THE BIOSAFETY ACT, 2012

_____

(Act No……7……of 2012)

ARRANGEMENT OF SECTIONS

PART I
PRELIMINARY

PART II
INSTITUTIONAL ARRANGEMENT

PART III
NOTIFICATION AND AUTHORISATION REQUIREMENTS

PART IV
REVIEW MECHANISMS

PART V
SAFEGUARDS

An Act

entitled

An Act to provide for the safe handling, transfer and use of genetically modified organisms and other matters incidental thereto.

Enacted by the King and the Parliament of Swaziland

PART I
PRELIMINARY

Short title and date of commencement

1. (1) This Act may be cited as the Biosafety Act, 2012.

(2) This Act shall come into force on a date to be appointed by the Minister by notice in the Gazette.

Interpretation

2. In this Act, unless the context otherwise requires-

"applicant" means a person or country submitting an application, notification or petition pursuant to the provisions of this Act;

"biosafety" means the mechanisms for ensuring the safe handling, transfer and use of products of biotechnology;

"Biosafety Clearing House" means the information exchange mechanisms established under article 20 of the Cartagena Protocol on Biosafety;

"Cartagena Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

"Committee" means the National Biosafety Advisory Committee as established in terms of section 6;

"Competent Authority" means the Swaziland Environment Authority as designated in terms of section 4;

"contained use" means any operation or activity, undertaken within a facility, installation or other physical structure, which involves GMOs that are controlled by specific measures that effectively limit their contact with and their impact on the external environment and the general population;

"export" means the intentional transboundary movement from the area of national jurisdiction of the country to the area of national jurisdiction of another country;

"facility" means any place designated by the Competent Authority as a place where GMOs may be stored;

"genetically modified organism (GMO)" means any biological entity capable of replication or of transferring genetic material and includes plants, animals, micro-organisms, cell cultures and other vector systems in which the genetic material has been altered through modern biotechnology and other genetic modification which occurs through techniques such as-

(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produce into a virus, bacterium, plasmid or other vector and their incorporation into host organisms in which they are capable of continued propagation;

(b) 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 (including protoplast) or hybridisation where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells;

"import" means the intentional transboundary movement into the area of national jurisdiction of the country from the area of national jurisdiction of another country;

"intentional introduction to the environment" means any deliberate use of GMOs, subject to this Act, that is not contained use, but does not include GMOs imported for direct use for food or feed or for processing;

"living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

"Minister" means the Minister responsible for environmental affairs;

"national focal point" means the Swaziland Environment Authority as designated in terms of section 5;

"operator" means any person in direct or indirect control of the living modified organism as authorised in terms of this Act, including *inter alia* the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, carrier or supplier;

"placing on the market" means making a GMO available to third parties whether there has been monetary exchange or not;

"Registrar" means the person appointed as such in terms of section 8;

"risk assessment" means the evaluation of risk in accordance with the guidelines set out in the second schedule;

"risk to human health" means the potential impact on human beings as a direct result of an adverse effect on the conservation and sustainable use of biological diversity; and

"third party" means any other person not directly involved within a transaction.

Application

3. This Act applies to the import, export, transit, contained use, release or placing on the market-

(a) of any genetically modified organism whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing;

(b) or a product of a genetically modified organism,

except for pharmaceuticals subject to the Pharmacy Act, 1929.

PART II
INSTITUTIONAL ARRANGEMENT

Competent Authority

4. (1) The Swaziland Environment Authority, as established in terms of the Environment Management Act, 2002, is designated as the Competent Authority for the purpose of implementation and the administration of this Act and any regulations made pursuant to this Act.

(2) The Management Board of the Swaziland Environment Authority shall also serve as the Board for the Competent Authority.

(3) The primary functions of the Competent Authority are to-

(a) receive, respond to and make decisions on notifications pursuant to section 10 and applications pursuant to section 12 in consultation with the National Biosafety Advisory Committee and in conformity with the requirements of this Act;

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

(c) promote public awareness and education concerning the activities regulated under this Act, including through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorisation process; and

(d) advise on and be responsible for the implementation of the national biosafety policy;

(e) identify priorities of scientific and technological research that shall enable the country to meet its national and international goals and priorities on biosafety;

(f) coordinate, monitor and supervise all sectoral activities that involve modern biotechnology and biosafety issues;

(g) ensure the integration of safe application of biotechnology on the national development planning and policy formulation in liaison with line ministries;

(h) 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;

(i) recommend measures necessary for the harmonisation of the plans and policies of various sectors that are involved in safe application of biotechnology; and

(j) generally administer and give effect to this Act.

National Focal Point

5. (1) The Swaziland Environment Authority shall serve as the National Focal Point.

