

BIOSAFETY BILL, 2007

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BIOSAFETY BILL, 2007

A Bill For

An Act to provide for an adequate level of protection in the field of the safe transfer, handling, transit and use of genetically modified organisms (GMOs) resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health and the environment.

Enacted by the Parliament of Lesotho.

Part I – Preliminary

Short title and commencement

1. This Act may be cited as the Biosafety Act, 2007 and shall come into operation on the day to be appointed by the Minister by notice in the Gazette.

Application

2. (1) This Act shall apply to the import, export, transit, contained or confined use, release or placing on the market of any GMO whether intended for introduction into the environment, for use as a pharmaceutical, for food, feed or processing that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(2) This Act shall not apply to the transboundary movement of GMOs which are pharmaceuticals for humans that are addressed by relevant international agreements or organizations.

Interpretation

3. In this Act, unless the context otherwise requires:

“Advance Informed Agreement” means consent of the Competent Authority, based upon full disclosure by the Applicant of all information required under this Act, before any activity involving a GMO is undertaken;

“applicant” means a person who submits an application in writing to the competent authority seeking approval to import, make contained or confined use, release or place on the market GMO, 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;

“Biosafety” means the goal of ensuring that the development and use of genetically modified organisms and products made from them do not negatively affect plant, animal or human health; genetic resources; or the environment; techniques and procedures adopted to avoid risk to human health and promote conservation of the environment, as a result of the use of the genetically modified organisms for research and commercial use.

“Committee” means the Scientific Advisory Committee established in terms of section 13;

“Council” means the National Biosafety Council established in terms of Section 6;

“Competent Authority” means the entity responsible for Administration and implementation of this Act;

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

“confined use” means a field trial of a GMO in an open system in which physical barriers are employed, to effectively limit their contact with, and their impact on humans and the external environment;

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

“Damage” means harm to biological diversity, human life or health, property, the environment or socio-economic conditions;

“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, and includes genetic modification which occurs through the following techniques:

- (a) 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;
- (b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and
- (c) Cell fusion or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cell;

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, statutory body, or agency in which any law vests functions for the protection in the field of a safe transfer, transit, handling and use of GMOs 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 environment;

“modern biotechnology” means the application of-

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

(b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or 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;

“Notification” means providing information to, and where appropriate, the lodging of an application with, the Competent Authority, at the same time, taking responsibility for the accuracy and completeness of the information so provided;

“Panel” means the Socio-economic panel established in terms of section 15;

“person” includes both natural and legal persons;

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

“ Protocol” means the Cartagena Protocol on Biosafety”;

“Registrar” means the Registrar appointed under section 11;

“risk sssessment” means the evaluation of a 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 or confined use, release or placing on the market of a GMO;

“socio-economic impact” means a direct or indirect effect of a GMO on the economy or on social or cultural conditions or on the livelihood or indigenous knowledge systems or technologies of a community or communities, and on the economy of the country;

“**transit**” means the intentional transboundary movement of a GMO through Lesotho from one country to another country.

PART II – THE INSTITUTIONAL ARRANGEMENT

Competent Authority

4. (1) The Department of Environment is designated as the Competent Authority for the purpose of the administration of this Act and the regulations made pursuant to this Act.

(2) The primary functions of the Competent Authority are:

(a) to receive, respond or make decisions on GMO notifications and applications in consultation with the Council or the Registrar, subject to the provisions of this Act;

(b) to establish mechanisms for ensuring the appropriate handling, dissemination and storage of documents and data in connection with notifications, applications and other matters covered by this Act; and

(c) to promote public awareness and education concerning the activities regulated under this Act.

Focal Point

5. The Competent Authority shall serve as a National Focal Point for liaison with the Secretariat and the Biosafety-Clearing-House of the

Cartagena Protocol and for facilitating the exchange of information among the relevant bodies and authorities.

