases and infrastructure for information exchange on biosafety shall be established and developed

- In order to provide the public opportunity to contribute towards the decision making process, the following procedure shall be followed:
    - Information about applications will be widely advertised in the print and electronic media, including community stations where possible.
    - The public shall be informed as to where dossiers can be viewed.
    - Procedures for making submissions and deadlines for submission shall be clearly stated.
    - In line with requirements of the Cartagena Protocol, mechanisms will also be put in place to protect confidential information as described, provided the NBAC is satisfied that protection is justified.
    - The public shall be represented in the NBAC through the Swaziland Consumers association or other suitable NGO

PART III

3.0 BIOSAFETY REGULATORY REGIME

3.1 Introduction

The NCC appointed a subcommittee to review the existing status of legislations to establish if whether they adequately address Biosafety issues. A survey of the existing legislations revealed that they do not explicitly address modern biotechnology and Biosafety issues. Only a few Acts implicitly impact on biotechnology but very little or non on Biosafety. These include: the phytosanitary laws; laws relating to intellectual property rights; legislation regulating agricultural products; legislation on public health, animal health as well as environmental protection. It also includes selected bills on, that are yet to be passed into law.

3.2.0. Existing legislations and their relevance to Biosafety

There are a number of pieces of legislation, scattered across a number of ministries that may have a bearing on the regulation of biotechnology and its products. These include:

3.2.1 Environment Management Act (EMA) of 2002

This is the principal legislation that deals with all environmental issues in the country. It is administered by the Ministry of Tourism, Environment and Communication (MTEC) through the Swaziland Environment Authority (SEA), the institution responsible for environmental regulation in the country. It repeals the Swaziland Environment Authority Act of 1992, and establishes the SEA as a government parastatal. SEA also inherits all the legal instruments enacted in terms of the 1992 Act, such as the Environmental Audit Assessment and Review Regulation, 2000 (EAARR), Waste Regulations, 2000 and others. The EMA recognizes the existence of the Environment Policy and provides for the

formulation of Biosafety Regulations. It also recognizes the Swaziland Environmental Action Plan (SEAP) which calls for the formulation of strategies such as the Waste Management Strategy, National Biodiversity Strategy and Action Plan (NBSAP), National Environmental Education Strategy (NEES). It does not specifically address the safety of modern biotechnology.

3.2.2 The Animal Diseases Act Of 1965

The Ministry of Agriculture and Cooperatives administers the Animal Diseases Act. It is an Act designed to control the spread of animal disease and as such it gives the Ministry the powers to cordon off certain areas suspected to be either infected or a source of infection for animal diseases. The Act also imposes standards on the control of the spread of animal diseases. However, it is silent on the modern biotechnology and its products. It has no provision for regulating importation or cross border movement of GM animals.

3.2.3 The Dairy Act 28 of 1968

The Ministry of Agriculture and Cooperatives administers the Act. It is an act that provides for the control and improvement of the dairy industry and its products. Dairy product is defined to mean:

i) Milk, milk product, such as milk powder or condensed milk contained in sealed containers; or
ii) Butter, whey, cheese, cream or ice cream; or
iii) Margarine or other substitute for butter made from vegetable or animal fats or a combination of those fats.

The Act establishes the Dairy Board a body corporate whose functions include *inter alia* organizing efficient, orderly and stable production of dairy products; regulating distribution and marketing of dairy products; ensuring that the quality of dairy products is of a standard suitable for public health; prescribing the types

grades and quantities of dairy products to be sold and used in Swaziland or exported.

The Dairy Regulations for *Inter alia,* registration and licensing of dairy premises; standard of composition and quality for dairy products; marketing of dairy products. In particular the regulations prohibit the export of dairy products unless accompanied by a permit and import of dairy products, which are not properly marked. However, the regulations are silent on marking of dairy products to reflect whether or not they contain GM ingredients.

3.2.4 The National Agricultural Marketing Board Act 13 of 1985

The Ministry of Agriculture and Cooperatives administers this Act. The Act establishes the National Agricultural Marketing Board (NAMBOARD) a body corporate whose functions include *inter alia* the registration of wholesale distributors, importers and exporters of scheduled products; facilitating the production, processing storage, transportation, distribution and sale of scheduled products. Scheduled products are defined as products designated as such in terms of the Schedule to the Scheduled Products Regulations of 1986. These include maize and maize products rice, all fresh commodities or products categorized as fruits, all fresh commodities categorized as vegetables, all slaughtered poultry and poultry products, wheat and wheaten products and live cattle and carcass meat. The Import and Export of Scheduled Products Regulations of 1991 provide for the registration of importers and exporters of scheduled products and permits for such registered importers and exporters. The Act is silent on the importation of GM scheduled products.

