

***DRAFT NATIONAL BIOSAFETY FRAMEWORK FOR
LESOTHO***

January 2005

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1 INTRODUCTION

The rate of biotechnological development whether real or claimed success, and the diversity of the techniques employed in biotechnology have all tremendously altered the scope of possible solutions to today's most compelling societal problems and at the same time has raised a number of safety concerns. The concerns of the *scientific community*, *the biotechnology industry* and *the general public* over the use of biotechnological techniques have led many countries to drafting biosafety regulations in an effort to avert any foreseeable, unforeseeable and possible risks associated with the applications of biotechnology. The constitution of a biosafety system is important in advancing the development of biotechnology, ensures a country's access to biotechnology products generated elsewhere and allows development agencies and private companies to invest in biotechnology in a particular country. At present and in so many developing countries, it is generally agreed that the technology is simply unavoidable and that ignoring it now will deal a severe blow to the future prosperity of science, industry and international trade.

Biotechnology, particularly genetic engineering may be one of the most important ways in which many developing countries can add value to their biological diversity and solve some looming and inevitable population pressures. The excitement over biotechnology and the multiplicity of the number of interested stakeholders have all compounded the discussion over the relevance, necessity, safety and utility of modern biotechnology. There is therefore a need to sift through and resolve real and hypothetical suspicions about the technology.

Regarding the planned introduction into the environment of GMOs, eminent scientists strongly believe that there is enough knowledge of the relevant scientific techniques and experience with genetic engineering and GMOs to act as a reference point for the safe introduction of such organisms into the environment (outside the research laboratories). Moreover, they further argue, that there is no evidence so far of the existence of, (i) extreme, unimagined and unmanageable dangers associated either with the techniques

used in modern biotechnology and their resultant products or in the transfer of genes between organisms and, (ii) of differences in the magnitude and type of risks emanating from the introduction of GMOs on the one hand and of unmodified organisms on the other hand into the environment (Committee on the introduction of genetically engineered organisms into the environment, 1987). In formulating policy, guidelines and regulation on biosafety a number of factors have to be considered in the context of the body of relevant information and experience accumulated so far. It should be very apparent that in order for the biosafety regulations to be successfully implemented there is a need for capacity building in the areas of drafting the regulation, implementation of the regulations, risk assessment and management

In recognition of the above facts, the draft National Biosafety Frameworks in this document seek to provide appropriate regulatory measures to assist all stakeholders in the establishment and maintenance of national and institutional capacities to provide for safety in biotechnology, development of human resources and efficient exchange of information.

2 BACKGROUND

In 1992 the nations of the world met at the United Nations Conference on Environment and Development (UNCED) to work out the strategies that would make them realise their dream. The direct result of the Conference was the development and adoption of Agenda 21 and Convention of Biological Diversity (CBD). As one of the countries that were represented at the Conference, Lesotho now has both the duty and moral obligation to fulfil her commitments. Both Agenda 21 and CBD recognise that biotechnology is important for the attainment of conservation and sustainable use of biological diversity, particularly in improving agriculture, environmental protection and in health care.

To facilitate the implementation of the aforementioned objectives, Lesotho participated in the negotiation and drafting of the Cartagena Protocol on Biosafety (CPB) with specific focus on transboundary movement of any LMOs resulting from modern biotechnology that may have adverse effects on the conservation and use of biodiversity and the adoption of appropriate procedure for Advance Informed Agreement (AIA). Lesotho signed the CPB on September 2001.

Lesotho has undertaken several initiatives and responses towards establishment of a National Biosafety System. Milestones include establishment of the National Coordinating Committee (NCC) which is in the process of formulating policies and guidelines governing biotechnology. Four baseline surveys have been conducted, with several workshops, training programs, consultative meetings and public lectures to solicit comments from stakeholders to be used for the formulation of the framework. A database of biosafety professionals has been established and continues to be updated who will be used in the implementation of the framework. Finally, a national biosafety clearing house website has been developed which will act as a national biosafety hub on biosafety issues.

Justification and a basis for Lesotho to develop state-of-the-art biosafety frameworks within the international and regional context are in line with the following: a) The Johannesburg Plan of Implementation. b) The Rio Declaration on Environment and Development: c) The Convention on Biological Diversity (CBD) d) The Universal Declaration On Human rights: e) the Aarhus Convention on Access to Information, Public participation in decision-making and Access to Justice in Environmental Matters, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, f) Organization of African Unity Model Law on the institution of a Biosafety System and g) SADC's interim guidelines on Biotechnology and Biosafety.

Establishment of biosafety frameworks also supports Lesotho's national priorities and goals which focus on enhancing economic growth, poverty reduction, and improvement of human resources, deepening democracy, peace and stability.

