



NATIONAL

BIOSAFETY POLICY

FOR LESOTHO

"STRIVING TO ACHIEVE SAFE

APPLICATION OF

BIOTECHNOLOGY"

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1. PREAMBLE

At the Earth Summit in 1992, the Convention on Biological Diversity (CBD) was signed and biological diversity was recognised as one of the important global issues for humankind survival. Lesotho was a participant from the beginning of these world initiatives and ratified the Convention on the 10th January 1995. The Convention focuses on the importance of maintaining an environment which sustains variety of plants and animals still existing and sets clear guidelines for achieving this goal.

Lesotho's Constitution contains a specific section requiring Lesotho (Section 36) to adopt policies which protect the environment, and the National Development Goals and Policies are progressive with regard to sustainable development and environmental protection. Some of these are set out in the Environment Act No.15, 2001.

In recognition of the potential risks of biotechnology and to the absence of central regulatory systems in many developing countries, in January 2000, the Conference of the Parties to the Convention agreed on the legally binding Protocol for protecting the environment from the potential risks posed by "Living Modified Organisms" well known as the Cartagena Protocol on Biosafety (CPB). The Protocol creates an enabling framework for the environmentally sound application of biotechnology, maximising the potential benefits that biotechnology offer while minimizing the possible risks to the environment and to human health.

The Cartagena Protocol on Biosafety (CPB) underlines the Government's commitment to the conservation of biological diversity and sustainable use of natural resources, which incurs a responsibility to regulate the use of modern biotechnology. It is important that decisions on the use of these technologies are based on scientific, economic, social and ethical evaluation.

Cautious but strategic application of modern biotechnology in Lesotho can assist the country to meet its National Goals, i.e. poverty reduction, improving human resources, at the same time protecting the environment. Biotechnology should be considered as one of the many tools that can assist the country to reach its goals.

Lesotho's National Biosafety Framework must strike a balance between the regulation, application and promotion of biotechnology, risk-benefit and cost-benefit. Evaluation of individual applications should be undertaken in full consideration of Lesotho's particular biophysical and socio-economic environment.

Networks of co-operations, collaborations and information exist on these levels in the biotechnology arena and Lesotho can make effective use of these. However, decision-making must be nationally driven throughout the process. Therefore, like most developing countries, Lesotho does not have financial resources to duplicate existing sub-regional, regional and global institutions and structures.

It is of a paramount importance that both the national, institutional and human capacity is developed so that Basotho can be able to decide on biotechnology applications. Lesotho has a variety of plants and animals, with unique life forms, some of which are not found in any other country. While a cautious application of biotechnology may prove important for the country in meeting its national developmental goals, certain biotechnology applications, practices and products may seriously contradict the economic, social and ethical norms of Basotho, including destruction to the biodiversity.

2. MISSION STATEMENT

In order for Lesotho to meet its national priority goals and its international obligation with assistance of a national biosafety policy, it must:

- Develop 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.
- Develop 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.
- Develop its own capacities related to biotechnology and biosafety through Research and Development (R and D) for informed decision making.
- Reaffirm its commitment to the principles of the 1992 Rio de Janeiro Declaration on Environment and Development.

3. GOAL

The goal of the National Biosafety Policy is to ensure safe use of biotechnology in order to protect human health and ensure the well-being of the environment, while maximizing the benefits from biotechnology.

4. OBJECTIVES

4.1 NATIONAL DEVELOPMENT OBJECTIVES

In order to attain its long-term goals, the Government of the Kingdom of Lesotho has formulated 8 broad national objectives (Vision 2020).

- To achieve a stable and united democracy
- To have a prosperous nation
- To have a nation at peace with itself and its neighbours
- To build a healthy nation
- To have a well developed human resource base
- To have a healthy environment
- To have a strong economy
- And to have technologically well equipped country.

This policy offers guidance for Lesotho to achieve some of its national goals by ensuring the safe use of biotechnology so as to have a prosperous and healthy nation without prejudice to public health, environmental health, national sovereignty and human dignity.