(2) The primary functions of the National Focal Point are to-

(a) receive, process and respond to information and notifications from the Secretariat of the Cartagena Protocol; and

(b) facilitate international information sharing as set out in section 26.

Establishment and composition of a National Biosafety Advisory Committee

6. (1) A Committee called the National Biosafety Advisory Committee is established for the purpose of conducting risk assessments and providing scientific and other technical advice and assistance to the Competent Authority.

(2) The Committee shall consist of officers not exceeding nine drawn from government agencies and independent institutions and having the qualifications as provided for in terms of the Fourth Schedule.

(3) The members of the Committee shall be appointed by the Minister for a term not exceeding three years which may be renewed.

Functions of the National Biosafety Advisory Committee

7. (1) The Committee shall be responsible for-

(a) conducting risk assessments;

(b) reviewing risk assessments provided in applications or notifications;

(c) reviewing risk management measures;

(d) recommending containment measures, limitations on the duration of authorisations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound condition and risk management measures;

(e) developing guidelines for the safe transport, confined trials and commercial release of GMOs and their products in line with accepted international standards;

(f) developing standards for occupational safety for workers involved with development, testing and release of GMOs and their products and processes;

(g) developing guidelines for safe disposal of waste and leftover planting material;

(h) developing guidelines for commercial release and marketing of GMOs and products thereof; and

(i) providing such other expert advice and assistance as the National Authority on Biosafety may request.

(2) The Committee may establish sub-committees that may be necessary for the furtherance of the objectives of this Act and designate chairpersons of any such committees, who shall be drawn from the members of the Committee.

(3) The Committee may appoint additional members to sub committees as may be required.

(4) The Committee may co-opt temporary non-voting expert advisors from scientific disciplines not otherwise adequately represented on the Committee and its subcommittees.

(5) Members of the Committee and its subcommittees and all advisors shall be required to disclose publicly any actual and potential conflicts of interest relating to any risk assessment or any other matter upon which the Committee is required to deliberate.

(6) Internal procedures for the operation of the Committee and its sub-committees shall be proposed by it and approved by the Competent Authority and such internal procedures shall provide for all matters necessary for the effective and transparent operation of the Committee and any sub-committees established and shall include, at the minimum, mechanisms and procedures for-

(a) designating chairpersons of the Committee and its subcommittees, appointing members of sub-committees and advisers and specifying rules of procedure for the Committee and its sub-committees, and for the participation of advisors in the Committee or its sub-committees;

(b) ensuring the absence of conflicts of interest among members of the Committee and its sub-committees in conformity with subsection (5); and

(c) ensuring the protection of confidential information as required by section 14 including a declaration that any information attained by virtue of membership in the Committee or a sub-committee, or appointment as an advisor to the Committee or a sub-committee, shall not be disclosed to others or used for any research,

development or commercial purpose without the express written authorisation of the applicant identifying the information as confidential pursuant to section 14.

National Biosafety Registry

8. (1) There shall be a National Biosafety Registry, created within the Swaziland Environment Authority which shall be manned by a Registrar and such other staff as may be necessary.

(2) The Registrar shall be a person who has specialised training and qualifications in biotechnology.

Functions of the Registrar

9. The Registrar shall perform the following functions-

(a) receive and screen completeness of a GMO application;

(b) forward applications to the Committee;

(c) where an approval has been given, issue a permit prescribed by this Act;

(d) where the Registrar has ascertained or suspects on reasonable grounds that GMOs are being imported, 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 the removal of such GMOs to a place or facility and in a manner prescribed by the Competent Authority, and

(ii) authorise an inspector to destroy such GMO or cause it to be destroyed;

(e) maintain a database of all applications received as well as all modern biotechnology applications being run in the country including information relating to monitoring and evaluation;

(f) furnish an inspector with a certificate of appointment;

(g) require the cessation of any genetic modification activity at facilities where the provision of this Act or the conditions of a permit have not been or are not being complied with; and

(h) attend meetings of the Board of the Competent Authority whenever matters under this Act are dealt with.

PART III
NOTIFICATION AND AUTHORISATION REQUIREMENTS

Notification requirements and procedures for contained use activities

10. (1) A person shall not conduct any contained use activities or import GMOs for contained use activities without prior submission of a notification to the Competent Authority as set out in this section.

(2) A notification of intent to conduct contained use activities shall be submitted at least sixty calendar days before the activities covered by the notification are due to begin.