Existing legislation

Existing legislation does not cover the core issues of the CPB as related to biotechnology or a body of techniques that utilize biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use. Since existing legislation is inadequate to enable proper and sustainable decision-making on the safe transfer, handling and use of LMOs in Lesotho, as per the guidance from the Cartagena protocol, a new specific legislation is needed for Lesotho. This will also ascertain safety by assessing, evaluating and managing potential detrimental impacts associated with LMOs and empower the stakeholders to voice their concerns and aspirations on LMO related matters. Also, sustainable use of LMOs will be ensured and relevant institutions and expertise will be improved.

Institutional structures

Institutional structures have been established, they consist of a) the National Executive Agency (National Environment Secretariat) tasked with ascertaining the efficient operation of the NBF project; b) a multi-disciplinary and multi-sectoral National Coordinating Committee consisting of representatives from both government and the

private sector. The committee manages the NBF project; c) the National Project Coordinator who is responsible for management, coordination and overseeing the NBF project; d) Focal points and e) Competent Authorities. There are two focal points in place, namely: the National Focal point for the Cartagena Protocol (Ministry of Environment, National Environment Secretariat – The Director’s office) and the Focal point for the biosafety clearing house (Ministry of Environment - National Environment Secretariat, Data Section). The Competent authority (ies) is the Ministry of Agriculture for agricultural LMOs and the Ministry of Health for health related LMOs.

Technical structures

In addition to institutional structures, Lesotho also has technical structures which can be useful for biosafety matters consisting of a) Laboratories particularly within the National University of Lesotho, Agricultural Research, Livestock and Health Research and Laboratory Services (Queen II Hospital). Generally, these laboratories are likely to require upgrading. b) Green houses found at NUL and Agricultural Research. c) Field tests are conducted by Agricultural Research while clinical tests are conducted by Health Research and Laboratory Services. Unfortunately, according to the results of the survey quarantine facilities are non-existent.

Research activities, human resources and related issues

On the basis of the above findings Lesotho generally needs to institute mechanisms to undertake the key activities for safe handling, use and transfer of LMOs and safe Research and Development of LMOs: contained use, deliberate release into the environment as well as into the market.

Regarding research activities, Agricultural Research is the only institution engaged in various research activities focusing on mass propagation of sweet potato; virus control of potatoes; germ plasma characterization of plants/crops; screening disease tolerance/resistance in plants and high yield in maize, sorghum wheat, beans, peas, and vegetables; improving grain quality in maize; phytosanitary services for grains; drought tolerance of maize and sorghum and control of various animal diseases.

Coming to human resources, Lesotho has sufficient numbers of individuals to constitute a biosafety committee that is capable of a) managing biosafety; b) developing national regulatory framework; c) make competent decisions on matters relating to notifications and other matters related to living modified organisms; d) raise public awareness and improve information flow to the public on the issues involved around the release of LMOs; undertake risk assessment and risk management. These individuals, however, will require specific training in various areas as outlined within the section dealing with capacity building.

In order to fulfil Lesotho's obligations under the CPB with the assistance of the UNEP-GEF Development of the National Biosafety Frameworks Project, Lesotho is developing and putting together its National Biosafety Frameworks as follows

3 NATIONAL BIOSAFETY POLICY

Lesotho's national priorities are found within several key documents which are all guided by the National development goals for 2002-2006 which place emphasis *on enhancing economic growth, poverty reduction, and improvement of human resources, deepening democracy, peace and stability*. In line with these aspirations, Lesotho has embarked upon several strategic initiatives in an attempt to improve the quality of life for its citizens under three major processes: the domestication of the Millennium Development Goals (MDGs), the formulation of a National Vision (Vision 2020) and the drafting of the Poverty Reduction Strategy Paper (PRSP). These initiatives echo one major priority: *poverty eradication and employment creation*. Biotechnology can contribute towards two MDGs: eradication of extreme poverty and hunger; and ensuring environmental sustainability, integration of sustainable development principles into country policies and programmes and reverse the loss of environmental resources. In a similar manner employment creation, food security and environmental conservation (protection and conservation of the environment and the natural resource base - *enhancing environmental health and safety*) as per the stipulations of the PRSP can also be partially met through the safe use of biotechnology.

The National Vision declares the aspiration of the country in terms of employment creation, and it goes further and pinpoints the need for a well-established technology. Technology development is envisaged as a tool to fuel mechanisms towards "empowerment and security for sustainable prosperity", and to bring to pass the vision statement which asserts that: "*By 2020, Lesotho shall be a stable democracy, united, prosperous nation at peace with itself and its neighbors. It shall have a healthy and well-developed human resource base. Its economy will be strong, its environment well managed and its **technology well-established.***"

The Science and Technology Department within the Ministry Of Communications, Science and Technology has developed a draft policy (Lesotho Science and Technology

Policy 2003-2008) which does not address biotechnology and biosafety, it only covers environment, wildlife and tourism in general with no specific goals and strategies for biosafety and biotechnology. So it is clear that Lesotho need a biosafety policy.

3.1 ELEMENTS THAT SHOULD BE CONTAINED IN A POLICY

Adequate policy framework should at least have elements specified below.