4.2 BIOSAFETY OBJECTIVES

The national policy shall:

- Guide the judicious use of modern biotechnology in Lesotho for sustainable development, in ways which do not in any way jeopardise human and environmental health including Lesotho's biodiversity and genetic resources.
- 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.
- Develop human resource and institutional development so that Lesotho can make an informed decision on the applications.
- Guide the Lesotho Government to form structures and laws to manage biotechnology and biosafety issues in the country.
- 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.
- 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.
- Provide an institutional framework for national decision-making and international cooperation in this area.
- Ensure that decision-making concerning advance approval is based on high level expertise, scientific risk assessment and precaution.

5 POLICY FRAMEWORK

5.1 SCOPE OF THE POLICY

This policy covers all GMOs (Genetically Modified Organisms) and their products or derivatives; this coverage includes all living organisms, germplasm, and all elements of genetic manipulation.

This national policy covers in detail

- 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.
- d. The biotechnology, research and development process, including academic, medical research, agricultural, industrial and other research.

- e. Occupational safety at workplaces, where biotechnology procedures are used or biotechnology commodities are handled.
- f. Any other measures to ensure public health and environmental safety with respect to the use of biotechnology in Lesotho.
- g. Public participation and awareness in the fields of biotechnology and biosafety.
- h. Include other pharmaceuticals that are not covered by other international agreements or organisations.

5.2 IMPLEMENTATION STRATEGY

This policy attempts to strike a balance between protection and promotion, which will embrace benefits of biotechnology without compromising safety of the people of Lesotho and harming the environment as well as protecting biological diversity. Lesotho will not allow herself to be used to test, purchase or dispose of products or technologies which are banned elsewhere, or which fail the safety standards of other nations. Adjusted measures are needed to ensure Lesotho's sustainable development with regard to:

a) Environmental resources

The Government of Lesotho will protect the country's environmental resources through rigorous risk assessment and management measures that will prevent accidental and intentional release of GMOs to the environment through careful scrutiny of applications by National Biosafety Council (NBC), containment of GMOs and guarding the borders to prevent smuggling of GMOs into the country that might contaminate the environment.

b) Economic growth

In order to boost economic growth the government of Lesotho will invest in biotechnology and encourage companies that deal with biotechnology to invest in Lesotho. The government will encourage farmers groups that are already engaged in commercial farming to embrace biotechnology in order to optimise yields.

c) Appropriate Technologies

The government will encourage the use of biotechnology by companies that develop country specific products and services that will benefit all citizens especially the very poor.

d) Cooperate investment and people's rights and livelihood.

The government will strike a balance between the intellectual property rights and at the same time protect the rights of Basotho to the use of genetic resources. Indigenous knowledge will also be protected.

e) Improvement of food security.

Food security will be improved through application of biotechnology as one of the tools that can be employed to improve agricultural output.

5.2.1 Institutional and Legal Frameworks

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.

Regulatory and 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. In order to trace GMOs at the point of import, sectoral legislation related to import control may require appropriate amendment and enforcement.

5.2.1.1 Activities of the institutional framework

There will be a single entry point for applications, whether for GM plants, animals and micro-organisms. When a Biosafety Law is in place there will be a biosafety administration (office) for processing of applications, which will consist of National Biosafety Council Registrar (NBCR), National Biosafety Council (NBC), and the Scientific Advisory Committee (SAC).

Due to lack of the National Biosafety Law and other institutional arrangements presently, there will be two different procedures that would be followed for the interim and permanent arrangements.

5.2.1.2 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.

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 falls within the scope of the CPB and should address the relevant information contained in the Annex 4 and 5 of this document. 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.

5.2.1.3 Permanent arrangements/structures

The Department of Environment would be designated as the Competent Authority for the purpose of the administration of the Biosafety Act. 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 and for facilitating the exchange of information among the relevant bodies and authorities.

When legislation is in place, a permanent advisory body shall be established. This would be known as National Biosafety Council (NBC). The NBC would consist of 7 members nominated by the Minister responsible for Environment as both The Focal Point and The Competent Authority, based on the expertise required; 2 members from the civil society organisations, 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.
- i. Identify priorities of scientific and technological research that can assist Lesotho to meet its national and international goals and priorities.
- ii. Serve as advisor and co-ordinator of sectoral activities that involves biotechnology and biosafety, including sectoral ministries, NGOs and private organisations.
- iii. Ensure the integration of safe application of biotechnology in the national development planning and policy formulation in liaison with line ministries.
- iv. Promote cooperation among Government Departments, Local Authorities, Private Sectors, Non-Governmental Organisations and other organisations for safe application of biotechnology.