3.2.5 The Plant Control Act 8 of 1981

The Ministry of Agriculture and Cooperatives administers the Plant Control Act. It is the main phytosanitary instrument in the country. The Act controls the importation and exportation of plants by requiring that all plant movement into and out of the country be given permits by the Ministry. It provides for phytosanitary procedures on all plant and plant living material by imposing the issuance of phytosanitary certificates. The Act provides for plant disease control even to the point of quarantine as well as schedules for plants and other living materials into categories for the issuing of permits. It also covers the control of noxious weeds and alien animals, which may be problematic to plants. Noxious weeds are not defined but the implication is that they are unwanted plants of which it is illegal to even propagate. However, the act is silent on the handling of GM crops.

3.2.6 The Flora Protection Act of 2001

The Ministry of Agriculture and Cooperation administers this legislation. It governs the protection of indigenous flora listed in the schedules to the Act. It makes it a criminal offence to cause damage to any of the species listed in the schedules. It covers the conservation of indigenous species by stating a requirement for the Environmental Impact Assessment for projects that would impact on indigenous species. It provides for permits to pluck, cut or uproot indigenous plants as well as exports of such resources. The Act does not mention any think about the regulation of GM crop to ensure protection of the conserved indigenous flora.

3.2.7 The Seed and Plant Varieties Act 7 Of 2000

The Seed and Plant Varieties Act is administered by the Ministry of Agriculture and Cooperatives. It provides for the control of sale, importation and exportation of seeds by requiring, *inter alia*, registration of new varieties of seeds. It also

controls the importation and exportation of seeds into the country by requiring permission and seed testing prior to the importation of the seed and permission prior to exportation of seed respectively. It also requires the application of phytosanitary procedures for the prevention of plant disease spread in terms of Part IV and V of the Plant Control Act, 1981. However the Act is silent on the importation and registration of GM seeds.

3.2.8 The Pharmacy Act 38 of 1929

The Ministry of Health and Social Welfare administers this Act. It makes provisions relating to chemists and to the sale, supply and possessions of pharmaceuticals by *inter alia* requiring registration of persons qualified to practise as chemists. It provides for regulations that set standards for the operation of chemists in Swaziland.

3.2.9 The Public Health Act of 1969

The Ministry of Health and Social Welfare administers this Act. It imposes standards for the sanitation, vaccines, monitoring and prevention of infectious diseases.

3.2.10 The Public Health Bill of 1999

The Bill is designed to improve the health status of the people. It seeks to repeal the Public Health Act of 1969 and to maintain all regulations made under that Act.

One of the objectives of the Bill is "the provision of the promotion of public health within the country and in this regard to provide for measures directed on preventing, suppressing and treating diseases and conditions as well as maintaining a healthy environment that is safe for human habitation and other forms of life".

The Bill puts a strong emphasis on food supply and food hygiene especially on the manufacture, preparation, packaging and labelling as well as sale and consumption of food. The Bill provides for the formulation of regulations to cover the quality of infant food, a field currently dominated by biotechnology. In as much as the Bill provides an opportunity for regulating genetically modified drugs and other products, it fails, however, to provide for a framework on management of GMOs in as far as risks to human health are concerned.

3.2.11 The Food, Cosmetics and Disinfectants Bill of 2001

This Bill is designed to control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants. It covers *inter alia*, the labeling of foodstuffs, cosmetics and disinfectants; prohibition of sale, manufacture or importation of certain articles. Although the bill is silent on GM food, it presents an opportunity for protection of consumers.

3.2.12 The Patents, Utility Models and Industrial Designs Act of 1997

The Ministry of Justice and Constitutional Affairs administers this Act. It is an Act to protect inventions, utility models and industrial designs. It provides for, *inter alia*, patents in respect of inventions, excluding inventions that are contrary to public order and morality. This Act repeals the Patents, Designs and Trade Marks Act, 1936.