- **Objectives:** encompassing national needs and priorities, customs and aspirations, ethics, capacity, economic needs, international obligations, transboundary movements, liability and redress, public involvement
- **Scope:** describing the activities and organisms covered
- **Responsible Ministry or Ministries** for implementation and a specified government department or agency
- **Advisory Bodies** to advise on technical aspect of technical decisions
- **General prohibition** on activities involving LMOs unless authorization/license or other approval has been obtained
- **System of permits or authorizations** for activities involving LMOs
- **Exemptions** or simplified procedure for fast tracking processes for low-risk LMOs
- **Public information and consultation system** on permit applications and policy issues
- Protection of **confidential commercial information**
- **Risk assessment procedure and risk assessment criteria**
- **Risk management conditions** (e.g. labeling and marking requirements)
- **Monitoring and inspection**
- **Liability for damage**

The above can be categorized into **administrative tasks, legal requirements** and **procedural requirements**. The conclusion is that there are ***no*** tools at the moment to enable proper and sustainable decision-making on the safe transfer handling and use of

LMOs in Lesotho. Lesotho as a signatory to the Cartagena Protocol on Biosafety needs to institute measures to enable informed decision- making on issues related to importing and using of LMOs. This will also ascertain safety by assessing, evaluating and managing potential detrimental impacts associated with LMOs and empower the stakeholders to voice their concerns and aspirations on LMO related matters. Also, the sustainable use of LMOs will be ensured and relevant institutions and expertise will be improved.

Attached to this document is the draft National Biosafety Policy for Lesotho which was drafted and structured based on the elements above (**Attachment 1**).

The Mission of the National Biosafety Policy is to assist Lesotho to meet its national priority goals and its international obligation by a) developing technologies that will address the issues of sustainable development, wealth creation, poverty and disease eradication, human development, food security, rural and social balance and gender equality, b) developing precautionary measures regarding production and application of biotechnology whose possible harmful side effects are unknown, but which may have undesirable side effects impacting on humans and biodiversity in general, and c) developing Lesotho's own capacities related to biotechnology and biosafety through Research and Development (R and D) for informed decision making

The Goal of this policy is to “safely use biotechnology in order to protect human health and ensure the well-being of the environment, while maximizing the benefits from biotechnology”.

The main objectives of the policy are to a) guide the judicious use of modern biotechnology in Lesotho for sustainable development, in ways which do not in any way jeopardize human and environmental health including Lesotho's biodiversity and genetic resources, b) ensure effective control of trans-boundary movements of genetically modified organisms or products thereof resulting from modern biotechnology, through the exchange of information and a scientifically based, transparent system of Advance

Informed Agreement, c) develop human resource and institutional development so that Lesotho can make an informed decision on the applications, d) guide the Lesotho Government to form structures and laws to manage biotechnology and biosafety issues in the country, e) create public awareness and understanding of biotechnology and biosafety, so that public opinion is incorporated at all levels of decision making regarding the use and application of biotechnology, f) enhance research and development in order to develop country specific products and applications that would enhance the socio-economic and environmental well being of Lesotho, g) provide an institutional framework for national decision-making and international cooperation in this area, h) ensure that decision-making concerning advance approval is based on high level expertise, scientific risk assessment and precaution.

The scope of the policy covers in details a) laboratory and field applications of biotechnology within Lesotho, whether currently known to science or those to be developed in future, b) the field of agriculture, human and veterinary medicine, food/beverage production, industry, environment management, industrial and domestic wastes, and other fields of current future application, c) the regulation process including notification, testing, information transfer and review, risk assessment including socio-economic impact and ethical considerations. Monitoring and enforcement measures pertaining to import and export of the products of biotechnology or laboratory or field use of biotechnology in Lesotho, including safe handling, disposal; contamination, control, monitoring and release, e) the biotechnology, research and development process, including academic, medical research, agricultural, industrial and other research, f) occupational safety at workplaces, where biotechnology procedures are used or biotechnology commodities are handled, g) any other measures to ensure public health and environmental safety with respect to the use of biotechnology in Lesotho, h) public participation and awareness in the fields of biotechnology and biosafety, and i) include other pharmaceuticals that are not covered by other international agreements or organizations.

It also contains an implementation strategy which has institutional arrangement both in the interim and for the permanent arrangement. Under this section the administrative arrangements are explained, these would assist in the implementation of the **policy** and the **law** (this will be explained in the coming sections).