- v. 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.
- vi. Provide guidance and advice on biosafety for the carrying out of risk assessments.
- vii. Chairperson of the NBC shall advise the Minister responsible for Environment directly
- viii. Recommend measures necessary for the harmonisation 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. This office shall be administered by a Registrar who shall be a public officer, and should be answerable to the Competent Authority. The NBCR is:

- i. Responsible for regulatory compliance.
- ii. May exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by Biosafety Law.
- iii. Whenever the registrar is for any reason absent or unable to perform his or her functions, or whenever a vacancy in the office of the registrar occurs. the NBC may designate a member of its staff to act in that capacity until the registrar resumes his or her functions, or a registrar is appointed in terms of the Law, and that member has, while so acting, such powers and shall perform such duties of the registrar as may be delegated or assigned to him or her by the NBC.

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.

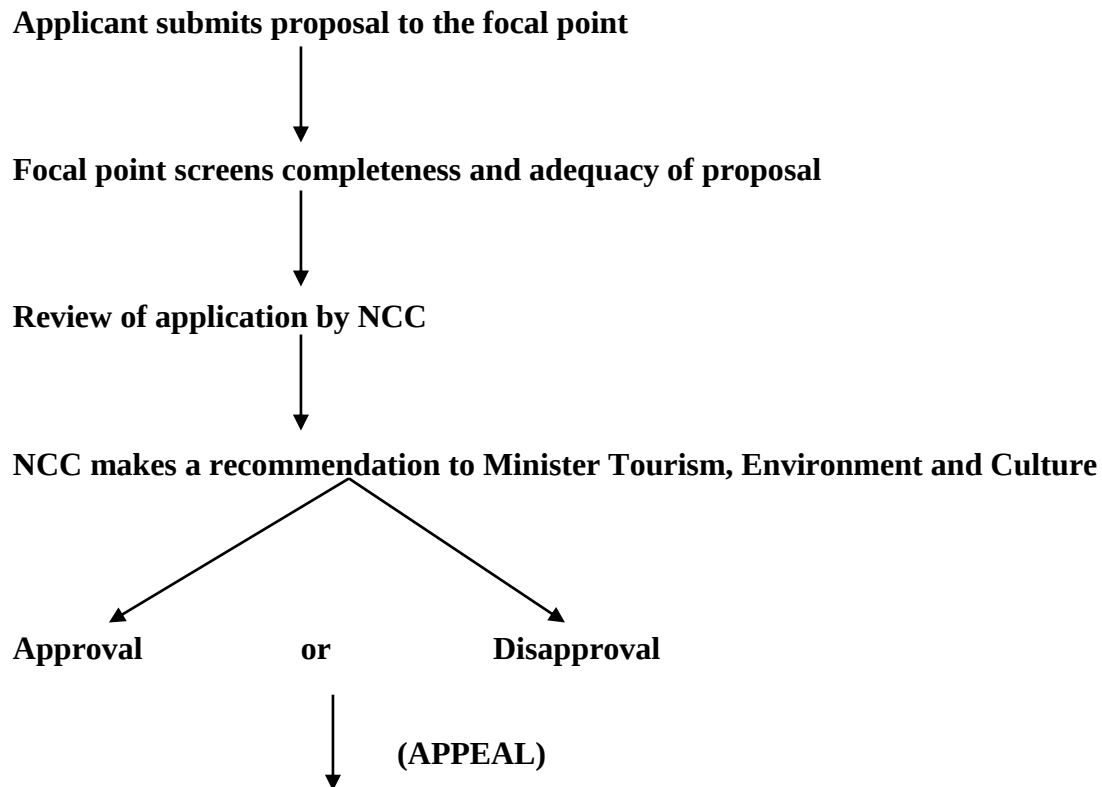
The NBCR shall receive and process applications in accordance with the Biosafety Law. The processed application would be assessed by the Council which shall meet at such times and places as the chairperson may determine, at least two times per year provided that the first meeting shall be held at a time and place to be determined by the Minister. The Ministry responsible for Environment shall be formally responsible for all decisions.