(3) The notification shall include-

(a) the name and contact information for the applicant;

(b) the location where contained use activities shall be undertaken;

(c) the nature and identity of the GMO involved;

(d) the nature and purpose of the activities, including such activities as storing, transporting, producing, culturing, processing, destroying, disposing or using the GMOs in any other way;

(e) a description of the containment measures to be provided and the suitability of those measures for the GMOs and activities to be undertaken;

(f) a description of any potential risks associated with the GMOs and activities to be undertaken; and

(g) a description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the GMOs that may occur as a result of the activities to be conducted.

(4) In response to the submission of a notification, the Competent Authority may, in consultation with Committee and in writing, request additional information, including a risk assessment carried out in a scientifically sound manner, in accordance with the second schedule and recognised risk assessment techniques.

(5) The Competent Authority shall make a final decision not later than sixty days either following the notification under subsection (1) or following receipt of the additional information requested under subsection (4) as to whether the proposed activities may proceed and if a decision is not made and communicated to the applicant the activities described in the notification may proceed.

(6) Where the Competent Authority decides that the proposed activities may not proceed or should be subject to limitations or conditions not set out in the notification, the Competent Authority shall include in its final written decision the reasons for the prohibition or any limitations or conditions that may be placed on the proposed activities.

Authorisation requirements for intentional introduction into the environment

11. (1) The following activities are prohibited unless authorised by the Competent Authority in conformity with this Act-

(a) the intentional introduction into the environment of a GMO for purposes other than placing on the market; and

(b) placing on the market of a GMO.

(2) A person shall not import a GMO for activities subject to subsection (1) without authorisation under this Act.

(3) A person proposing to export a GMO covered by this Act from the country to another country party to the Cartagena Protocol shall-

(a) notify the Competent Authority of the proposed country party of import, in writing, prior to the first transboundary movement of the GMO for intentional introduction into the environment of the country party of import by supplying, at a minimum, information specified in the first schedule, in accordance with the Cartagena Protocol and any applicable domestic legislation;

(b) include a declaration that all information provided in such notification is factually correct;

(c) prior to shipment, provide to the Competent Authority with a copy of the authorisation granted by the importing country where authorisation is required under the Cartagena Protocol and the applicable laws of that country.

Application procedures for introduction into the environment

12. (1) A person proposing to introduce a GMO into the environment or place it on the market shall submit to the Competent Authority an application that complies with the requirements of this section and describe the activities for which authorisation is sought, except as provided under section 19.

(2) Applicants shall include in their submissions-

(a) the information specified in the first schedule, with the exception of any information the Committee identifies as unnecessary in pre-application consultations;

(b) a risk assessment in conformity with the second schedule; and

(c) any additional information applicants deem relevant to an assessment of the potential risk and benefits of the requested activity.

(3) Applicants shall include a declaration that the information Contained in their submissions is factually correct.

(4) An applicant may withdraw without prejudice the application at any time prior to the issuance of a final decision by the Competent Authority without prejudice.

GMO for direct use as food, feed or processing

13. (1) A person shall not import a GMO for direct use as food, feed or for processing without prior submission, within the time prescribed in the regulations, of a notification, in writing, to the Competent Authority containing information specified in the third schedule and any other information as may be prescribed by the Competent Authority.

(2) The provisions of section 10 (4) to (7) shall apply to GMOs as may be appropriate.

(3) Subject to subsection (5) food or feed produced from a GMO shall not be placed on the market until sixty days after a risk assessment carried out in accordance with the second schedule have been submitted to the Competent Authority.

(4) Upon submission of a risk assessment in terms of subsection (3) the Competent Authority may, in consultation with the Committee, request additional information.

(5) The Competent Authority shall make a final decision as to whether the food may be placed on the market or not, not later than sixty days either following receipt of the risk assessment under subsection (3) or following receipt of the additional information requested under subsection (4) and if no such decision is made and communicated to the applicant the activities described in the notification may proceed.

(6) Where the Competent Authority decides that the food or feed may not be placed on the market or should be subject to limitations or conditions not set out in the

submissions under subsections (1), (3) and (4), the Competent Authority shall include in its final decision the reasons for the prohibition or any limitations or conditions that may be placed on the permitted activities.

Confidential information

14. (1) The Competent Authority shall-

(a) permit an applicant to identify information provided to the Competent Authority in accordance with the requirements of this Act and any regulations promulgated under this Act, including information contained in notifications, applications and other written submissions, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;

(b) decide whether the Competent Authority accepts as confidential the information designated by the applicant;

(c) prior to any disclosure of information identified by an applicant as confidential, inform the applicant of the rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation and for internal review of the decision; and

(d) in the event that an applicant withdraws or has withdrawn an application, respect the claim of confidentiality, including claims for that information on which the Competent Authority and the applicant disagree as to its confidentiality.