4 NATIONAL BIOSAFETY LAW

Requirements for protecting the environment and health of the Basotho people are entrenched within several legal instruments in Lesotho. These are listed below:

a) The Constitution: Environmental protection is entrenched in the Constitution of Lesotho, Section 36 which declares that “Lesotho shall adopt policies designed to protect the environment of Lesotho for the benefit of both the present and future generations and shall endeavor to assure all citizens a *“sound and safe environment adequate for their health and well-being”*.” The Development of Biosafety framework is in line with the requirements of the Constitution.

b) The Environment Act: Sections 66, 67, 68 and 69 addresses issues of Conservation of biological diversity while subsequent sections cover various aspects of environmental management. The Act does not deal specifically with issues of biosafety.

c) Environment Act (Act 15 of 2001): The Act focuses on pollution control and has sections dealing with prohibition of discharge of hazardous substances, chemicals and materials or oil into the environment and the spiller liability; it has a section for conservation of biological safety. The Act (section 75) states that the Authority, shall in consultation with the relevant line Ministry:

- I) Identify materials and processes that are dangerous to human health and the environment
- II) Issue guidelines and prescribe measures for the management of materials and processes identified

Under section 66 the Act deals with Conservation of biological diversity and stipulates that “the authority shall in consultation with the relevant Line Ministry, issue guidelines and prescribe measures for the conservation of biological diversity”. These sections do

not cover all the criteria and issues of biosafety as per the requirements of the Cartagena protocol on biosafety.

d) Customs Act No. 10 of 1982: Provides for levying of Customs, Exercise and Sales Duties and surcharge, the prohibition and control of the importation, export or manufacture of certain goods and for matter incidental thereto and connected therewith. The Act is also not specific to the biosafety issues.

e) Dangerous Medicine Act No 21 of 1973: Provides for regulation of importation, exportation, production, disposal and control of habit forming medicines and potentially harmful medicines; also provides for the prohibition of the dealing in, and the use or possession of dependence-producing medicines in relation to certain acts in connection to such medicines; the establishment of rehabilitation centers and to provide for related and incidental matters.

These Acts do not cover the core issues of the CPB as related to biosafety or a body of techniques that utilize biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use. All these Acts are very old, except for the Environment Act and since they do not say anything about core issues of biosafety they are inadequate and a new specific legislation is needed.

Since existing legislation is inadequate to enable proper and sustainable decision-making on the safe transfer, handling and use of LMOs in Lesotho, the country as per the guidance from the CPB needs a new specific legislation for biosafety. This will also ascertain safety by assessing, evaluating and managing potential detrimental impacts associated with LMOs and empower the stakeholders to voice their concerns and aspirations on LMO related matters. Also, sustainable use of LMOs will be ensured and relevant institutions and expertise will be improved.

From the draft National Biosafety Policy a National Biosafety Bill was developed (please check Attachment 2 for the Bill). The Bill would be administered by Ministry

responsible for Environment as both the Competent Authority and the Focal Point. The Bill would establish the **National Biosafety Council (NBC)**, whose members shall be appointed by the Minister responsible for Environment. According to the Bill only the Ministry responsible for Environment would be a Competent Authority.

The **NBC** shall consist of seven members from different ministries and others from the Civil Society Organizations. The main function of the Council is to make recommendations for the Minister responsible for Environment who is responsible for decision making. The recommendations are made based on scientific risk assessment, socio-economic considerations, ethics and public concerns.

The Bill also establishes a National Biosafety Council Registrar (NBCR) within the Competent Authority. The Registrar is answerable to the Competent Authority for discharge of duties under the Bill.

The main functions of a Registrar are to assess for regulatory compliance and may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by the Bill.

For the purpose of doing Scientific Risk Assessments a Scientific Advisory Committee (SAC) shall be established which shall serve as an advisory body to the NBC on scientific and technical issues and shall be appointed by the Minister (Environment). Members of the Committee shall be knowledgeable in the fields of science applicable to the development and release of GMOs at hand. Other functions of the Committee can be seen in the Bill in Attachment 2.

The Socio-economic Panel may be formed in accordance with the requirements of this Bill. The Bill also describes application requirements (for different GMO applications e.g. Contained and Confined Use, for Introduction into the Environment, and for Direct Use as Food, Feed, or Processing) and approvals. Risk assessment and Risk management

procedures are also described. Review mechanisms and decision making procedure are clearly shown in the Bill.

The Competent Authority, the NBC, the NBCR, the SAC and the Socio-economic Panel shall protect information determined by the Competent Authority as being confidential, after a claim for confidentiality is made by the applicant. Other important sections of this Act are Liability and Redress, Offences and Penalties, and Enforcement which include Inspections.

5 SYSTEM FOR HANDLING REQUESTS: RISK ASSESSMENT, DECISION MAKING ETC. (ADMINISTRATIVE FRAMEWORK)

A sound national institutional framework is necessary to coordinate, regulate and enforce biosafety matters in the country. The institution responsible for biosafety should have the legal authority and shall ensure that biosafety is approached in a holistic manner to maintain its effective cross-sectoral nature.

Administrative processes include *notification, information transfer and review, risk assessment, approval or refusal, risk management*, including monitoring and enforcement measures pertaining to laboratory use, research and development activities, or field release procedures including handling, containment, monitoring, agreed disposal or destruction procedures, and contingency plans for spillage or accidental release.

