

THE BIOSAFETY BILL, 2007

MEMORANDUM

The objectives of this Bill are to—

- (a) regulate the research, development, application, import, export, transit, contained use, release or placing on the market of any genetically modified organism whether intended for use as a pharmaceutical, food, feed or processing, or a product of a genetically modified organism;
- (b) ensure that any activity involving the use of any genetically modified organism or a product of a genetically modified organism prevents any socio-economic impact or harm to human and animal health or any damage to the environment, non-genetically modified crops and biological diversity;
- (c) set and implement standards for the assessment, evaluation and management of any potential risk involving the use of any genetically modified organism or product of a genetically modified organism;
- (d) establish the National Biosafety Authority and prescribe its powers and functions;
- (e) provide for the establishment of the Scientific Advisory Committee;
- (f) provide for public participation, information and consultation in the field of biosafety;
- (g) provide for a mechanism for liability and redress for any harm or damage caused to human and animal health, non-genetically modified crops, socio-economic conditions, biological diversity or the environment by any genetically modified organism or a product of a genetically modified organism;
- (h) provide for the formation and registration of institutional biosafety committees; and
- (i) provide for matters connected with or incidental to the foregoing.

S. NKONDE,
Solicitor General

N.A.B. 3, 2007
2nd February, 2007

THE BIOSAFETY ACT, 2007

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GOVERNMENT OF ZAMBIA

ACT

No. 10 of 2007

I hereby signify my assent to the Bill

Signed.....

President

Date of Assent: 24th April, 2007

An Act to regulate the research, development, application, import, export, transit, contained use, release or placing on the market of any genetically modified organism whether intended for use as a pharmaceutical, food, feed or processing, or a product of a genetically modified organism; ensure that any activity involving the use of any genetically modified organism or a product of a genetically modified organism prevents any socio-economic impact or harm to human and animal health, or any damage to the environment, non-genetically modified crop and biological diversity; set and implement standards for the assessment, evaluation and management of any potential risk involving the use of any genetically modified organism or product of a genetically modified organism; establish the National Biosafety Authority and prescribe its powers and functions; provide for the establishment of the Scientific Advisory Committee; provide for public participation, information and consultation in the field of biosafety; provide for a mechanism for liability and redress for any harm or damage caused to human and animal health, non-genetically modified crop, socio-economic conditions, biological diversity or the environment by any genetically modified organism or a product of a genetically modified organism; provide for the formation and registration of institutional biosafety committees; and provide for matters connected with or incidental to the foregoing.

[3rd May, 2007

ENACTED by the Parliament of Zambia

Enactment

PART I

PRELIMINARY

Short title and commencement	1. This Act may be cited as the Biosafety Act, 2007, and shall come into force on such date as the Minister may, by statutory instrument, appoint.
Interpretation	<p>2. In this Act, unless the context otherwise requires—</p> <p>“advance informed agreement” means the consent obtained before any activity is undertaken based upon full disclosure of all relevant information and the taking of full responsibility by the supplier of the information for its accuracy and completeness;</p> <p>“applicant” means any person making an application for the approval of the Authority, or the person to whom the approval is given;</p> <p>“Authority” means the National Biosafety Authority;</p> <p>“biosafety” means a set of measures, policies and procedures used or established for assessing, preventing, monitoring and managing any risk associated with genetically modified organisms to human health and safety and to the environment;</p> <p>“biotechnology” means the development of products by exploiting biological processes or substances using intact original or modified organism or by using active cell components;</p> <p>“Cartagena Protocol” means the Protocol on Biosafety under the Convention on Biological Diversity;</p> <p>“control” means to examine, regulate, manage or direct any activity within a person’s jurisdiction;</p> <p>“contained use” means any operation in which any genetically modified organism or product of a genetically modified organism is 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 prevent its contact with, and its impact on, humans, biological diversity and the external environment;</p> <p>“environment” means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms;</p> <p>“export” means the intentional transboundary movement of any genetically modified organism or a product of a genetically modified organism from one country to another country;</p>