The Minister responsible for Environment shall liaise with other line ministries in order to incorporate biosafety issues in their already existing inspectorates, so that they can carry out inspection activities.

Members of the NBC shall include adequate expertise in Agriculture, Plant Breeding, Microbiology and Molecular Biology, Human and Veterinary Medicine, Environmental Management, Food Production and Processing, Social Sciences and Economics and any other field deemed necessary for fair and adequate evaluation of applications and reviewers assessment reports.

Establish a socio-economic panel which shall serve as an advisory body on socio-economic issues, which shall be appointed by the Minister responsible for Environment from time to time.

5.2.1.4 STEPS IN REVIEWING AN APPLICATION FOR GMO'S (INTERIM APPLICATION AND PROCEDURES)



5.2.1.5 STEPS IN REVIEWING AN APPLICATION FOR GMO'S (PERMANENT APPLICATION)

Lesotho shall adopt the European Unions contained use system concept (contained use regulations 2000), which holds that:

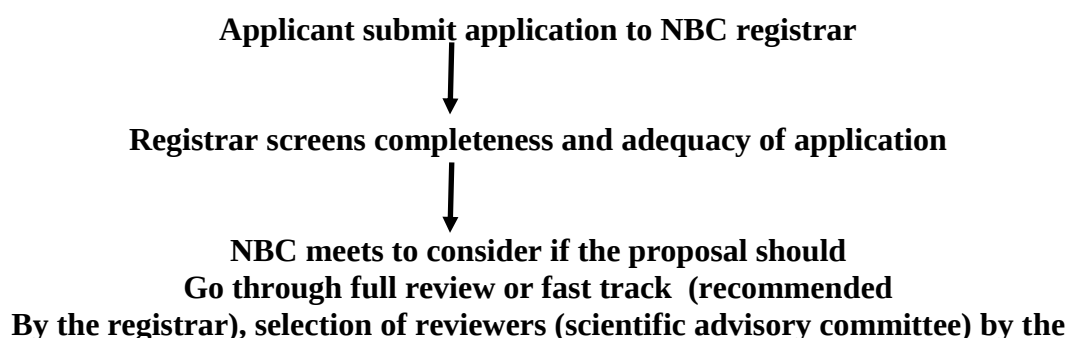
- Genetically modified organisms (GMOs) especially genetically modified micro-organisms are classified according to their level of risk to human and environmental health;
- Such classification be in line with sound international practice and based on risk assessment;
- Containment and other protective measures must correspond with the classification of contained use;
- In cases of uncertainty, containment and other protective measures for a higher classification level should be applied until less stringent measures are justified by appropriate data;
- Appropriate measures should be adopted and used for control of the disposal of material from contained uses of GMOs, in accordance with good microbiological and hygiene practice;
- These measures shall be reviewed periodically, to reflect the pace at which biotechnology is advancing;
- Persons working with contained use systems shall be consulted about their occupational hazards;
- The desirability of a list of GMOs that are safe to human health and the environment should be considered;
- There now exists considerable information on the risks associated with the contained use of GMOs, particularly Genetically Modified Micro-organisms.