3.3.0 The Biosafety Bill

It is clear from the review of local legislations that the sectoral pieces of legislations are not adequate to address biosafety. The country therefore generally lacks legislation designed to protect its citizens' health and the environment from the potential risks of modern biotechnology, in line with the objectives of the CPB. In particular, there is no legislation regulating genetically modified food and feed in order to ensure consumer protection, or allow consumers and farmers to

decide if they want to buy food or feed produced from GMOs or not. An Act had then to be drafted to enable the country to have an adequate level of protection of, the environment, human, and animals and in relation to safe transfer, handling and use of GMOs. In this regards, the NCC appointed a drafting team that has developed a draft Biosafety bill as presented on Annex 2. It is hoped that this bill will soon be enacted into a biosafety Act. The draft biosafety bill has the following components:

3.3.1 Objectives of the new Bill.

The objectives of the Bill are to ensure an adequate level of protection in the field of the safe transfer, handling and use of genetically modified organisms (GMOs); to provide a transparent process for review and decision-making on GMOs and related activities; to implement the Cartagena Protocol on Biosafety to the satisfaction of Convention on Biological Diversity.

3.3.2 Approving authority for biosafety and biotechnology matters

The new Act details the approving authority, its structure, composition, powers and duties. The focal point shall be the Swaziland Environment Authority, found in the Ministry of Tourism, Environment and Communication. The Swaziland Environment Authority Board (SEAB) is designated the Competent Authority. It will be appointed by the Minster responsible for environment. The SEAB will be composed of senior government officers and individuals representing such subjects as: Environment; Agriculture; Health; Trade, Food aid, Forestry, Fisheries, Customs, Intellectual Property Rights, Education, Industry, Civic Society and Consumers. They will be a National Biosafety Advisory Committee (NBAC) that will advise the decision making body on matters of biotechnology and Biosafety including trans-boundary movements of GMOs, modern biotechnology research and risk assessment. The law approves the appointment of a Registrar that shall co-ordinate all activities of the SEAB, NBAC, biotechnology promoters and the public.

3.3.3 Procedure for granting approval

The Act shall give to the SEAB powers to grant approval for any release of product of modern biotechnology to the environment. This will also include approval of any research activities on modern biotechnology, imports and export of GMOs and other products of modern biotechnology. All applications for the modern biotechnology activities will be approved by the SEAB under the advice of the NBAC.

3.3.4 Public awareness and transparency

There should be transparency when GMOs are introduced in the country for the first time. This would include the conducting of GMO related research work. The materials being forwarded to seek approval should be made available for public inspection and comment. The public will be invited through the print media to comment on applications and mandatory periods for commenting are stipulated in the act. The rights to appeal from any aggrieved party should include the applicant and all those who have made comments, observations, reservations and objections.

3.3.5 Labelling and identification of GMO products

All genetically modified organisms should be mandatory labelled. This will include imports, local products and food aid.

3.3.6 Risk assessment and risk management

The National Competent Authority on Biosafety shall ensure that appropriate and adequate risk assessments are carried out for all activities that require

authorisation. Risk assessment, including the auditing of risk assessments, shall be carried out in a scientifically sound manner, in accordance with the second schedule and recognised risk assessment techniques and shall take into account available information concerning any potential exposure to the GMO and such risk assessments shall be based on the information included in the application and any other available scientific evidence.

The National Biosafety Advisory Committee shall audit risk assessments submitted by the applicant and shall conduct or cause to be conducted any additional risk assessments as required on a case-by-case basis and in carrying out its risk assessment and auditing activities, it shall take into account any risk management measures proposed by the applicant and any additional risk management measures that may be necessary to minimize any identified risks.

Upon conclusion of the risk assessment and auditing process, the National Biosafety Advisory Committee shall provide to the Competent Authority a risk assessment report that gives its opinion, with justifications, on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the GMO. The National Authority on Biosafety shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control risks identified during the risk assessment process and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of GMOs on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

3.3.7 Liability and redress for damages attributed to release of GMOs

The new act addresses the damages caused by the release of GMOs to the environment, animal and public health. The law specifies that a person who imports, makes contained use of, releases or places on a market a GMO or a product of a GMO shall be liable for any harm caused by such GMO and to make compensation for any harm occasioned. It also states that where there has been

harm to the environment or biological diversity, the party liable to pay compensation, shall also pay costs of reinstatement, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventive measures. Where human health is adversely affected by a GMO or a product of a GMO, legal action shall be taken against the responsible party, and the resulting decision shall determine:

- the amount of medical expenses;
- compensation for any disability suffered;
- and compensation for loss of life, as the case may be.