National Biosafety Council

6. There is established the National Biosafety Council, within the Competent Authority.

Composition of the National Biosafety Council

7. (1) The National Biosafety Committee shall consists of -
- (a) five ex-officio members each representing the following Ministries:
 - i. Ministry responsible for environment;
 - ii. Ministry responsible for agriculture;
 - iii. Ministry responsible for health;
 - iv. Ministry responsible for trade; and
 - v. Ministry responsible for science and technology.
 - (b) two members appointed by the Minister from the Civil Society Organisations.
- (2) All members shall have training in at least one of the following fields of study:
- (a) agriculture;
 - (b) environmental management;
 - (c) environmental economics;
 - (d) food production and processing;
 - (e) genetic engineering;
 - (f) human or veterinary medicine;
 - (g) microbiology;

- (h) molecular biology;
 - (i) plant breeding; or
 - (j) any other field that shall be deemed sufficient for fair and adequate evaluation of applications and review or assessments of reports.
- (3) The ex-officio members shall be officers holding offices not below the level of a Director or equivalent.
 - (4) The Minister shall cause the names of the members of the Council appointed under section 7 (1) (b) to be published in the Gazette.
 - (5) The Minister shall designate a chairman and a deputy chairman from among the members of the Council.

Tenure of Office

- 8.** (1) A member appointed in terms of section 7(1) (b),
- (a) shall hold office for a period not exceeding three years from the date of appointment and shall be eligible for reappointment upon an expiration of his term in office;
 - (b) may resign his office upon giving one month notice in writing to the Minister.
- (2) A member appointed in terms of section 7 (1) (b) may be removed from office as a member -
- (a) if he has been absent from 3 consecutive meetings of the Council without the permission of the chairman; or
 - (b) if in the opinion of the Minister, he is unable to discharge the functions of his office due to infirmity of the body or mind or for misconduct, or for any other valid reason.

(3) Where a member appointed in terms of section 7 (1) (b) has resigned or been removed from office, the Minister shall, by notice in the Gazette, fill the vacancy with a new appointment in accordance with Section 6 and the person so appointed shall hold office for the unexpired term of his predecessor.

(4) A member may be paid such allowances and expenses as the Minister may, after consultation with the Minister responsible for finance, determine.

Functions of the Council

9. The functions of the Council are -

- (a) to advise and be responsible, subject to the provisions of this Act, for the implementation of the national biosafety policy;
- (b) to identify the priorities of scientific and technological research that will enable the country to meet its national and international goals and priorities;
- (c) to coordinate, monitor and supervise all sectoral activities that involve modern biotechnology and biosafety issues;
- (d) to ensure the integration of safe application of biotechnology in the national development planning and policy formulation in liaison with line ministries;
- (e) to promote cooperation among Government Departments, Local Authorities, Private Sectors, Non-Governmental Organisations and other organisations for safe application of biotechnology;
- (f) to 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;
- (g) to provide guidance and advice for the carrying out of risk assessments;

- (h) to evaluate or cause the evaluation of the risk assessment and consider the result of such evaluation in making recommendation for a decision on any application to import, transit, make contained or confined use, release or place on the market a GMO;
- (i) to consider such measures , as may be necessary to avoid adverse effects on the environment, biological diversity, human health and on socio-economic conditions arising from a GMO;
- (j) to evaluate the information presented by the applicant to the Competent Authority and in the Biosafety- Clearing-House and to make appropriate recommendation to the Competent Authority;
- (k) to review any decision regarding the GMO upon receipt of new scientific information and to make necessary recommendation to the Competent Authority;
- (l) to recommend measures necessary for the harmonisation of the plans and policies of various sectors that are involved in safe application of biotechnology;
- (m) to prepare and publish reports;
- (o) to advise on the appointment of members of the Scientific Advisory Committee; and
- (p) to carry out such other functions as may be incidental or conducive to the exercise by the Competent Authority of any or all functions provided under this Act.

Meetings of the Council

10. (1) The Council shall meet –

- (a) at such times and places as the chairman may determine; and

(b) at least two times per year.

(2) The first meeting shall be held at a time and place to be determined by the Minister.

(3) The chairman shall at the written request of not less than three members convene a special meeting to transact any extraordinary business on a date specified in the request.

(4) A written notice shall be addressed and send to the members at least one month prior to the date of the meeting.

(5) A quorum for any meeting of the Council shall be five members.

(6) A decision of the Council shall be taken by consensus.

(7) The minutes of every meeting of the Council shall be recorded in a minute book by the Secretary and signed by the Chairman and the Secretary.

(8) The Council may, whenever it deems necessary, co-opt non voting knowledgeable persons to serve on the Council to advise on any issue.