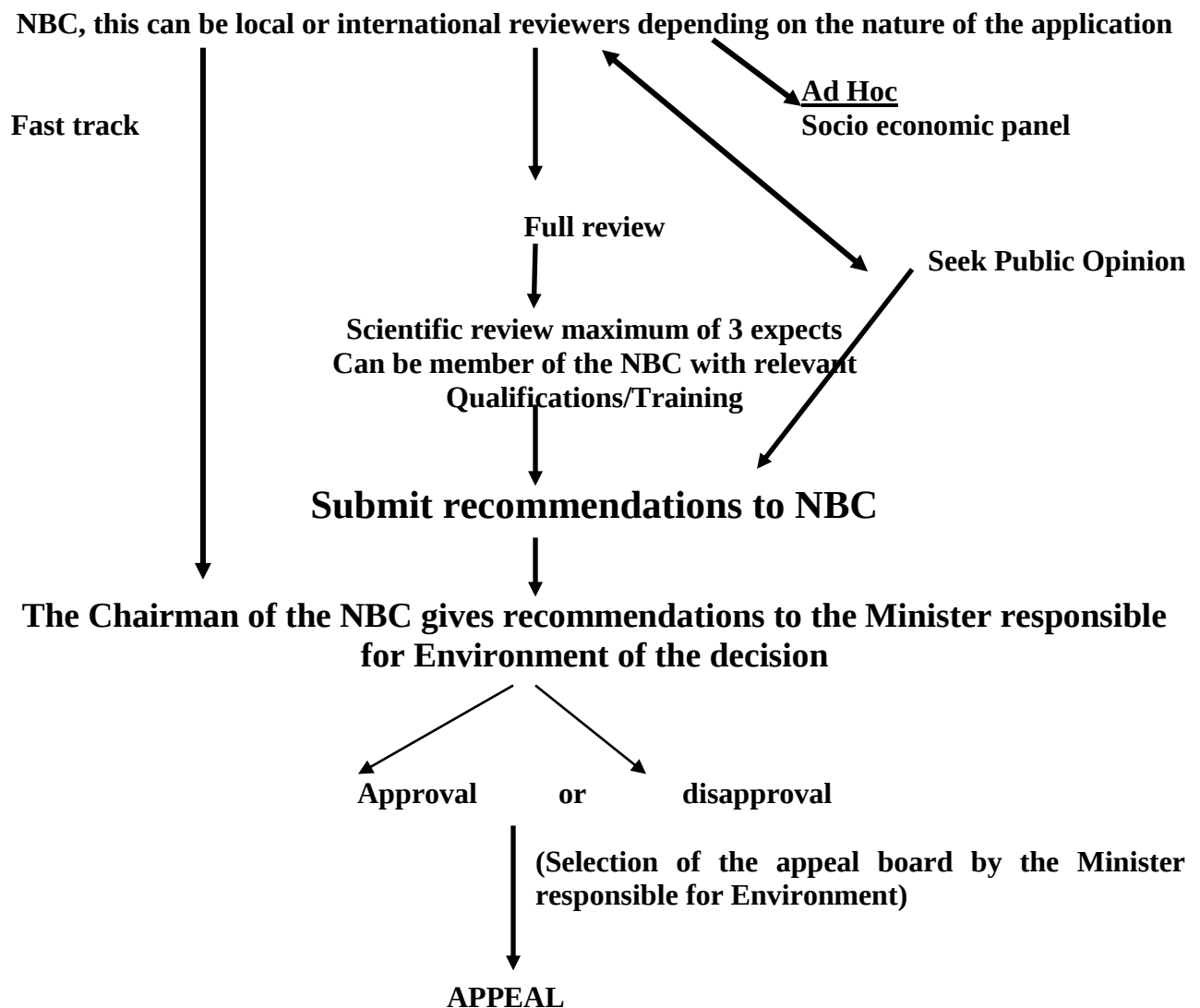
The following four classes are thus recommended:

- | | |
|---------|---|
| CLASS 1 | Activities of no or negligible risk – for which level 1 containment is enough to protect human and environmental health |
| CLASS 2 | Activities of low risk – for which level 2 containment is enough to protect human and environmental health |
| CLASS 3 | Activities of moderate risk – for which level 3 containment is enough to protect human and environmental health |
| CLASS 4 | Activities of high risk – for which level 4 containment is enough to protect human and environmental health. |

In all cases, uncertainty should lead to the use of the most stringent protective measures until sufficient evidence, by agreement of the NBC justifies the application of less stringent measures.

The following are considered “potentially harmful effects on human and/or environmental health”; diseases to humans, including allergenic or toxic effects; disease to plants, animals or other organisms; adverse effects resulting from the inability to treat disease or other effective prophylaxis; adverse effects resulting from establishment or dissemination in the environment; adverse effects resulting from the natural transfer of inserted genetic material to other organisms.





5.2.2 Research and development structures

Promotion of the safe use of biotechnology in Lesotho involves the strengthening of research, development and bio-safety capacities. Under the Department of Science and Technology, the Government of Lesotho, in collaboration with other institutions (such as the National University of Lesotho, Lesotho Agricultural College) should liaise with heads of regional training programmes to determine a strategy for training Basotho in biotechnology procedures, bio-safety guidelines, risk assessment and risk management. Government shall liaise with training programme heads to ensure effective placement of such graduates in regulatory and related government agencies.