In general, fines for breach of any of the laws for biosafety will be specified in the special regulations of the Bill.

PART IV

4.0 SYSTEM TO HANDLE NOTIFICATIOS AND REQUESTS FOR AUTHORIZATION.

4.1 Introduction

Swaziland, currently, does not have a specific authority to handle GMOs and GMO products. The proposed biosafety policy recommends that the Ministry of Tourism, Environment and communication, specifically the Swaziland Environment Authority (SEA), should be designated the national focal point to liaise with Cartagena Protocol secretariat. The Swaziland Environment Authority Board (SEAB) is also designated Competent National Authority to perform administrative functions under CPB. This decision was reached after several deliberations with relevant biotechnology and biosafety stakeholders. The SEAB is composed of senior government officers from key ministries that have a bearing on biotechnology and biosafety.

The Minister for Environment shall be the minister responsible for the administration of the National Biosafety framework. Figure 1 shows the administrative structure of the National Biosafety Framework. As can be seen from Figure 1, the Minister shall appoint the National Biosafety Advisory Committee that shall advise the Swaziland Environmental Authority Board on all matters of biotechnology and biosafety in the country. A biosafety office, that shall serve as the single point of entry for all applications will be created within the SEA. The office shall be manned by a biosafety registrar. The duties of the Registrar are stated below.

i. Receipt of all applications
ii. Checking all such applications for completeness of information
iii. Acknowledgement of all such applications
iv. Forwarding of applications to the NBAC

v. Maintaining a database of all applications as well as all modern biotechnology applications being run in the country, as well as all information relating to monitoring and evaluation
vi. Notification of decisions to applicants
vii. Serving as secretary to the NBAC
viii. Serve as a link with the Biosafety Clearing House

The procedure for handling GMOs and other products of modern biotechnology has been streamlined in the new proposed biosafety policy and legalised in the proposed biosafety Act. The description includes: procedures for handling applications for release & imports and procedures for handling notifications or requests for authorization.