(9) The Council may invite written comments from knowledgeable persons on any aspect of a GMO which lies within the mandate of the Council.

(10) Subject to this Act, the Council shall regulate its own procedure.

Registrar

11. (1) There is established, within the Competent Authority, for the purpose of this Act, the office of the Registrar.

(2) The office of the Registrar shall be administered by a Registrar who shall be:

- (a) a public officer appointed by the Public Service Commission; and
- (b) answerable to the Competent Authority for discharge of duties under this Act.

Functions of the Registrar

12. (1) The Registrar shall, subject to section 11 (2)(c) -

- (a) receive and screen completeness of a GMO application for submission to the Council;
- (b) where an approval has been given, issue a permit required or prescribed by this Act;
- (c) where he has ascertained or suspects on reasonable grounds that GMOs are being imported or locally produced or used contrary to the provisions of this Act or the conditions of an issued permit,
 - (i) 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;;and
 - (ii) authorize an inspector to destroy such GMO or cause it to be destroyed, subject to procedures and other provisions as set out in this Act or regulations made under this Act;
- (d) amend the conditions of or withdraw a permit issued under this 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 this 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;
- (h) promote public awareness and education concerning the activities regulated under this Act and coordinate public participation; and
- (i) serve as secretary of the Council.
- (j) issue advanced informed agreements and permits for GMO confined and contained use.

Scientific Advisory Committee

13. (1) There is established a Scientific Advisory Committee, which shall serve as an advisory body to the Competent Authority on scientific and technical issues.

(2) Members to the Scientific Advisory Committee shall be appointed by the Minister in consultation with the Council on the ~~on the~~ basis of expertise required to review a specific GMO.

(3) Members to the Committee shall be persons who are knowledgeable in the fields of science applicable to the development and release of GMOs.

Functions of the Committee

14. The Committee shall,

- (a) act as an advisory body on all matters concerning or related to the GMOs; and
- (b) advise, on request or of its own accord, the Minister, the Competent Authority, the Council, the Registrar, other

Ministries and appropriate bodies, on matters concerning GMOs; and

- (c) carry out risk assessment of GMOs on a case by case basis in accordance with section 21 (2).

Socio-Economic Panel

15. (1) There is established a Socio-economic Panel which shall serve as an advisory body on socio-economic issues concerning the proposed application or use of GMOs.

(2) Members to a socio-economic Panel and shall be appointed by the Minister whenever relevant expertise is required.

PART III – APPLICATIONS AND APPROVALS FOR GMOs

GMOs for Contained and Confined Use

16. (1) No person shall import, transit, or carry out any contained and confined use activities of, or place on the market a GMO without an Advance Informed Agreement and a permit issued by the Registrar of the Competent Authority.

(2) Any person who intends to transit, make any import or carry out any contained and confined use activities involving GMOs shall within the time prescribed by the regulations, submit an application in writing to the Competent Authority.

(3) The application shall include,

- (a) the name and contact information of the applicant;
- (b) the location where contained use activities will be undertaken;
- (c) the nature and identity of the GMOs involved;

- (d) the nature and purpose of activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing, or using of the GMO in any other way;
- (e) a description of the contained or confined measures to be provided and the suitability of those measures for GMOs and activities to be undertaken;
- (f) a description of any potential risks associated with GMOs and activities to be undertaken;
- (g) a description of remedial measures to be undertaken in the event of any unintentional introduction into the environment, of GMO that may occur as a result of the activities to be carried out; and
- (h) such other information as may be prescribed from time to time by the Competent Authority.

GMOs for Intentional Introduction into the Environment

17. (1) No person shall import a GMO for intentional introduction into the environment without an Advance Informed Agreement and a permit issued by the Registrar..

(2) A person wishing to intentionally introduce a GMO into the environment shall, within the time prescribed by the regulations, submit an application in writing to the Competent Authority.

(3) An application made pursuant to subsection (2) shall include -

- (a) the information specified in Schedule I;
- (b) a risk assessment in conformity with Schedule II;
- (c) any additional information that the applicant may deem necessary to an assessment of the potential risks or benefits of the requested activity, and

(d) any other information as may be prescribed from time to time by the Competent Authority.