Nationally various government departments that can directly be involved with LMOs and biosafety issues have been identified. These ministries have working structures that can be modified to incorporate biosafety issues particularly in the areas of monitoring, evaluation, analysis and testing. These departments include:

- Ministry of Agriculture and Food Security
- Ministry of Trade, and Industry.
- Food and Nutrition Coordination Office
- Disaster Management Authority
- Food and Management Unit
- Ministry Tourism, Environment and Culture
- Lesotho Revenue Authority
- Ministry Of Health and Social Welfare to deal with medical biotechnology products and their safety

5.1 PROPOSED ADMINISTRATIVE FRAMEWORK FOR LESOTHO

There will be a single entry point for applications, whether for GM plants, animals and micro-organisms. There will also be a biosafety administration (office) for processing of applications which will consist of National Biosafety Council Registrar (NBCR) and a number of assistants that may be necessary. The NBCR will perform the following duties a) receive and screen completeness of a GMO application for submission to the Council; where an approval has been given, issue a permit b) where he/she has ascertained or suspects on reasonable grounds that GMOs are being imported or locally produced or used contrary to the provisions of the Biosafety Act or the conditions of an issued permit; serve a notice upon any person by whom or on whose behalf GMOs are being imported into, produced or used within the country for removal of such GMOs to a place or facility and in a manner prescribed by the Competent Authority, c) authorize an inspector to destroy such GMO or cause it to be destroyed, subject to procedures and other provisions as set out in the Biosafety Act or regulations made under the Biosafety Act; d) amend or withdraw a permit issued under the Biosafety Act; e) furnish an inspector with a certificate of appointment; f) require the cessation of any genetic modification activity at facilities where the provisions of the Biosafety Act or the conditions of a permit have not been or are not being complied with; g) ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the environment from hazards; i) promote public awareness and education concerning the activities regulated under the Biosafety Act and to coordinate public participation; and h) serve as secretary of the Council

There will be two different procedures to follow, in *the interim* and *after both the Biosafety Policy and the Biosafety Act have been approved*.

5.1.1. INTERIM ARRANGEMENT

Presently, the Ministry of Tourism, Environment and Culture (MTEC) through the Department of Environment is the Focal Point for notifications while the Competent Authorities are the Ministries of Agriculture and Food Security and Ministry of Health and Social Welfare. Thus the Focal Point and Competent Authorities will perform all duties assigned to those offices by the CBD Secretariat.

Applications for the movement of LMOs (LMOs as defined in the CPB) into Lesotho shall be based on the Advance Informed Agreement. Notification shall cover import, export, research and development activities. For import, notification should be prior to the first intentional transboundary movement for all LMOs that fall within the scope of the CPB and should address the relevant information contained in the annex 3 and 4 of the Draft National Biosafety Policy. Notifications should be sent to Lesotho Focal Point (Ministry of Tourism, Environment and Culture through the Department of Environment), the details can be found on the Biosafety-Clearing-House (BCH). The Party of export shall ensure that legal requirements for the accuracy of information provided by the exporter are met.

Acknowledgement of notification shall be made in accordance with the CPB procedures and time frames. Failure by the Focal Point to acknowledge receipt of notification shall not imply its consent to an intentional release or transboundary movement of LMOs. The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical concerns.

The National Coordinating Committee (NCC) which was formed in line with the UNEP-GEF NBF project would be used as Interim Technical Review and Advisory Body. Applications to use biotechnology products or procedures shall be processed by the NCC, which shall consult international and/or local experts as required to reach sound decisions on the desirability and risks of all applications. The NCC directly advises the Minister of Environment on decisions pertaining to applications, through Director Department of

Environment who is a member and the chair of the NCC. The permit to research and develop LMOs, import and release of LMOs for whatever purpose shall be made by the Minister responsible for Environment based on the advice from the NCC.

The decision would be on case by case basis. Decision making procedure shall cover field trials, releases for domestic use as food or feed, for processing, and placing in the market of an LMO. The decision may be reviewed by the NCC based on the new information on adverse effects on conservation and sustainable use of biological diversity, also taking into consideration the risks to human health. The applicant in consultation with the focal point shall take steps to inform the public about applications, so that when the NCC makes a decision the public comments are incorporated. An applicant, notifier, or exporter may request for review of the decision taken by the appropriate agency under the following conditions, i) a change in a piece of relevant information or, ii) other circumstance has become available.

5.1.2. Permanent Arrangement/Structure

The Department of Environment would be designated as the Competent Authority for the purpose of the administration of the Biosafety Law. The Competent Authority shall also serve as a National Focal Point for liaison with the Convention on Biological Diversity (CBD) Secretariat and the Biosafety-Clearing-House of the Cartagena Protocol on Biosafety (CPB) and for facilitating the exchange of information among the relevant bodies and authorities.