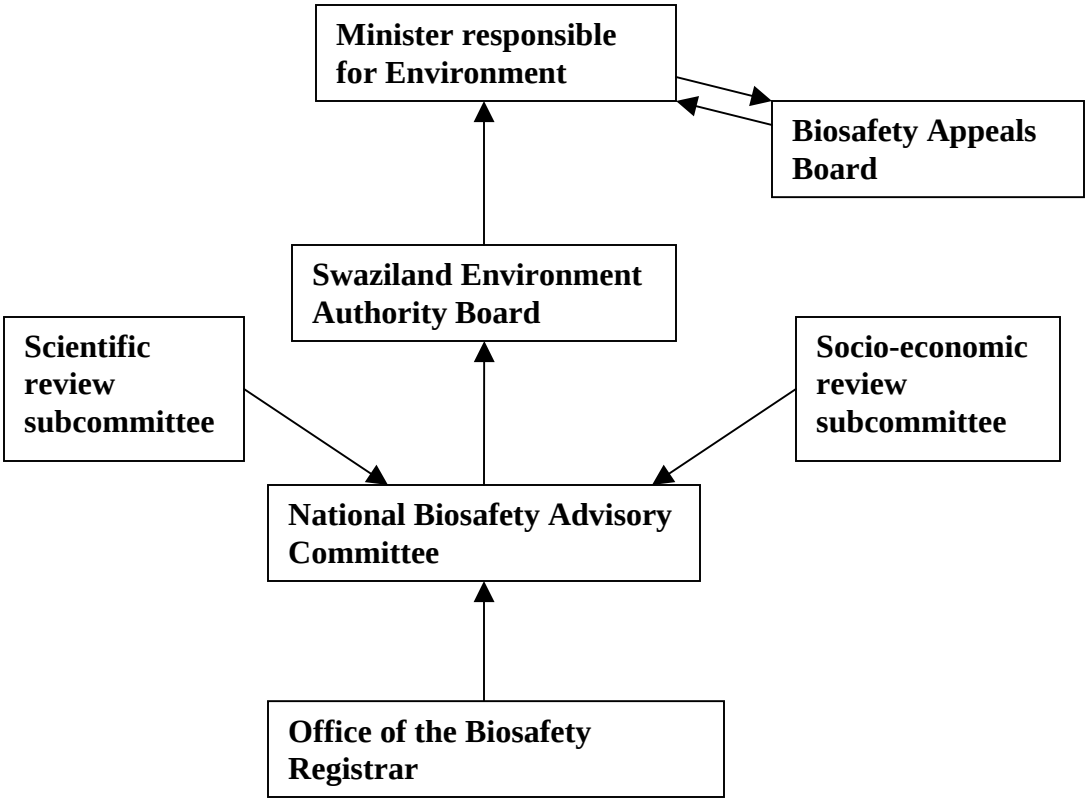

Figure1: Schematic representation of institutional arrangement for regulation of biotechnology

4.2 Procedure for handling applications.

The biosafety policy and Act proposes the procedure for handling applications as follows:

i. An application consisting of a letter signed by the legal person who make the request will be sent to the competent authority and be received by the Biosafety Registrar.
ii. The Biosafety Registrar shall receive, record and assign tracking number for application.
iii. Screening of application for completeness of information, both administrative and technical, will be done and if not complete, additional information will be requested from the applicant.
iv. Acknowledgement of application and notification of applicant that request complies with requirements will be done within 90 days.
v. The application or request will be sent to the NBAC for classification of the level of risk.
vi. Panel of experts selected to evaluate risk assessment carried out by the applicant; separate panel to consider socio-economic issues relating to the application considers application;
vii. Public notified through the print media and given opportunity to comment on application in writing within 60 days.
viii. NBAC makes recommendation based on input from recommendation of experts, socio-economic panel and public input and forwards it to decision-making panel.
ix. Biosafety Registrar notifies applicant of decision **together with all conditions that must be met** in the case of a positive decision as prescribed by the NBAC.
x. After permit or consent has been granted, and the activity has started, a system of monitoring and inspection begins.

4.3 National Competent Authority

The proposal to use SEA as Biosafety Focal Point and to use SEAB as the National Competent Authority is based on the fact that that the Swaziland Environment Authority, is already an established structure under specific legal enactment, thus it can be conveniently used in a coordinated way within the biosafety framework. As the biosafety focal point, SEA should house the office of the Biosafety registrar that will play a great role in the handling of applications and notifications.

Figure 2 below shows the handling of applications and notifications on introduction of GMOs. Figure 2: Proposed procedure for handling applications