GMO for Direct Use as Food, Feed, or Processing

18. A person who wishes to import a GMO for direct use as food, feed or processing shall submit, within the time prescribed in the regulations, an application, in writing, to the Competent Authority, containing information specified in Schedule III and any other information as may be prescribed by the Competent Authority.

Exemptions

19. The Competent Authority may exempt any GMO or activity from the requirements of sections 16, 17, and 18, where it determines that it has sufficient experience or information to conclude that the GMO or activity do not pose a significant risk to the conservation and sustainable use of biological diversity, taking also into consideration risks to human health.

Biosafety-Clearing-House

20. The Competent Authority shall inform the Biosafety-Clearing House of any notification, decision or any activity that is required to be made or conducted under the Protocol.

PART IV – RISK ASSESSMENT AND MANAGEMENT

Risk Assessment

21. (1) The Competent Authority shall make no decision on any application to import, make contained or confined use of, transit, release or place on the market a GMO without the assessment of risks to the environment, biological diversity and human health, including the socio economic conditions and cultural norms.

(2) The risk assessment of a GMO shall be carried out by the Committee, on a case by case basis and in accordance with Schedule II.

(3) 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 contained or confined use, release or place on the market a GMO.

(4) Where the evaluation of the assessment shows that the risk cannot be avoided, the Competent Authority shall refuse approval for the import, transit, contained or confined use, release or placing on the market a GMO.

(5) The applicant shall bear all costs of evaluating the application or carrying out the risk assessment.

(6) Fees payable under this section shall be set out in the regulations to this Act.

Risk management

22. (1) The Competent Authority 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.

(2) Without limiting the generality of section 22 (1), the Competent Authority in consultation with the Council may,

- (a) 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;
- (b) prohibit further import, transit, contained or confined use, release or place on the market of any GMOs, if it becomes satisfied that it contains characteristics or specific traits which pose unacceptable risks to the environment, biological diversity, or to health;
- (c) order the cessation of any activity involving GMOs that are proven to cause risks to the environment, biological diversity or health;
- (d) order the cessation of any activity, which is being undertaken in violation of this Act or any decisions, made under this Act;

- (e) require the person responsible for any activity under this Act, 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;
- (f) 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;
- (g) 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
- (h) 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.

Unintentional release and emergency measures

- 23.** (1) The Competent Authority shall, in consultation with the Council, ensure that before any import, contained, confined use or transit:
- (a) an emergency plan is drawn up, by the applicant, for the protection of the environment, biological diversity and health in the event of an accidental or unintentional release; and
 - (b) information on safety measures and procedure to be adopted in the case of any accidental or unintentional release, is made available by the applicant to persons likely to be affected by it.
- (2) The information on safety measures shall be updated and made available periodically to the general public.
- (3) The applicant shall inform the Competent Authority of any accidental or unintentional release immediately after it has occurred and provide the following information -

- (a) the circumstances of the accident;
- (b) the identity and quantity of GMO released unintentionally;
- (c) any measure necessary to assess the effects of the accident on the environment, biological diversity or health; and
- (d) the emergency measures taken or to be taken.

PART V– DECISION MAKING AND COMMUNICATION PROCEDURE

Decision Making Procedure

24. (1) The Competent Authority shall, in consultation with the Council, evaluate the information presented to the Competent Authority or in the Biosafety Clearing House, as the case may be and may decide that the applicant -

- (a) needs to provide more information to enable decision-making;
 - (b) may proceed with his request;
 - (c) may proceed with his request but only under such conditions as the Competent Authority may specify; or
 - (d) not be allowed to proceed with the request.
- (2) The Competent Authority shall notify its decision to -
- (a) the applicant in writing and if an approval has been given shall, through the Registrar, issue a permit to that effect;
 - (b) the public ; and
 - (c) the Biosafety–Clearing-House.
- (3) The Competent Authority may, prior to its making a decision, request for further information as it may deem necessary and any

applicant who fails to supply the required further information shall be deemed to have withdrawn his application;

(4) An approval shall specify the step-by-step sequences of implementation and that risk assessment be conducted at each step;

(5) Any approval for import, contained or confined use, transit, release of a GMO shall require the applicant to carry out monitoring and evaluation of risks on a continuing basis for a period commensurate with the life cycle of the species, as determined by the Competent Authority;

(6) No approval shall be given unless there is a firm and sufficient evidence that the GMO poses no unmanageable risks to the environment, biological diversity or human health;

(7) Where there is a reason to suspect threats of serious damage, lack of scientific evidence shall not be used as a basis for not taking preventive measures;

(8) The Competent Authority shall, as a condition for approval, require the applicant to furnish evidence of insurance cover or some other arrangements sufficient to meet its obligations under this Act.