When legislation is in place, there will be a single entry point for applications, whether for GM plants, animals and micro-organisms, and a permanent advisory body shall be established which would be known as **National Biosafety Council (NBC)**. It will consist of 7 members; 2 members nominated by the Minister responsible for Environment as both The Focal Point and The Competent Authority based on the expertise required (from the civil society organizations), and 5 ex-officio members, coming from 5 key Ministries which are:

- Ministry responsible for Environment
- Ministry responsible for Agriculture and Food Security
- Ministry responsible for Health
- Ministry responsible for Trade and Industry
- Ministry responsible for Science and Technology

The NBC would be provided with all necessary powers to facilitate implementation of the National Biosafety Policy through the following functions a) advise the Government of Lesotho on National Biosafety Policy, linkages with other sectoral policies and programmes and the modalities of their implementation, b) identify priorities of scientific and technological research that can assist Lesotho to meet its national and international goals and priorities, d) serve as advisor and co-ordinator of sectoral activities that involves biotechnology and biosafety, including sectoral ministries, NGOs and private organizations, e) ensure the integration of safe application of biotechnology in the national development planning and policy formulation in liaison with line ministries, f) promote cooperation among Government Departments, Local Authorities, Private Sectors, Non-Governmental Organizations and other organizations for safe application of biotechnology, g) promote cooperation and information exchange in biotechnology and biosafety with similar bodies in other countries and with international bodies concerned with safe application of biotechnology, h) provide guidance and advice on biosafety for the carrying out of risk assessments, i) chairperson of the NBC shall advice the Minister responsible for Environment directly, j) recommend measures necessary for the harmonization of the plans and policies of various sectors that are involved in safe application of biotechnology.

National Biosafety Council Registrar's (NBCR) office would be established within the Competent Authority in accordance with the Biosafety Law. This office shall be administered by a Registrar who shall be a public officer, and would be answerable to the Competent Authority. The Registrar would receive and screen Notifications/Applications for completeness before submission to the National Biosafety Council, and where an

approval has been given, issue a permit required. Acknowledgement of Notification shall be made in accordance with the Biosafety Law. The office of the Registrar is responsible for any other regulatory compliance in accordance with Biosafety Law

Because decision-making procedures shall take into consideration risk assessment, the NBC shall appoint a team of experts, which will serve as the Scientific Advisory Committee (SAC) which shall serve as an advisory body to the NBC on scientific and technical issues and shall be appointed by the Minister in consultation with the Council from time to time on the basis of expertise required to review a specific GMO. The SAC shall carry out Risk Assessment procedures in accordance with the Biosafety Law

From time to time a Socio-economic Panel would be established which shall serve as an advisory body on socio-economic issues concerning the proposed application or use of GMOs and shall be appointed by the Minister from time to time whenever is necessary.

The permit to research and develop, import and release of LMOs for whatever purpose, shall be made by the Minister responsible for Environment based on the advice from the NBC. The NBC make their recommendations based on the SAC recommendation report, the public comments, socio-economic panel and the National Biosafety Policy.

5.2 RISK ASSESSMENT

Risk Assessment shall take into consideration precautionary approach. Where the transboundary movement, use or handling of GMOs or products thereof may cause, or has a proven or theoretical potential to cause harm to biodiversity, ecosystem, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk. The risk assessment should take into account, all relevant scientific theory, evidence and experience, including previous risk assessments.

If the risk cannot be minimized or managed using risk management strategies, it may be concluded that the intended operation should not proceed, or a risk/benefit analysis might be carried out to determine whether a higher level of risk is acceptable and whether the intended operations should proceed. All costs of risk assessment and other administrative charges shall be borne by the applicant.

The Council shall evaluate or cause the evaluation of the risk assessment and consider the result of such an evaluation in making decision on any application to import, transit, make, confined use, release or place on the market of a GMO based on Scientific Advisory Committee risk assessment recommendation report. Where the evaluation of the assessment shows that the risk cannot be avoided, the Council shall refuse approval for the import, transit, contained or confined use, release or placing on the market of a GMO.

5.3 RISK MANAGEMENT

The type of risk management procedure to be adopted will depend on the GMO and the particular application. The Council shall impose such measures, as may be necessary, to avoid adverse effects on the environment, biological diversity, human health and on the socio-economic conditions arising from a GMO.

If the Council see fit it may,

- Subject any GMO to undergo a period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before it is put to its intended use;
- Prohibit the import, transit, contained or confined use, release or place on the market of any GMOs, if it is satisfied that it contains characteristics or specific traits which pose unacceptable risks to the environment, biological diversity, or to health;

- Order the cessation of any activity involving GMOs that are proven to cause risks to the environment, biological diversity or health;
- Order the cessation of any activity, which is being undertaken in violation of the Biosafety Bill or any decisions, made under the Bill;
- Require the person responsible for any activity under the Biosafety Bill, to take such measures as may be necessary to prevent or limit any harm to the environment, biological diversity or health or to restore the environment to its previous state as far as feasible;
- Undertake measures, as necessary, at the cost of the person responsible for any activity involving a GMO, in the event that such person fails to undertake safety measures to which the Competent Authority has issued notification;
- Take measures, as necessary, in the case of imminent and serious danger to the environment, biological diversity or health caused by a GMO at the cost of the person responsible for causing such danger, and
- Require the applicant to submit reports periodically in respect of the monitoring and evaluation of risks carried out after approval of the import, contained or confined use, release or placing on the market of a GMO.