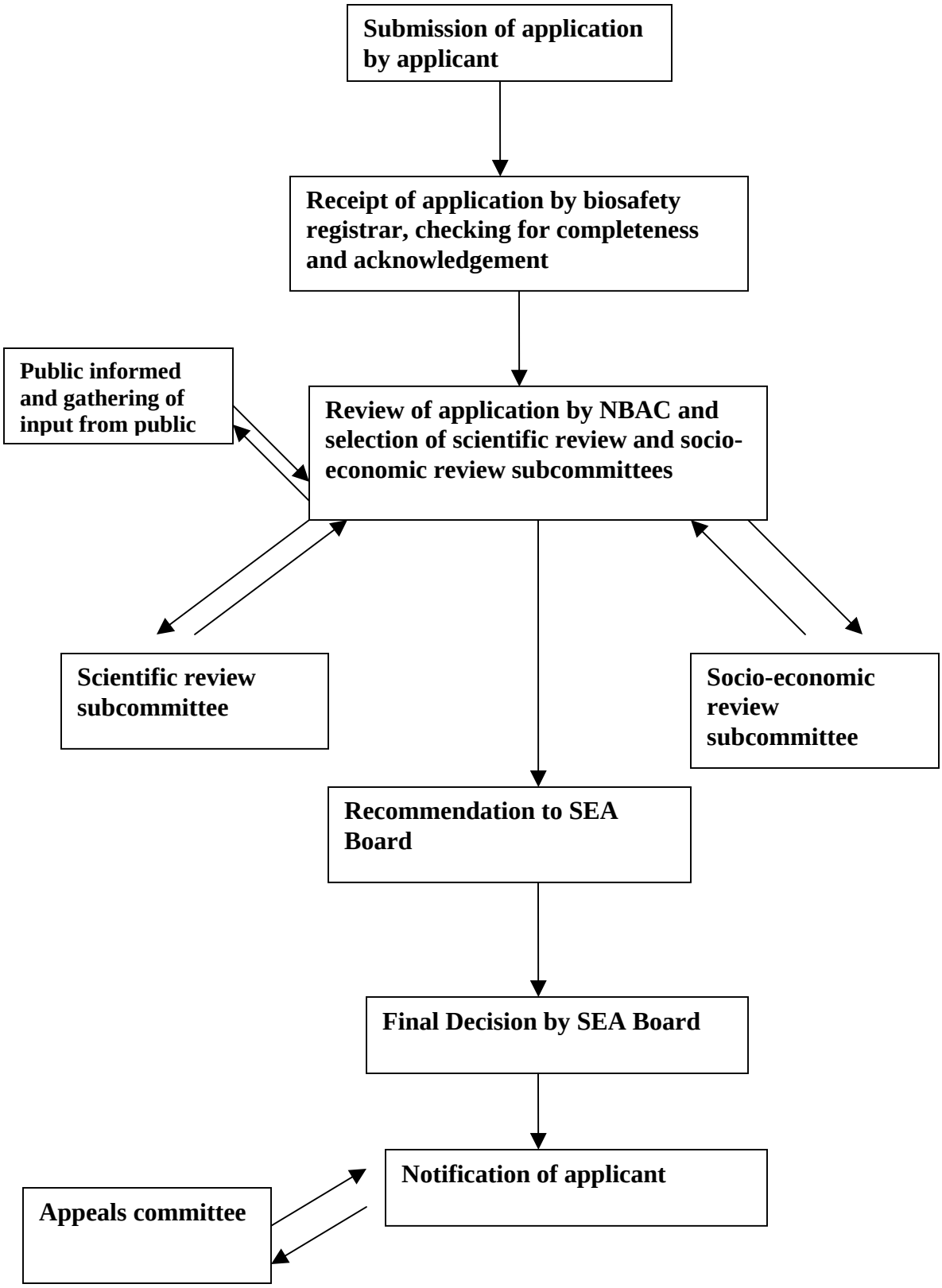

Figure 1: Proposed procedure for handling applications

In order to implement a system of concurrent approval, the SEA board that shall be acting as competent authority should be carefully reconstituted to include all stakeholder ministries. Representation of ministries in charge of the following subjects will be desirable: Environment; Agriculture; Health; Trade, Food aid, Forestry, Fisheries, Customs, Intellectual Property Rights, Education, Industry, Civic Society and Consumers.

Table 1 shows the composition of the current SEA board and the proposed SEA board once it has become National Competent Authority on Biosafety.

4.4. The decision making provisions

The decision making body shall follow the provisions outlined below as stated in the biotechnology and biosafety policy:

i. Whilst a positive decision based on scientific risk assessment can be overturned on the basis of socioeconomic risk, a negative decision based on scientific risk assessment **cannot** be overturned on the basis of socioeconomic gain or political pressure.

ii. The Government of Swaziland reserves the right to review her decisions as new information becomes available on the risks to public health, animal health and the environment.

iii. No LMOs will be released commercially before confined release is carried out.

iv. Where field trials have been approved, a separate application for commercial release must be lodged with the NBAC.

4.5 Time frame

According to the Cartagena Protocol, minimum periods within which particular steps in the procedure of receiving applications, risk assessment and evaluation, and decision making have been set. These should be done on a case by case basis. The Protocol state that the time allowed for the entire process from date of receipt of an application to notifying the decision to the applicant is 270 working days. As stated in section 4.2 above, the application shall be acknowledged with 90 working days of receipt by the registrar.

4.6. Cost recovery

It is stipulated in the biotechnology and biosafety policy that the entire cost from application to risk assessment and management should be borne by the applicant.

4.7. Public comments

According to article 23 of the Cartagena Protocol, the public are an important stakeholder in the introduction of GMOs in the environment. It is therefore obligatory that the public is consulted in the decision making process. The public in this case is to be understood to be referring to any Swazi person that may have an interest in the modern biotechnology subject that is at stake. All application shall be open to the public and the decision shall also be published once it has been conveyed to the applicant. The public shall be given 60 working days to comment on the application. The print Media shall be used to convey the notice to the public and the public will be expected to raise their objections or queries in writing to the National Competent Authority.

4.8. Procedure for handling appeals

The National Competent Authority upon receipt of recommendations from the national biosafety advisory committee may decide to allow or to conditionally allow, or to deny approval of an application. The applicant will be given the privilege to appeal if he is not satisfied with the decision. The minister shall appoint an appeals board that will communicate its recommendation to the national competent authority for a final decision.