PART VI– REVIEW MECHANISMS

Review of Decisions

25. (1) The Competent Authority shall in consultation with the Council review any decision regarding the GMO at any time upon obtaining significant new scientific information indicating that the GMO or activities involved, may adversely affect the conservation and sustainable use of biological diversity, taking also into account risks to human health.

(2) The Competent Authority shall inform the applicant of its intent and reasons for initiating a review of the decision prior to the undertaking of such review.

(3) The applicant may request the Competent Authority to review its decision regarding a GMO or an activity conducted or proposed to be conducted by the Applicant where the applicant considers that -

- (a) a change in the circumstances has occurred that may have a material effect on the outcome of the risk assessment upon which the decision was based; or
- (b) additional scientific or technical information has become available that may have a material effect on the decision including any conditions, limitations or requirements imposed by an approval.

(4) If upon review under sub-sections (1) and (2) in consultation with a Committee, the Competent Authority finds that a change is warranted, it may issue an order changing the decision including any conditions in the approval in a manner that is consistent with the validated scientific evidence or other accepted scientific methodology.

(5) The Competent Authority shall –

- (a) provide the applicant with the written decision pursuant to review conducted; and
- (b) set out reasons for its decision.

Right of Appeal

26. (1) A person who is aggrieved by the decision of the Competent Authority under this Act may, within the prescribed period, and in the manner prescribed and upon the payment of a prescribed fee, appeal against such decision to the Minister who shall appoint an appeal board for the purposes of the appeal concerned.

(2) An appeal board shall consist of at least three persons who, in the opinion of the Minister, have expert knowledge on GMOs and who are suitable to decide on the issues of the appeal concerned.

(3) The Minister shall designate one of the members as chairman of the board .

(4) A person designated pursuant to subsection (3), shall recuse himself as a member of the appeal board if he has any direct or indirect interest in the subject matter of the appeal or if , for any reason, there is or there is likely to be a conflict of interests as a result of his participation in the proceedings of the appeal board.

(5) There may be paid to a member of an appeal board who is not a public servant such allowances as the Minister may determine with the concurrence of the Minister of Finance.

(6) An appeal board may,

- (a) confirm, set aside or amend the decision or action appealed against.
- (b) refer the matter back to the Competent Authority for reconsideration
- (c) make such other order as it may deem fit.

(7) If a decision or action which is the subject of an appeal is,

- (a) set aside the fee referred to in subsection (1) shall be refunded;
- (b) amended, such portion of the fee referred to in subsection (1) as the appeal board concerned may determine, shall be refunded to the appellant.

(8) The decision of the appeal board, together with the reasons which the decision was based, shall be in writing, and their copies be furnished to the Minister.

(9) The Appeal Board shall, within two weeks of its decision on a matter under this section, furnish the Minister with a copy of its decision and reasons for such decisions.

(10) The A person who remains aggrieved following an appeal under subsection (1) or who does not receive a response within the stipulated time, shall have the right to appeal to a competent court of law.

PART VII – PUBLIC INFORMATION, AWARENESS AND PARTICIPATION

Public Awareness

27. (1) The Registrar shall promote awareness and education of the public on biosafety matters, through the publication and dissemination of information on the provisions of this Act, regulations and other available guidance documents or materials aimed at improving understanding of biosafety, relevant approval and notification requirements.
- (2) The Registrar shall publish, on a regular basis,
- (a) information on any GMO, which has been granted or denied approval for import, transit, contained or confined use, release or placing on the market; and
 - (b) any risk assessment report with respect to a GMO; and
 - (c) persons who have applied to import or make contained or confined use of, transfer, release or place on the market a GMO.
- (3) The Registrar shall establish and maintain a registry of-
- (a) GMO for which approval is granted; and
 - (b) GMO and activities that are exempted in accordance with Section 19.