(2) The Competent Authority shall neither use nor permit the use of confidential information accepted as confidential under subsection (1) for any purpose not specifically authorised under this Act except with the written consent of the applicant and shall ensure that such information is protected by all persons involved in handling or reviewing applications or other written submission under this Act.

(3) Without prejudice to subsection (1) (d), the following information shall not be considered confidential-

(a) the name and address of the applicant;

(b) a general description of the GMO;

(c) a summary of risk assessment performed on the GMO; and

(d) any methods and plans for emergency response.

Acknowledgement and preliminary response

15. (1) The Competent Authority shall, upon receipt of an application submitted under section 12, immediately refer the application to the Committee for prompt screening for apparent completeness.

(2) The Competent Authority shall, based on information provided by the Committee, within thirty days of receipt of application acknowledge receipt of the application and make a preliminary response in writing to the applicant.

(3) The preliminary response shall include-

(a) the date of receipt of the application;

(b) whether the application appears to contain the required information or, if not, what additional information within the scope of first schedule is required.

(4) Where additional information is required, the number of days the Competent Authority has to wait for the information shall not be included in calculating the timeframe for making a final decision under section 18.

Unintentional introduction into the environment

16. (1) An operator with knowledge of an unintentional or unauthorised introduction into the environment of a GMO subject to this Act that is likely to have significant adverse effects on the conservation or sustainable use of biological diversity, taking into account also risks to human health, shall, within twenty-four hours of when the operator knew of the introduction, notify the Competent Authority of the occurrence.

(2) A notification under subsection (1) shall include the following-

(a) available relevant information on the estimated quantities and relevant characteristics and traits of the GMO;

(b) information on the circumstances and estimated date of the introduction;

(c) any available information about the possible adverse effect on the conservation and sustainable use of biological diversity, as well as available information about possible risk management measures;

(d) any other relevant information; and

(e) a point of contact for further information.

(3) The Competent Authority, in consultation with the Committee, shall consult with operators providing notifications under subsection (1) and determine whether any action is necessary to minimise any adverse effect on the conservation and sustainable use of biological diversity, taking into account also risks to human health.

(4) Where the Competent Authority knows of an occurrence within its jurisdiction resulting in an introduction that leads to an unintentional transboundary movement of a GMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health, in another country, the Competent Authority shall notify affected or potentially affected countries, the Biosafety Clearing House and where appropriate, relevant international organisations.

Risk assessment and risk management

17. (1) The Competent Authority shall ensure that appropriate and adequate risk assessments are carried out for all activities that require authorisation under section 11.

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

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

(4) Upon conclusion of the risk assessment and auditing process, the Committee shall provide to the Competent Authority a risk assessment report that gives its opinion, with justifications, on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the GMO.

(5) The report referred to in subsection (4) shall include a summary of the risk assessment that does not include any confidential information subject to protection under section 15.

(6) The Competent Authority shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control risks identified during the risk assessment process and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of GMOs on the

conservation and sustainable use of biological diversity, taking also into account risks to human health.

(7) The Competent Authority shall provide the risk assessment report described in subsections (4) and (5) to the applicant within three days of receipt of the report from the Committee and the applicant may submit comments on the report in writing within thirty days of its receipt of the report and any such comments shall be considered by the Competent Authority, in consultation with the Committee, in decision-making under section 18 (2).

Decision-making and communication of decision

18. (1) The Competent Authority shall, following receipt of the risk assessment report, make a decision concerning the authorisation requested in the application submitted under section 12.

(2) Any decision rendered under subsection (1) shall be based upon-

(a) the information submitted by the applicant under section 11;

(b) the risk assessment report prepared by the Committee in accordance with section 17 (4) and (5);

(c) any written comments provided by the applicant in accordance with section 17 (7); and

(d) any relevant comments submitted by the public pursuant to section 25.

(3) In reaching a decision the Competent Authority may also take into account, consistent with the international obligation of the country, socio-economic considerations arising from the impact of GMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

(4) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account also risks to human health, shall not prevent the Competent Authority from making a decision, as appropriate, in order to avoid or minimise such potential adverse effects.

(5) A final decision shall be made and communicated to the applicant within one hundred and twenty days of receipt of application submitted for the intentional introduction into the environment of a GMO for purposes other than placing on the market and within two hundred and seventy days of receipt of an application submitted for the placing on the market of a GMO.

(6) The final decision of the Competent Authority shall be recorded in a decision document that-

(a) identifies the applicant and summarises the nature of the request;

(b) describes the procedure followed in reviewing the application;

(c) includes the summary of the risk assessment conducted by the Committee;

(d) states whether the activity is authorised, with or without conditions, or whether the requested activity is prohibited; and

(e) provides the reasons for the decision.