4.9 Projects to be implemented

a). Establishment of a biosafety clearing house

b) Appointment of the registrar and biosafety committees

PART V

5.0. MONITORING AND ENFORCEMENT

5.1 Introduction.

The national biosafety system shall have a mechanism for monitoring, risk assessment surveillance and general inspection. Before products of modern biotechnology are introduced into the country, it must be ascertained that they will cause no harm to human health, animal health and the environment. Swaziland may not have sufficient laboratory facility to enable adequate assessment, but expertise from elsewhere could be exploited. External and local expertise should be judiciously exploited to regulate production, importation and monitoring of products of modern biotechnology that are imports or are on transit.

5.2 Monitoring and Inspection

In Swaziland, there are presently no monitoring and enforcement systems in place specifically for Biosafety. However, inspection of trans-border and consumer products is done for public health reasons. Monitoring for biosafety reasons may thus take precedence from this experience provided proper capacity building has been undertaken. For the purposes of biosafety, monitoring and inspection shall be used as tools to ensure that stakeholders concerns are addressed and that there is compliance with the biosafety legislation. An applicant who releases a product of modern biotechnology to the environment shall be obligated to monitor the effects of the product to the environment, human and animal health. Inspectors mandated by the competent authority shall enforce compliance with the biosafety legislations.

Monitoring and inspection will be done on food aid, imported feeds and foods, field trials, confined trials, pre and commercial releases of GM materials and live imports.

The National Competent Authority in collaboration with stakeholders shall prepare an elaborate monitoring plan. As stipulated in the Biotechnology and Biosafety Policy, monitoring and inspection of modern biotechnology products will be carried out at the following stages and points:

- Point of entry-
- Storage and handling
- Transportation and security
- Research laboratories
- Contained release facilities
- Field trials
- General release
- Post-release

The following types of monitoring shall be undertaken as the need arises:

- Case specific monitoring
- General surveillance monitoring
- Voluntary monitoring
- Experimentation monitoring
- Tracking and surveillance.

5.3 Personnel and Institutions for monitoring and Inspection.

The Environment and Management Act of 2002 empowers Swaziland Environment Authority (SEA), the designated Competent Authority, to appoint inspectors for enforcement of compliance to legal instruments. In this regards, the National Competent Authority shall appoint inspectors to ensure compliance with the regulatory regime. The inspectors will work with relevant statutory officers in enforcement of compliance as follows:

- At the border posts, they will work with Custom Officers to monitor trans – border movements imports and exports

- At dry ports and grain storage sites, they will works with supervisors from National Disaster Task Force to monitor food aid and imported grains.
- At seed depots, they will work with seed control laboratory technicians
- At research and trial stations, they will work with research supervisors.

As stated in the Biotechnology and Biosafety Policy, some capacity for regulatory procedures exists in the institutions listed below. Laboratory and personnel from these institutions can be used for analysis and detections of GM materials during monitoring and inspections:

- Ministry of Agriculture & Cooperatives (MOAC)
  - Agricultural Research Division
  - Animal Genetic Resources Unit
  - Central Veterinary Laboratory
  - Citrus Board
  - Cotton Board
  - Dairy Board
  - Forestry Section, National Herbarium
  - Fisheries Section
  - Meat Hygiene Laboratory
  - National Agricultural Marketing Board (NAMBOARD)
  - National Plant Genetic Resources Centre
  - Seed Quality Control Services
  - Swaziland Sugar Association
- Ministry of Tourism, Environment & Communication
  - Swaziland Environment Authority
- University of Swaziland
  - Department of Animal Health and Production
  - Department of Biological Sciences
  - Department of Crop Production
  - Department of Home Economics
  - Department of Chemistry

However, all of these need to be strengthened both in terms of human resources and infrastructure.

5.4 Risk Assessment.

The biosafety Act clearly states that risk assessment should be done on a case by case basis to all genetically modified organisms that are introduced to Swaziland. By definition it "refers to a process of evaluation including identification of the attendant uncertainties, of the likelihood and severity of an adverse effect or event occurring to man or the environment following exposure under defined condition to a risks". A risk assessment system comprises of hazard identification, hazard characterization, hazard characterization, exposure characterization and risk characterization. The competent authority on a case by case basis shall appoint risk assessment team.