Lesotho shall rationalize its investment by making maximum use of existing regional and other education and training bodies in biotechnology and bio-safety, and by preparing its undergraduates for easy training into such programs, by means of curriculum stream options. It shall also include awareness models for non-specialist undergraduates in fields such as trade, finance, health, agriculture and environmental management. Biotechnology issues shall be incorporated into schools curriculum.

Government regulatory and policy agencies shall endeavour as a matter of agency to identify and implement appropriate in-house or continuing education and training mechanisms for their existing staff and notify the Ministry of Finance of financial needs requested from government and non-government sources.

5.2.2.1 Risk Assessment and containment of laboratory and field trials

- *Laboratory use* of biotechnology can be in any field, such as Agriculture, the beverage industry, mining and veterinary and medical research
- *Field releases* are currently most likely in agriculture and industry, e.g. genetically modified crops or waste management (i.e. municipal or industrial use of genetically modified micro organisms for sewage or sludge treatment). But they may also occur in other fields.
- Given the potential risks to human and environmental health resulting from introduction into the environment of genetically modified organisms and food stuffs, proposed food releases must be stringently assessed and controlled on the basis of credible and locally appropriate scientific data.
- A clear distinction must be made between viable and non-viable genetically modified organisms or products. Viable products (i.e. which can grow and reproduce e.g. whole grain for livestock feed) are capable of fundamentally greater environmental impacts when released, and require stringent control.

5.2.2.2 Laboratory Containment standards

Ministry responsible for Environment, as a Competent Authority, in collaboration with other line Ministries, shall formulate biosafety guidelines to cover laboratory practices, glasshouse experiments with GMOs, large and small-scale field trials, and large and small scale clinical trials.

5.3 LIABILITY AND REDRESS

This Policy shall facilitate for liability and redress. Where any person or group of people are responsible for damage, injury or loss, they would be liable and would be responsible for redress.

5.4 FINANCIAL IMPLICATIONS

Biotechnology is a specialised field of technology. It should be taken as an important component of a national science and technology strategy, which involves a huge investment in infrastructure, equipment and specialised training.

All scientific and socio-economic reviews shall be paid for by the applicant. The Ministry of Finance and Planning shall approve budget for biosafety and biotechnology activities, e.g. National Biosafety Council. It is hoped that in the long run monies that accrue from applications will sustain biotechnology and biosafety activities.

5.5 POLICY LINKAGES

This national policy deals with a specialised topic. However, due to the cross sectional nature of biotechnology and biosafety which involves fields like agriculture, public health, waste management, mining and other areas, policies of all these other fields may need revisiting to determine what, if any amendments, need to be made to take into account biotechnology and biosafety. Further, the important risk-assessment and regulatory implications for the safe use of biotechnology in Lesotho including border control, trade, environmental assessment and public health assessment and enforcement require detailed analysis of existing policies and practices.

The constitutions

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 ‘safe and sound environment adequate for their health and well-being’”. The development of the National Biosafety Policy is in line with the requirements of the Constitution.

The Environment Policy of 1998

The policy provides the protection and promotion of human health and the environment, it addresses the issues of biological diversity and it highlights the importance of public participation, in environmental issues.

National Science and Technology Policy (Draft)

The Policy recognises biotechnology as one of the key technologies which has the potential to provide very substantial benefits to society in a wide range of sectors. It also provides a platform on which the Government of Lesotho will strive to facilitate the development of biotechnology in the country by creating high quality infrastructure, while at the same time minimising all potential risks posed by biotechnology.

National Strategy on Lesotho’s biological diversity

Management of “biotechnology on an environmentally sound basis” is outlined among the objectives of this national strategy. Cognizant of the fact that currently modern biotechnology research and development activities are virtually non-existent in Lesotho, the country imports and uses biotechnology products. The national strategy necessitates creation of defensive measures/actions concerning manufacture and utilization of biotechnology products, which might have unsafe side effects to humans and biodiversity as, indicated in Table 2 below;

Table 2: stipulations of the National Strategy on Lesotho’s Biological Diversity regarding biotechnology