(7) Any specific conditions, limitations or requirements related to the authorisation shall be clear on the face of the decision document.

(8) A person shall not vary the purpose of the authorised activity as set forth in the decision document unless the person obtains authorisation from the Competent Authority.

(9) GMOs or activities authorised under this section shall be included in the registry to be established under section 8.

Simplified application and review procedures

19. (1) The Competent Authority may approve a facility, including an installation or other physical structure, for which further notification is not required under section 10 for designated types or classes of contained use activities conducted in conformity with applicable laws, regulations and good laboratory practice standards and procedures; and requirements for this purpose shall be established by regulation under section 34.

(2) The Competent Authority may exempt any GMOs or activities from the requirements of sections11 and 12 where it determines that sufficient experience or information exists to conclude that the GMOs or activities do not pose a significant risk to the conservation and sustainable use of biological diversity, taking into account also risks to human health.

(3) Where sufficient experience or information exists to conclude that GMOs or activities are not likely to pose a significant risk to the conservation and sustainable use of biological diversity, taking into account also risks to human health, but an exemption under subsection (2) is not warranted, the Competent Authority may designate types or categories of GMOs or activities otherwise subject to sections 11

and 12 that my proceed sixty days after the submission of a notification conforming to subsection (4).

(4) A notification of an intent to conduct an activity for which a designation has been made with respect to an activity or GMO under subsection (3) shall be submitted to the Competent Authority at least sixty days before the activity covered by the notification is due to begin and shall the notification shall include-

(a) the name and contact information for the person submitting the notification;

(b) the location where the activity shall be undertaken;

(c) the nature and identity of the GMO involved;

(d) the nature and purpose of the activity;

(e) a description of any containment measures to be provided and the suitability of those measures for the GMO and activity to be conducted; and

(f) a description of remedial measures to be undertaken in the event of any unintentional introduction into the environment of the GMO that may occur as a result of the activity to be conducted.

(5) The Competent Authority shall publish notice of any proposal to exempt or apply simplified procedures to GMOs or activities under subsections (2) and (3) in accordance with section 25 and transmit the proposal to the Committee for review.

(6) The Competent Authority shall make a final decision on proposals under subsections (2) and (3) based upon the scientific review conducted by the Committee and relevant comments submitted by the public and any such exemptions or simplified procedures established under this section shall apply equally to the designated GMOs or activities whether undertaken domestically or abroad.

(7) The Competent Authority shall exempt from further regulation under this Act GMOs or categories of GMOs agreed pursuant to Article 7(4) of the Cartagena Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity.

(8) GMOs or activities exempted or subject to simplified procedures under subsections (2), (3) or (7) or as a result of a successful petition under section 18 shall be included in the registry established under section 8.

Petition for exemption or simplified procedures

20. (1) A person may petition the Competent Authority to exempt or to apply simplified procedures for GMOs or activities under section 19(2) or (3) at any time.

(2) Petitions shall contain the following information-

(a) name and address of the applicant;

(b) name and description of the GMOs or types and classes of GMOs and activities for which exemption or simplified procedures are sought;

(c) a comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;

(d) any information known to the applicant that would be unfavourable to the petition.

(3) Within ten days of receipt, the Competent Authority shall publish the petition in accordance with section 25 and transmit the petition to the Committee for review.

(4) The Competent Authority shall make a final decision on the petition based upon the scientific review conducted by the Committee and relevant comments submitted by the public and the decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the applicant within one hundred and twenty days of receipt of the petition by the Competent Authority.

PART IV
REVIEW MECHANISMS

Review of decisions

21. (1) The Competent Authority, in consultation with the Committee, may review any decision under sections 9, 10 or 19 (1), (2) or (3) at any time upon obtaining significant new scientific information indicating that the GMOs or activities involved may adversely affect the conservation and sustainable use of biological diversity, taking into account also risks to human health and the Competent Authority shall inform the applicant of its intent and reasons for initiating a review of the decision prior to undertaking the review.

(2) An applicant may request the Competent Authority to review its decision under section 10, 11 or 19 (1), (2) or (3) with respect to an activity conducted or proposed to be conducted by the applicant where the applicant considers that-

(a) a change in 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 under an authorisation.

(3) Where, upon review under subsections (1) or (2) in consultation with the Committee, the Competent Authority finds that a change is warranted, it may issue an order changing the decision and conditions in the authorisation in a manner that is consistent with the validated scientific evidence or other accepted scientific methodology.

(4) A written decision, pursuant to a review conducted under subsection (1), shall be provided to the applicant by the Competent Authority within ninety days from the date the applicant is notified of the review and shall set out the reasons for the decision.