Public Participation

28. (1) The Registrar shall, upon receipt of the information referred to in Sections 16, 17 and 18, make available, the said information, to the public and relevant line Ministries.
- (2) The public may make comments within such period as may be specified.

(3) In cases where the Registrar arranges for a public consultation with regard to any proposed import, transit, contained or confined use, release or placing on the market of a GMO that shall be announced in the media with national coverage.

(4) The Competent Authority shall, in making or reviewing its decision, take into account the views and concerns of the public expressed in accordance with subsections (2) and (3).

Confidential Business Information

29. (1) The Competent Authority, the Council, the Registrar, the Committee and the Panel shall protect information determined by the Competent Authority as being confidential, after a claim for confidentiality is made by the applicant.

(2) In no case may the following information supplied by the applicant be kept confidential :

(a) general description of the GMO, names and addresses of the applicant and purpose of the import, transit, contained or confined use, release or placing on the market of a GMO;

(b) methods and plans for monitoring a GMO; and

(c) the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

(3) The Competent Authority may make available the information, referred to in subsection (1), to the public, notwithstanding that it may be commercially confidential if it decides that it is in the public interest to do so.

(4) If the applicant withdraws the application before approval, the Competent Authority, the Council, the Registrar, the Committee and the Panel, shall respect the confidentiality of the information except for the information referred to in subsections (2) and (3).

PART VIII- IDENTIFICATION AND DOCUMENTATION

Documentation for GMO for Contained and Confined Use

30. (1) GMOs imported into or exported from Lesotho for contained or confined use shall be accompanied by a permit from the Competent Authority and a documentation from the exporter that -

- (a) clearly identifies them as GMOs;
- (b) specifies any requirement for the safe handling, storage, transport and use;
- (c) provides a contact point for further information, including the name and address of the individual and institution to whom the GMOs are consigned; and
- (d) contains a declaration that the transboundary movement is in conformity with the requirements of this Act.

(2) The permit and documentation accompanying GMOs for contained or confined use shall remain available for inspection on the premises where the contained or confined use activities are carried out during office hours.

Documentation for GMOs for Direct Use as Food or Feed or for Processing

31. (1) GMOs imported into or exported from Lesotho for direct use as food or feed or for processing shall be accompanied during the transboundary movement upon delivery to the port of entry by a permit from the Competent Authority and documentation from the exporter that clearly identifies that the goods “may contain” GMOs and are not intended for intentional introduction into the environment.

(2) The accompanying document shall provide a contact point for further information and a declaration that the transboundary movement is in conformity with the requirements of this Act.

Documentation for GMOs intended for Intentional Introduction into the Environment

32. (1) GMOs that are imported into or exported from Lesotho for intentional introduction into the environment shall be accompanied by a permit from the Competent Authority and by documentation from the exporter that -

- (a) clearly identifies them as GMOs;
- (b) specifies the identity and relevant traits or characteristics;
- (c) has any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and
- (d) contains a declaration that the transboundary movement is in conformity with the requirements of this Act.

PART IX – EXPORTING GMOs

Exporting a GMO from Lesotho

- 33.** (1) A person who intends to export a GMO from Lesotho, shall provide the Competent Authority with a written Advance Informed Agreement of the competent authority of the importing country.
- (2) The presentation of the Advance Informed Agreement by an exporter shall, in no way, absolve the exporter from complying with any other laws governing foreign trade.
 - (3) There shall be no approval for the export of GMOs that are banned under this Act.

PART X – ENFORCEMENT

Inspectors

34. (1) There shall be appointed qualified inspectors for the purpose of ensuring compliance with this Act, and any regulations made pursuant to this Act.

(2) An inspector shall be furnished with a certificate signed by the Registrar, stating that he has been appointed as an inspector under this Act, and at the request of any person affected by the exercise or performance of duties by such an inspector, shall exhibit this certificate to such a person.