5.5 Methodology for risk assessment.

The biosafety bill clearly states that the process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances. To fulfil its objective, risk assessment entails, as appropriate, the following steps-

(a) an identification of any novel genotypic and phenotypic characteristics associated with the genetically modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking into account also risks to human health;

(b) an evaluation of the likelihood of these adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) an evaluation of the consequences should these adverse effects be realised;

(d) an estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realised;

(e) a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the genetically modified organism in the receiving environment.

5.6 Risk Management

It is the process of measuring or evaluation of the risks and development strategies to manage the risk followed by monitoring and reviewing the risk mitigation measures. The evaluation includes the process of interpreting, comparing judging the significance of and deciding to tolerability of the risks that are identified and estimated during risks assessment. Another important component of risk management is development and evaluation of risk mitigation process. This is the process of identifying evaluating the efficacy and feasibility and selecting appropriate measures in order to reduce the risks associated with product of modern biotechnology. Once a risk assessment has been completed, proper decision on acceptance or rejection of the application, this is known as

implementation. If the risk assessment ends with a decision to approve the application, Monitoring should follow. This is a process of observing the consequences of introducing the technology to the environment. It includes conducting review of the risks assessment, mitigations, and risk management decision. The National Competent Authority will develop clear guidelines for both risk assessment and monitoring.

5.8 Priority project

a) **Development of Risk assessment and management guidelines**
b) **Development of monitoring guidelines**
c) **Capacity building on risk assessment and monitoring**

PART VI

6.0 MECHANISM FOR PROMOTING AND FACILITATING PUBLIC AWARENESS EDUCATION AND PARTICIPATION

6.1 Introduction

The Cartagena Protocol explicitly states that the public as a very important stakeholder in biotechnology and biosafety, must be informed on modern biotechnology matters. It is obligatory that the public must be consulted in the decision making process regarding GMOs in particular, and must be informed regarding the results of the decision making process. The national biotechnology and biosafety policy recognises this principle as it clearly states that 'it is essential that the public is provided with balanced information on biotechnology and its applications and further, that opportunity is provided for their input in decision making'.

Should all applications be opened to public comment? The proposed Biosafety Bill for Swaziland makes it mandatory that all applications should be opened to the public when products of modern biotechnology are introduced into the country for the first time. And also the decision should be published to the public once it has been conveyed to the applicant. When the public is notified about applications, they will be afforded opportunity to respond within 60 days before a decision is taken on the matter. This will ensure prevalence of a full transparent process.

6.1 Public Awareness

Several public awareness programs were conducted to educate the public on modern biotechnology benefits and potential risks. The NCC conducted a series of stakeholders' workshops in the four districts of the country. Stakeholders included extensions officers,

school inspectors, farmers, private companies, government officers, researchers, university teachers, senior government officers and Parliamentarians. Presentations were distributed in handouts, brochures, and posters. Some materials were presented in drama form.

A database of involvement of individuals and organizations in biotechnology and biosafety was created and this will be posted in SEA website. Additional details on guidelines and handling of applications will be posted in the SEA website. The public is understood as every Swazi person in the country with this understanding, several publications on biotechnology were released in the print media to rich the public.

6.3 Public Participation

In Swaziland information about requests and applications will be published in the news papers. Hard copies of the documents will also be made available to the public through libraries in the city councils, university campuses, government ministries or from the focal point.
Another public participation route will be direct interaction with the communities using: extension services in the rural development area centres; or public health promotion facilities in community health centres; community developer's facilities in the *tinkundla* (community centres).

A process of public notification that has been used successful by the Swaziland and Environment Authority when seeking for public comment in environmental impact assessment report is using the national libraries and newspapers. This arrangement is will be followed for public participation in handling of modern biotechnology request. In this case, the public will be given 60 days to respond to application and after a decision has been reached, those who had queries will be informed of the decision through the same avenues.

The Registrar's office will keep records of applications and objections including decisions taken by the Competent Authority. Registrar will keep records of all interested parties that had legitimate interest in handling of Biosafety matters. These will include NGO's consumer groups, environmental activities, farmers groups, seed and animal processors and distributors, research and university organizations.

6.4. Priority Projects

- **Improve development of public awareness materials**
- **Strengthen public awareness activities by conducting more workshops**

Annexes

a) The Draft Biotechnology and Biosafety Policy

b) The Biosafety