(5) A written decision, in response to a request for review under subsection (2), shall be provided to the applicant by the Competent Authority within ninety days of the request and shall set out the reasons for the decision.

Right of appeal

22. (1) An applicant who is aggrieved by a decision of the Competent Authority may appeal to the Minister, on either procedural or substantive grounds within twenty one days after the applicant was informed of the decision.

(2) In deciding an appeal, the Minister shall seek advice of a panel of advisors, appointed by the Minister and composed of-

(a) an expert in socio-economics;

(b) an expert in the relevant biotechnology; and

(c) a legal expert.

PART V
SAFEGUARDS

Monitoring and submission of new information

23. (1) Operators shall monitor their activities to ensure that the operators comply with the requirements of this Act and any conditions or requirements imposed in connection with the authorisation or allowance of activities under this Act.

(2) Operators that become aware of any significant new scientific information indicating that authorised activities with GMOs may adversely affect the conservation and sustainable use of biological diversity, taking into account also risks to human health, or pose potential risk not previously known or considered, shall immediately advise the Competent Authority of the new information and newly identified risk and of the measures put in place to ensure the continued safe use of the GMOs.

(3) Subject to the protection of confidential information in accordance with section 14, operators shall supply to the Competent Authority, upon request and in accordance with regulations promulgated under the authority of this Act, such information about their activities as is necessary for it to carry out its supervisory, monitoring or enforcement tasks under this Act or to deal with any emergency situations.

Cessation orders

24. (1) The Competent Authority may issue an order for the immediate cessation of any activity covered by an authorisation or which has been subject to a notification submitted under this Act or for the immediate imposition of additional risk management measures with respect to such activity, if the Competent Authority determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account also risks to human health, on the basis of-

(a) one or more tests conducted and evaluated in a manner consistent with accepted scientific procedures; or

(b) other validated scientific evidence.

(2) The Competent Authority may also issue a cessation order upon the failure of an operator to demonstrate substantial compliance, after a reasonable period of time, with an order issued under section 21(3) or, with respect to an authorisation granted or notification submitted under this Act, when there exists a material infringement of any provision of this Act or regulations under this Act.

(3) An order issued pursuant to subsections (1) or (2) shall be withdrawn once the Competent Authority determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, taking into account also risks to human health.

PART VI
PUBLIC INFORMATION, AWARENESS AND PARTICIPATION

Public awareness and participation

25. (1) The Competent Authority shall promote awareness and education of the public and those conducting activities subject to the Act concerning biosafety matters through the publication and dissemination of this Act and regulations made under this Act, as well as guidance documents and other material aimed at improving understanding of biosafety and related authorisation and notification requirements.

(2) The Competent Authority shall publish, on a regular basis-

(a) notices concerning proposals under section 19(2) and (3); and

(b) proposed decisions on applications and petitions filed pursuant to sections 10 and 19.

(3) Upon request, the Competent Authority shall make available to any person portions of any application or petition subject to subsection (2)(b) that do not qualify as confidential information under section 14 without prejudice to section 11(1)(d).

(4) A person may submit written comments on a proposed decision on any application for placing a GMO on the market or any petition for an exemption within sixty days from the date the notice is posted and such comments shall be considered as part of the decision-making process in accordance with section 15(2), comments received by the Competent Authority and responses to those comments shall also be made available to the public upon request.

(5) The Competent Authority shall publish notices of final decisions concerning all applications or petitions under sections 11 and 20 and notices concerning the final resolution of any compliance matters under sections 31 and 32 in cases involving non-compliance with material provisions of this Act.

International information sharing

26. (1) The Competent Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of GMOs to the area of national jurisdiction of the country.

(2) The Competent Authority shall provide to the Biosafety Clearing House-

(a) a copy of this Act, including any amendments, decisions pursuant to sections 19 (2) or (3), regulations promulgated

under this Act, and any other legislation or national guidelines of relevance to the implementation of the Cartagena Protocol or the management of GMOs;

(b) summaries of risk assessments generated pursuant to section 17 (4);

(c) final decisions regarding the importation or intentional introduction into the environment of GMOs pursuant to section 11;

(d) reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Protocol;

(e) within thirty days of taking a decision under section 21, a copy of the decision describing the changes to the previous decision and the reasons for the decision; and

(f) any other information required under the Cartagena Protocol or other international agreements concerning the subject matter addressed by this Act.

(3) Where the Competent Authority renders a final decision regarding domestic use, including placing on the market, of a GMO that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorisation of that GMO, as specified in the third schedule, is provided to the Biosafety Clearing House within fifteen days of making the decision.