Appropriate risk management measures for releases will vary considerably from case to case. They will be determined by the risk assessment, the organisms involved and the method of release. In addition to general precautions to control release, risk management measures often focus on the control of the dissemination of the released organisms and control of the gene flow from the released organism

Risk Management procedure would form part of the permit requirements that must be adhered to for compliance.

6. MONITORING AND EVALUATIONS (FOLLOW UP ACTIONS)

Monitoring in biotechnology has different meanings and interpretations depending on who is involved. For the purpose of these drafts, monitoring will be defined in two ways, firstly, monitoring can be done to check compliance to the Biosafety Law or to the permit and this will be referred to as **Inspection, (this is usually done by regulators)**. Secondly, monitoring can be the measure and comparison of factors (e.g. monitoring of a new plant varieties for relative performance) and is a normal component of all stages of research and development, this will be referred to as **Monitoring, (usually done by the applicant but can also be ordered by a regulator)**.

6.1 INSPECTION

In the interim inspectors from Customs, Environmental Health, Agriculture and Trade would be trained in biosafety so as to include biosafety inspection as part of their every day duties. Due to level of work load that this inspectors have the Biosafety policy and the biosafety Law provide for getting biosafety specific inspectors.

The Biosafety Law would provide for methods of ensuring compliance, this would be facilitated by appointed qualified inspectors. These inspectors shall be furnished with certificates signed by the Registrar, stating that they have been appointed as inspectors under Biosafety Law, and at the request of any person affected by the exercise or performance of duties by such inspectors, they shall exhibit this certificate to such a person. Inspectors may, conduct an investigation to determine whether the provisions of the Biosafety Act and of a permit are being or have been complied with. Inspectors are given power to enter any place or facility during normal working hours and without giving prior notice. They can also inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in the Biosafety Law or permits, can request any information regarding such an activity or process from the

owner or person in charge of the carrying out of such activities. They are given powers to seize any appliance, book, statement or document and take samples of material or substances which appear to provide proof of a contravention of any provision of permit; and give notice to the owner of any material, substance, appliance, book, statement or document seized or to the person who had control over it immediately before any seizure to remove the seized items at such person's cost within a period and to a place specified in such notice.

6.2 ROUTINE INSPECTION

An inspector may during office hours, without warrant, enter any place or facility registered in terms of the Biosafety Law in order to, a) open any container found in or upon such place or facility and which the inspector believes on reasonable grounds to contain material of any GMO ; b) examine the material of any GMO and take samples thereof; c) inspect any activity or process carried out in or upon the place or facility in connection with the GMO; and d) require the owner or occupier thereof to produce for inspection or for the purpose of obtaining copies or extracts from any book, label, or other document with respect to the administration of the Biosafety Law.

6.3 MONITORING

Monitoring programs is usually associated with field-test releases of genetically modified organisms which are done as part of risk management schemes, but a developer through out the stage of GMO development device monitoring programs for performance evaluations. Monitoring programs fall into three categories, Experimentation, Tracking and Surveillance.

Biosafety Law for provision of additional information, it is through this part of the law that monitoring can be ordered and this law also provide for inclusion of permit provisions that can include monitoring. This excises is done by the developer but can be inspected from time to time by biosafety inspectors.

7. PUBLIC PARTICIPATION

Since the 1992 Earth Summit in Rio de Janeiro, the inclusion of requirements of public participation in international conventions and agreements has become almost a matter of course. Principle 10 of the Rio Declaration states that environmental issues “are best handled with the participation of all concerned citizens”. Public participation is an important mechanism for ensuring that the strategy or policy process is nationally owned and is appropriate and relevant to the specific national or local context.

Promotion and facilitation of public awareness and participation on matters relating to biosafety is important for countries to fulfill their obligations under Article 23 of the Biosafety Protocol. As such public awareness, education and participation is a legal obligation that emanates from the international level. However, the rules of international law contained in treaties depend on national laws for their domestic implementation.

It should be pointed out that public participation or consultation exercises will not naturally lead towards consensus – that is, general agreement with “expert” opinion. Involvement of the public in decision making around biotechnology result in situations where the poor people’s voices, concerns and participation is giving a technical input to national decision making process – rather than pursuing the interests of those who have power.

Public participation is necessary to ensure that National Biosafety Frameworks is effective, though it is not necessarily regarded as a necessary foundation for drafting rules or establishing administrative systems. For the rules of the Protocol to be effective, it is important that all stakeholders are aware of them and the obligations they entail. Knowing the rules and obligations, groups and individuals such as farmers, laboratory technicians, freight drivers, and public officials such as customs officers, emergency services and government inspectors will know how to handle GMO’s in transit safely. So

public participation does not necessarily mean public consultation but merely public involvement in some cases.

7.1 PUBLIC INVOLVEMENT DURING THE DEVELOPMENT OF THE NBF

Public participation in the development of a biotechnology / biosafety policy. And biosafety regulation is important to make better informed, more appropriate, more legitimate and ultimately more effective policies. Challenges arising from this exercise involve lack of knowledge about biotechnology let alone biosafety issues and illiteracy in general.