Actions	Sub-actions
Establish and Strengthen Biotechnology Management Institutions	a) Improve national capacity, manage and reduce risks associated with biotechnology b) Improve coordination of national and regional policies on biosafety c) Expand international information exchange and networks on Living Modified Organisms (LMOs) and their products d) Strengthen research, education, awareness and institute training on biosafety e) Establish a National Focal Point and Competent Authority for the management of biotechnology f) Set up a national tracking system for movement of LMOs

Strengthen the Management of Living Modified Organisms and their Products.	a) Control trans-boundary movement of Living Modified Organisms (LMOs) b) Improve coordination of national and regional policies on biosafety c) Improve national capacity to monitor the effects of LMOs d) Prevent the illegal trafficking of LMOs by setting up information and alert systems; monitoring and assessing the illegal movement of LMOs at the national level; and strengthening national capacity to detect illegal trafficking e) Develop national biosafety guidelines, regulations and legal measures to manage LMOs effectively f) Strengthen national capacity to manage LMOs by participating in international negotiations for the development and management of LMOs together with their respective biosafety protocols
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5.5 DEFINITIONS

“Advance Informed Agreement” means consent obtained based upon full disclosure of all relevant information before any activity is undertaken;

“Applicant” means any person who submits an application in writing to the competent authority seeking approval to import, make contained use, release or place on the market genetically modified organisms or products of genetically modified organisms, or where the context so requires, any person to whom the approval is already granted;

“Biosafety-Clearing-House” means the information exchange mechanism established under the Cartagena Protocol on Biosafety;

“Competent Authority” means the entity responsible for implementation of this Bill

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

“Export” means the intentional transboundary movement from Lesotho to another country;

“Genetically Modified Organism (GMO)” means any biological entity, capable of replication or of transferring genetic material and includes plants, animals, micro organism, cell cultures and other vector systems in which the genetic material has been altered through modern biotechnology. This includes genetic modification which occurs through the following techniques:

- i. recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means

- outside and organisms into a virus, bacterium, plasmid, or other vector, and their incorporation into a host organism in which they are capable of continued propagation;
- ii. techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and
 - iii. cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells;
- And includes a product of GMO intended for food.

“Import” means the intentional transboundary movement into Lesotho from another country;

“Line Ministry” means a Ministry, Parastatal, or agency in which any law vests functions for the protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

“Minister” means the Minister responsible for Tourism, Environment and Culture;

“Modern biotechnology” means the application of:

- (i) In-vitro nucleic acids techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- (ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection;

“National Focal Point” means the entity designated to be responsible on behalf of Lesotho for liaison with the Secretariat of the Cartagena Protocol on Biosafety;

“National Coordinating Committee” means a multi-disciplinary and multi-sectoral committee established to advise and guide the preparation of the National Biosafety Framework;