PART VII
IDENTIFICATION, DOCUMENTATION AND LABELLING

Documentation for GMOs intended for contained use

27. (1) GMOs that are imported into or exported from the country for contained use shall be accompanied by documentation that-

(a) clearly identifies the GMOs as GMOs;

(b) specifies any requirements for the safe handling, storage, transport and use; and

(c) provides a contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned.

(2) Any additional documentation or identification requirements

applicable to imports or exports subject to subsection (1) and agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with section 34.

Documentation for GMOs for direct use as food, feed or for processing

28. (1) GMOs that are imported or exported from the country for direct use as food, feed or for processing shall be accompanied during the transboundary movement and upon delivery to the port of entry by documentation that clearly identifies that the goods "may contain" GMOs and are not intended for intentional introduction into the environment.

(2) The accompanying document shall also provide a contact point for further information.

(3) Any additional documentation or identification requirements applicable to imports or exports subject to subsection (1) and agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with section 34.

Documentation for GMOs intended for intentional introduction into the environment

29. (1) GMOs that are imported into or exported from the country for intentional introduction into the environment shall be accompanied by documentation that-

(a) clearly identifies the GMOs as GMOs;

(b) specifies the identity and relevant traits and characteristics, 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 or exporter; and

(c) contains a declaration that the movement is in conformity with the requirements of the Cartagena Protocol applicable to the exporter.

(2) Any additional documentation or identification requirements applicable to imports or exports subject to subsection (1) (a) and agreed upon under the Cartagena Protocol shall be addressed by regulation in accordance with section 34.

Labelling of GMOs

30. (1) A GMO or product of a GMO shall be clearly identified and labelled as such, and the identification shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability.

(2) A GMO or any product of a GMO shall be clearly labelled and shall comply with such requirements as may be imposed by the Competent Authority, to

indicate that it is or has been derived from a GMO, and where applicable, whether it may cause allergic reactions or pose other risks.

PART VIII
ENFORCEMENT

Enforcement

31. (1) The Competent Authority may appoint as inspectors such number of public officers who possess relevant qualifications for the purposes of ensuring compliance with this Act and its regulations.

(2) The inspector shall have the following powers-

(a) at any reasonable time or in a situation in which, in the opinion of the inspector, there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account also risks to human health, at any time to-

(i) enter premises, including but not limited to a facility, vessel or property, which the inspector has reason to believe it is necessary to enter and take with that inspector any person duly authorised by the Competent Authority; and

(ii) take any equipment or material required for any purpose for which the power of entry is being exercised,

(b) to carry out such tests, inspections and make such recordings, as may be necessary;

(c) to direct that any, or any part of premises which the inspector has power to enter, or anything in or on such premises, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any test or inspection;

(d) to take any samples of any organisms, articles or

substances found in or on any premises which the inspector has power to enter, and of the air, water or land in, on, or in the vicinity of, the premises;

(e) in the case of anything found in or on any premises which the inspector has power to enter, which appears to that inspector to contain or to have contained GMOs which have adversely affected or are likely to adversely affect the conservation and sustainable use of biological diversity, taking into account also risks to human health, to cause that thing to be dismantled or subjected to any process or test (but not so as to damage or destroy it unless this is necessary);

(f) in the case of anything mentioned in paragraph (e) or anything found on the premises which the inspector has power to enter which appears to be a GMO or to consist of or include GMOs, to take possession of that thing and detain it for so long as is necessary for all or any of the following purposes, namely to-

(i) examine that thing and do to it anything which the inspector has power to do under that paragraph;

(ii) ensure that the thing is not tampered with before the examination of the thing by the inspector is completed; and

(iii) ensure that the thing is available for use as evidence in any proceedings for an offence under section 33;

(g) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for the inspector to see for the purposes of any test or inspection under this section and to inspect, and take copies of the records , or of any entry in those records;

(h) to require any person to afford the inspector such facilities and assistance with respect to any matters or things within the control of that person or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on that inspector by this section;

(i) such other powers as may be necessary for the purposes mentioned in subsection (1) which is conferred by regulations made by the Competent Authority.

(3) Where goods are seized by an inspector without reasonable cause, the aggrieved person may bring an action in any competent court for appropriate relief, including an order for the return of the goods seized, and, if the claim prevails, shall be entitled to the costs of such proceedings.

Liability and redress

32. (1) An operator shall be liable for any damage, injury or loss caused by such GMO and to make and to make compensation therefor, and where more than one operator is responsible for the damage, injury or loss, such liability shall be joint and several.

(2) Where there has been harm to the environment or biological diversity, the party liable to pay compensation, shall also pay the costs of reinstatement, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventative measures, as well as damages for harm to any person deriving from harm to the environment or biological diversity.