(3) An inspector may, on the authority of a warrant issued in terms of this section –

- (a) conduct an investigation to determine whether the provisions of this Act are being or have been complied with;
- (b) without giving prior notice, enter any place or facility in respect of which he has reason to believe that a contravention of the provisions of this Act is taking place, to
- (c) inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;
- (d) request any information regarding such an activity or process from the owner or person in charge of the Carrying out of such activities
- (e) 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 this Act; and
- (f) give notice to the owner of any material, substance, appliance, book, statement or document seized under paragraph (e) or to the person who had control over it immediately before any seizure under paragraph (e) to

remove the seized items at such person's cost within a specified period and to a place specified in such notice.

(4) A warrant referred to in subsection (3) shall be issued by a Magistrate having jurisdiction in an area in which the place or facility in question is situated, and shall only be issued if it appears from the information on oath that there are reasonable grounds to believe that any material, substance, appliance, book, statement or document that may relate to the contravention of this Act, is upon or in such place or facility. A warrant issued in terms of this section shall be executed with strict regard to decency and order.

(5) If no criminal proceedings are instituted in connection with any item referred to in this section and seized in terms of paragraph (e), or if it appears that such an item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.

(6) After the conclusion of criminal proceedings, any item seized in terms of subsection (3) and which served as an exhibit in the proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the Registrar.

Routine Inspection

35. An inspector may, during office hours, without warrant, enter any place or facility registered in terms of this Act 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 of a place or facility 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 this Act.

PART XI – LIABILITY AND REDRESS

Liability and Redress

36. (1) A person who, imports, transit, conduct contained or confined use of, releases or places on the market a GMO, shall be strictly liable for any harm caused by such GMO, and the person shall fully compensate the affected person.

(2) Liability shall attach to the person with operational control of the GMO at the time the incident causing damage occurs.

(3) If there is more than one person responsible for the damage, injury or loss, then the liability shall be joint and several.

(4) In the case of harm to the environment or biological diversity compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures.

(5) Liability shall also extend to harm or damage caused directly or indirectly by the GMO to the economy, social, cultural practices, the livelihood, indigenous knowledge systems or technologies of a community or communities.

(6) The harm sustained shall include disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to the biological mass, and damage to the economy of an area or community.

(7) Any action in respect of the harm caused by a GMO shall lapse only after a reasonable period from the date on which the affected person or the community could reasonably be expected to have learned of the harm, taking due account of:

(a) the time the harm may take to manifest itself; and

- (b) the time that it may reasonably take to correlate the harm with the GMO, having regard to the situation or circumstance of the person or community affected.

(8) A person or group of persons may be entitled to bring a claim and seek redress in respect of the breach or threatened breach of any provision of this Act-

- (a) in that person's or group of person's interest;
- (b) in the interest of, or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;
- (c) in the interest of, or on behalf of, a group or class of persons whose interests are affected;
- (d) in the public interest; and
- (e) in the interest of protecting the environment or biological diversity.

(9) No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

PART XII - OFFENCES AND PENALTIES

Offences and Penalties

37. (1) A person who -

- (a) imports, transits, releases, places on the market or makes contained or confined use of a GMO without a permit from the Competent Authority;
- (b) violates any conditions of a permit issued under this Act;

- (c) withholds information that has become available to him after the approval of his application, and that could change the evaluation of the risk posed by his project,
- (d) provides false, misleading or deceptive information in order to secure an approval and a permit under this Act;
- (e) does not package or identify any GMO in accordance with this Act;
- (f) packages or identifies any GMO in a manner that is false, misleading, deceptive or in contravention of this Act;
- (g) exports a GMO without the Advance Informed Agreement of the importing country; or
- (h) violates any other provision of this Act or any condition or requirement imposed under this Act;

commits an offence and is liable on conviction to imprisonment for a term of not less than 5 years but not exceeding 25 years or to a fine of not less than M10, 000 but not exceeding M250,000 or to both.

(2) A person shall upon conviction of an offence under subsection (1) be prohibited from engaging in any activity in relation to GMOs.

(3) The prohibition referred to in subsection (2) shall extend to any corporation, body or legal entity that may be devised to avoid the effect of the said order.

(4) A person who repeatedly commits any other offence under this Act may be prohibited from engaging in any activity in relation to GMOs.

(4) Where the offence is committed by a corporation or company and where the court feels that a custodial sentence ought to be imposed, the executive officer in charge at the time the offence is committed, shall be liable to imprisonment.