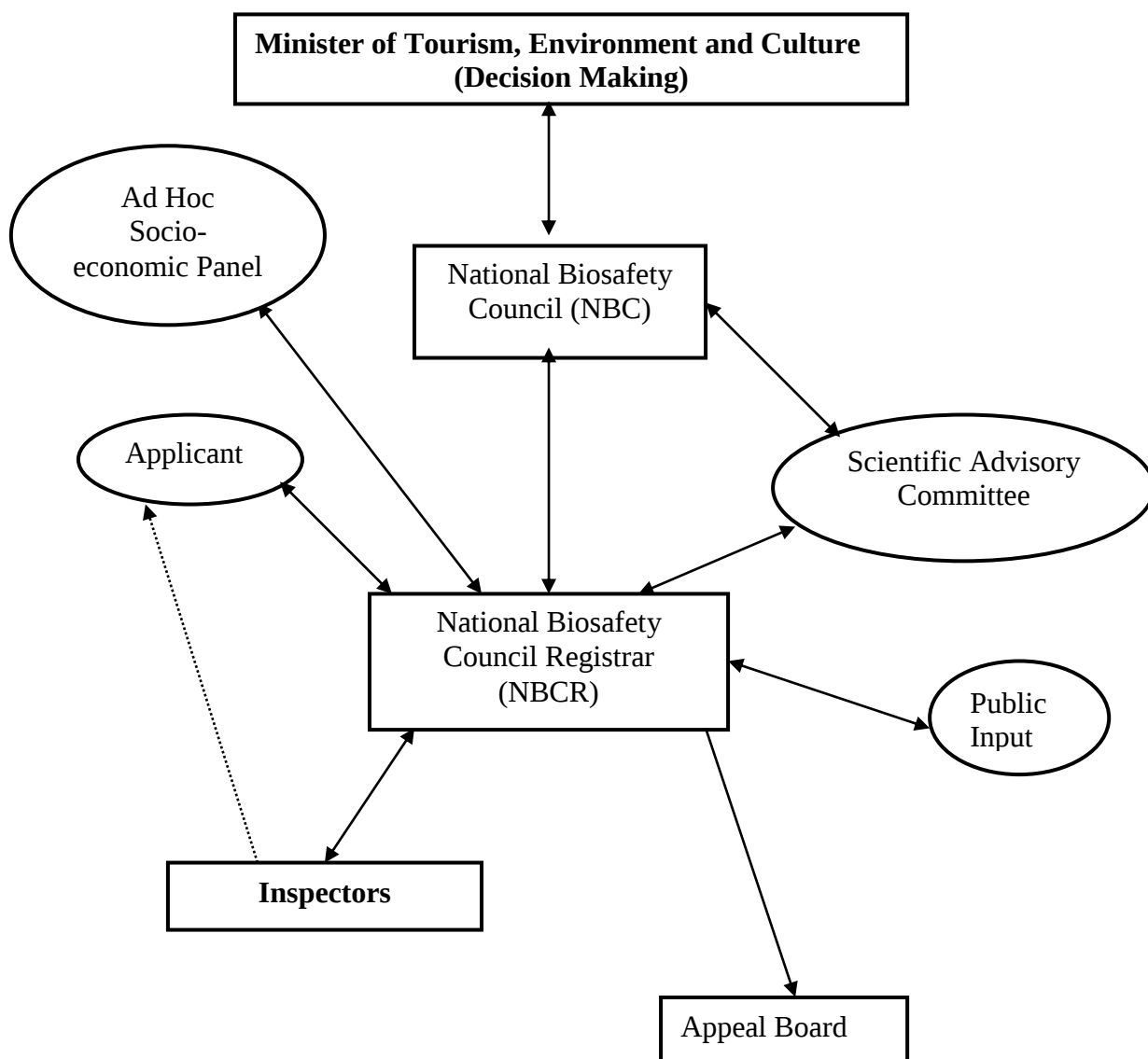
“Notification” means providing information to, and where appropriate, the deposit of samples with, the competent authority;

“Person” includes both natural and legal entities;

“Placing on the market” means supplying or making available to third parties a genetically modified organism, whether there has been monetary exchange or not, and include the giving of food as aid;

“Risk Assessment” means the evaluation of the direct or indirect, short, medium or long-term risk to the environment, biological diversity or human health, including socio-economic conditions or to ethical values arising from the contained use, release or placing on the market of a genetically modified organism or of a product of a genetically modified organism;

Regulatory Structure



List of Expertise needed to review GMO application.

- Molecular biology
- Microbiology
- Biochemistry
- Ecology
- Pollination biology
- Human health
- Veterinary science
- Plant physiology
- Plant biology
- Soil biology
- Plant taxonomy
- Environmental risk assessment
- Weather
- Entomology
- Agronomy
- Plant genetics
- Transport
- Legal and any other field that may be necessary depending on the nature of the application.

RISK IMPACT ASSESSMENT, CONTAINMENT MEASURES AND CLASSIFICATION FOR GMOS

Carry out risk assessment



Determine appropriate containment measures



Compare appropriate containment measures with containment tables (Schedule 1, EU Contained Use Regulations 2000)



Do measures correspond exactly to those specified for a given containment level?



Assign activity to class corresponding



Notify according to class



Apply full containment measures as determined by risk assessment



Do measures fall between two containment levels, i.e. all specified measures at lower level apply, but one or more are requirements only at the higher level?



Assign activity to class corresponding to the to containment level higher of the two containment levels



Notify according to class and apply containment measures. Notifier may seek competent authority agreement to omission of certain measures, only if justified by risk assessment



If notifier makes no Application for Omission of measures:



Apply full containment measures specified at relevant containment level

If competent authority does not agree to omit measures:



Apply full containment measures specified at relevant containment level

If competent authority agrees omit measures:



Apply containment measures shown to be appropriate by risk assessment and agreed by competent authority