In developing countries like Lesotho where illiteracy remains high, it is a challenge to pass technical information involving science to the public, especially when a topic at hand has generated public debate on social and ethical issues like biotechnology. In order to generate truly participatory methods of involving the public in important decisions about biotechnology, the divide between expert and lay knowledge must be eroded. This means that the consultation process must be guided, not by scientists but by citizens themselves.

In Lesotho, when realizing the importance of public participation during the development of the NBF, it was decided that biosafety policies formulation would involve the public from beginning to end. The public was divided into different target groups, for example journalists, government officials, politicians, farmers, scientists' business people and the general public. All were approached differently.

During the inception of the project, there was a formation of a National Coordinating Committee (NCC), which was tasked with overseeing the implementation of the project. The NCC has representation from local NGO's (2), different governmental agencies and independent farmers associations (2). It was formed such that it consists of people from different sites of the GMO debate.

Baseline studies that were done during the second phase of the project indicated that it was imperative for the formulation of the national policy to hold national consultative workshops for different stakeholders, as a means to solicit stakeholders' opinion. In these consultative workshops, stakeholders were made aware of the CPB rules, their different obligations as groups and as individuals. They were also made aware and familiarized with environmental issues associated with biotechnology products and a working knowledge of the biosafety review process, and also that they need to recognize what constitutes a potential risk and what risk management strategies may be applicable.

7.2 PUBLIC INVOLVEMENT DURING THE IMPLEMENTATION OF THE NBF

Government Ministries in Lesotho are centrally organized into units by sectors, while +biosafety issues cut across virtually all these sectors. This common involvement in concerns with biosafety can be harnessed to provide appropriate inter-sectoral integration and coordination.

The effective management and implementation of the NBF is dependent to a large extent on the commitment and genuine involvement of all interested groups at both central and local levels. Those with a role to play range from the small local farmers to scientists who are developing the technology. At all stages it is essential that local people are empowered so that they can participate constructively in decision making.

The National Biosafety Policy of Lesotho would ensure the creation of public awareness and understanding of biotechnology and biosafety is such that public opinion is incorporated at all levels of decision making regarding the use and application of biotechnology. It would be required by law that the National Biosafety Council (NBC), should take public opinion into consideration in decision making. No decision would be considered legitimate if public opinion was never considered. (Please refer to the Policy and the Bill for details).

NBCR has a duty to promote public awareness and education concerning the activities regulated under the Bill and to coordinate public participation, this would be done through a specific Biosafety Web site (Link to the BCH), local Newspapers, Traditional structures and many other communication tools.

GENERAL COMMENTS

1. This document should have had “**a preface**” which introduces the subject and spells out importance of having a national biosafety framework. The preface should also touch briefly on Lesotho’s efforts in putting in place the key elements of the framework namely the policy, legal, administrative and technical instruments already set in place to address safety for the environment and human health in relation to modern biotechnology
2. The section on policy should summarize all the key aspects of the **current policy**. The summary given in the document is not comprehensive and compelling enough. (This is perhaps explained by the fact that the current draft policy is essentially in the “making” and is not a finished product as such).
3. The section of the framework highlighting the **regulatory aspects** of the framework has left out a commentary on provisions of the current draft biosafety bill including a mention of the significance of implementing regulations as an important aspect of the national biosafety framework.
4. The section on the **system for handling requests** needs to be re written to spell out:
 - Institutional arrangements in place to handle applications/notifications.
 - Specific risk assessment roles of these institutions
 - Administrative processing of applications
 - Data Storage mechanisms
 - Mechanisms for dealing with issues of confidentiality
 - Capacity building requirements
 - Practical details regarding handling, transport, packaging and identification of GMO materials under application/notification

- Decision making
- Mechanisms for regional and international cooperation in regard to the transboundary movements of GMOs. etc

5. The section **on inspections, monitoring and enforcement** should cover information that facilitate application notification process and effectively check compliance with law and take on remedial actions through enforcement. It should be based on national standards and should respond quickly to intelligence reports. To do this, the system should spell out:

- Institutional arrangements in place for monitoring and enforcement
- Specific inspection, monitoring and enforcement role of these institutions
- Permit conditions and spell out powers of inspectors with regard to right to enter premises, power to take written statements, improvement notices, prohibition notices and prosecution steps.
- Capacity building requirements for inspections.
- Practical details regarding inspections of facilities and infrastructure - the dos and don'ts.
- Mechanisms for regional and international cooperation and collaboration

6. Lastly, the section of the framework highlighting **the public awareness and participation** should spell out in very clear terms:

- The context and principles of public awareness and participation within the Lesotho framework.
- Highlights of strategies for public awareness in Lesotho
- Public engagement mechanisms
- Capacity building
- Feedback mechanisms

- Mechanisms for regional and international cooperation and collaboration.

In summary, all the above elements need to be systematically extracted from the Policy, Biosafety bill, *Regulations and Manuals* then assembled coherently into a comprehensive National Biosafety Framework.