(3) The right to bring any action in respect of the harm caused by a GMO or a product of 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 or the product of the GMO having regard to the situation or circumstance of the person or community affected.

(4) Any person, group of persons or any private or state organisation may bring a claim and seek redress in respect of a breach or threatened breach of any provision of this Act causing or threatening damage to the environment or to biological diversity-

(a) in the interest of that person or group of persons;

(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 a class of persons whose interests are affected;

(d) in the public interest; or

(e) in the interest of protecting the environment or biological diversity,

and costs shall not be awarded against that person, group of persons or private or state organisation 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.

Offences and penalties

33. (1) A person who contravenes a provision of this Act or fails to comply with a cessation order or regulation issued pursuant to this Act commits an offence and shall, on conviction be liable to a fine not exceeding one hundred thousand (E100 000.00) Emalangeni or a term of imprisonment not exceeding two years or both, including additional penalties not exceeding five hundred (500) Emalangeni for each day that the offence is continued after legal service of a cessation order upon that person.

(2) A person who repeatedly and knowingly commits offences under this Act and is convicted for such offences may be prohibited from engaging in any further activities under this Act.

PART IX
IMPLEMENTATION MEASURES

Regulations

34. (1) Consistent with the objective and scope of this Act, the Minister may, in consultation with the Competent Authority, make regulations as may be necessary for implementing the provisions of this Act.

(2) The Competent Authority shall publish a schedule of fees and require the payment of such fees in order to cover administrative costs of processing notifications, applications and petitions submitted under this Act.

(3) The Minister may, in consultation with the Competent Authority, amend any schedule to this Act.

(4) Without derogating from the generality of the foregoing provisions, the Minister shall, make regulations governing the conduct of contained use activities, including relevant definitions, risk classifications, waste disposal requirements and procedures and requirements for risk assessments.

FIRST SCHEDULE
(Section 11(3), 12(2))
Information required in applications

1. Name, address and contact details of the exporter.

2. Name, address and contact details of the importer.

3. 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 in the State of export.

4. Intended date or dates of the transboundary movement, if known.

5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or the parental organisms related to biosafety.

6. Centres of origin and centres of genetic diversity, if known, of the recipient organism or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism.

9. 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.

10. Quantity or volume of the genetically modified organism to be transferred.

11. A previous and existing risk assessment report consistent with the Second Schedule.

12. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

13. Regulatory status of the genetically modified organism within the State of export (for example, whether it is prohibited in the State of the export, whether there are other restrictions, or whether it has been approved for the general release) and, if the genetically modified organism is banned in the State of export, the reason or reasons for the ban.

14. Result and purpose of any notification by the exporter to other States regarding the genetically modified organism to be transferred.

15. A declaration that the above-mentioned information is factually correct.

SECOND SCHEDULE
(section 17)
Risk Assessment

Objective

1. The objective of the risk assessment, under this Act, 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 into account risks to human health.

Use of risk assessment

2. Risk assessment is, among other things, 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 may take into account expert advice of, and guidelines developed by, relevant international organisations.

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. Risk 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 living 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 fulfil its objective, risk assessment entails, as appropriate, the following steps-

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

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

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

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

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

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

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 organism. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) donor organism(s). 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 of origin, and its host range;

(d) Insert(s) and/or 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 organism;

(f) Detection and identification of the genetically modified organism. Suggested detection and identification methods and their specificity, sensitivity 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 organisms; 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.

THIRD SCHEDULE
(Section 26)
Information requirements for notices to the biosafety clearing house

1. The name and contact details of the applicant for a decision for domestic use.

2. The name and contact details of the authority responsible for the decision.

3. Name and identity of the genetically modified organism.

4. Description of the gene modification, the technique used, and the resulting characteristics of the genetically modified organism.

5. Any unique identification of the genetically modified organism.

6. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

7. Centres of origin and centres of genetic diversity, if known, of the recipient organism, the parental organisms and a description of the habitats where the organisms may persist or proliferate.

8. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or related to biosafety.

9. Approved uses of the genetically modified organism.

10. A risk assessment report consistent with the second Schedule.

11. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

FOURTH SCHEDULE

(Section 6)

Membership of the National Biosafety Advisory Committee

1. A biodiversity specialist;
2. A crop specialist;
3. A veterinary specialist;
4. An animal production specialist
5. A crop protection specialist;
6. A representative of Non Governmental Organisations;
7. A representative of the business sector;
8. A representative of farmers;
9. A legal expert;
10. A health specialist;
11. A food safety specialist;
12. A trade specialist (WTO focal point); and
13. A representative of the Ministry responsible for Information, communication and Technology.