PART XIII – MISCELLANEOUS

Transitional Provisions

38. (1) Any application pending at the date of the entry into force of this Act shall be subject to the provisions of this Act.

(2) An application for approval shall be made in accordance with Sections 16, 17 or 18 as the case may be, for any import, contained or confined use, release, or placing on the market of a GMO that has already been carried out prior to the coming into force of this Act.

(3) An application in terms of subsection (2) shall be submitted to the Competent Authority within a time limit to be determined by the Competent Authority.

(5) If the application has been made within the prescribed time limit, the activity in respect of which the application is made may continue until a decision is made by the Competent Authority pursuant to Section 24.

Regulations

39. (1) The Minister may make regulations for the purpose of giving effect to the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), Regulations made under subsection (1) may -

- (a) prescribe the internal procedures for the operation of the Competent Authority, the Council, the Registrar, the Committee and the Panel established for the purpose of this Act;
- (b) govern the conduct of contained or confined use activities, including relevant definitions, risk classifications, waste and disposal requirements and procedures and requirements for risk assessments;

- (c) regulate risks identified during risk assessment process and impose mechanisms, measures or actions that need to be taken to ensure safe use of GMOs;
- (d) prescribe any additional documentation or identification requirements applicable to the import of GMO intended for contained or confined use, food or feed or for processing, or intended for intentional introduction into the environment;
- (e) set standards to which facilities or activities involving GMOs shall conform;
- (f) prescribe fees to cover administrative costs of processing notifications, applications or petitions to be submitted under this Act;
- (g) Prescribe the time-limits within which any action or activity could be taken under this Act;
- (h) Prescribe anything required or to be prescribed under this Act.

Schedule I

Information Required in Applications (Section 17)

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the genetically modified organism, as well as the domestic classification, if any, of the biosafety level of the genetically modified organism.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (f) Centre of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organisms.
- (i) Intended use of the genetically modified organism or products thereof, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- (j) Quantity or volume of the genetically modified organism to be transferred.
- (k) A previous and existing assessment report consistent with Annexure II.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling documentation, disposal and contingency procedures, where appropriate.
- (m) Regulatory status of the genetically modified organism within the state of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the genetically modified organism is banned in the State of export, the reason or reasons for the ban.

- (n) Result and purpose of any notification by the exporter to the other States regarding the genetically modified organism to be transferred.
- (o) A declaration that the above –mentioned information is factually correct.

Schedule II

Risk Assessment (Sections 17 and 21)

Risk Assessment

Objective:

1. The objective of risk assessment, is to identify and evaluate the potential adverse effects of genetically modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk Assessment:

2. Risk Assessment is, inter alia, used by competent authorities to make informed decisions regarding genetically modified organisms.

General principles:

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
5. Risks associated with genetically modified organisms or products thereof, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
6. Risk assessment should be carried out on a case-by case basis. The required information may vary in nature and level of detail from case

to case, depending on the genetically modified organism concerned, its intended use and the likely potential receiving environment.

Methodology:

7. 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.
- 8 To fulfill 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 environment, taking also into account risks to human health;
 - (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of the exposure of the likely potential receiving environment to the genetically modified organism;
 - (c) An evaluation of the consequences should these adverse effects be realized;
 - (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 released;
 - (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.

Points to consider:

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:
 - (a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms,

including information on taxonomic status, common name, origin, centers of origin, centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

- (b) *Donor organism or organism*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- (c) *Vector*. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) *Genetically Modified Organism*. Identity of the genetically modified organism, and the differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms;
- (f) *Detection and identification of the genetically modified organism*. Suggested detection and identification methods and their specificity, and reliability;
- (g) *Information relating to the intended use*. Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organism; and
- (h) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Schedule III

Information Requirements for Notices to the Biosafety-Clearing House (Section 18)

- (a) The name and contact details of the applicant for a decision for domestic use.
- (b) The name and contact details of the authority responsible for the decision.
- (c) Name and identity of the genetically modified organism.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism.

- (e) Any unique identification of the genetically modified organism.
- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centres of origin and centers of genetic diversity, if known, of the recipient organism and /or parental organism and a description of the habitats where the organism may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organisms related to biosafety.
- (i) Approval uses of the genetically modified organism.
- (j) A risk assessment report consistent with Schedule II.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.