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- “ exporter ” means any legal or natural person who arranges for any genetically modified organism or a product of a genetically modified organism to be exported;
- “ genetically modified organism ” means any biological entity, capable of replication or of transferring genetic material or any plant, animal or microorganism, in which the genetic material has been altered through modern biotechnology;
- “ gene technology ” means any technique that involves the isolation, characterisation, modification and introduction of deoxyribonucleic acid (DNA) into living cells or microorganisms;
- “ gene therapy ” means the replacement of a defective gene in a person or animal suffering from a genetic disease;
- “ hazard ” means an intrinsic biological, chemical or physical characteristic of a genetically modified organism, which could lead to an adverse impact on the environment and health;
- “ import ” means the intentional transboundary movement of any genetically modified organism or a product of a genetically modified organism into one country from another country;
- “ importer ” means any legal or natural person who arranges for any genetically modified organism or a product of a genetically modified organism to be imported;
- “ inspector ” means any person appointed as an inspector under this Act;
- “ microorganism ” means any cellular or non-cellular microbiological entity that is able to reproduce or transfer genetic material;
- “ modern biotechnology ” includes the application of the following techniques:
- (a) any recombinant nucleic technique involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism into a virus, bacterium, plasmid or other vector, and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
 - (b) any technique involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; and

- (c) any cell fusion, including protoplast fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells;
- “ monitoring ” means the maintaining of regular surveillance, the checking of the warning about or the recording of a situation or process;
- “ notification ” means providing information to and, where appropriate, the lodging or depositing of samples with the Authority;
- “ organism ” means a biological entity, cellular or non-cellular, capable of metabolism, replication, reproduction or transferring genetic material and includes a microorganism;
- “ permit ” means a permit issued under this Act;
- “ person ” includes any research, university or other academic institution;
- “ placing on the market ” means supplying, selling, advertising, donating or making available to any third party of any genetically modified organism or product of a genetically modified organism;
- “ product ” means any material derived by processing, or howsoever, from any genetically modified organism;
- “ Registrar ” means a person appointed as Registrar under this Act;
- “ release ” means any intentional introduction into the environment, of a genetically modified organism or a product of a genetically modified organism for any commercial purpose, food aid, remediation, research purpose in any field experiment, use of a genetically modified organism or a product of a genetically modified organism in any greenhouse, aquaculture facility, animal accommodation, unless the facility is approved for contained use as part of an approved laboratory or other installation, disposal of waste containing any genetically modified organism or a product of a genetically modified organism, the import, export or transport of any genetically modified organism or a product of a genetically modified organism;
- “ risk ” means the probability of incurring or causing a loss, injury, an adverse impact or a misfortune on any human, plant or the environment;

- “ risk assessment ” means an evaluation of any direct or indirect, short, medium and long term risk to human or animal health, the environment, biological diversity and to the socio-economic conditions or ethical values of the people of Zambia arising from the import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;
- “ risk management ” means measures necessary to prevent and manage adverse effects of any genetically modified organism or product of a genetically modified organism on human or animal health, non-genetically modified crop, biological diversity, the environment, or socio-economic conditions;
- “ socio-economic impact ” means any direct or indirect effect to the economy, social or cultural practices, livelihoods, indigenous knowledge systems or indigenous technologies as a result of the import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;
- “ trial release ” means the release of any genetically modified organism into the environment in the open under conditions where the degree of dissemination of the genetically modified organism is prevented by chemical or physical barriers or by built-in barriers which prevent the survival of the organism in the environment;
- “ Tribunal ” means the Tribunal established under this Act;
- “ use ” excludes the acquisition by purchase or otherwise, by a member of the general public or any utilisation or dealing thereafter, unless specific conditions are attached to the utilization;
- “ user ” means any natural or legal person or institution responsible for the use of a genetically modified organism; and
- “ waste ” means any matter, whether gaseous, liquid or solid or any combination thereof, which is, in the opinion of the person in whose possession or under whose control it is, an undesirable or superfluous by-product, emission, residue or remainder of any process or activity in connection with any genetically modified organism.

3. This Act applies to the import, development, export, research, transit, contained use, release or placing on the market of any genetically modified organism whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing, or a product of a genetically modified organism. Scope

PART II
THE NATIONAL BIOSAFETY
AUTHORITY

Establishment
of National
Biosafety
Authority

4. (1) There is hereby established the National Biosafety Authority which shall be a body corporate with perpetual succession and a common seal, capable of suing and being sued in its corporate name, and with powers, subject to the other provisions of this Act, to do all such acts and things as a body corporate may by law do or perform and as are necessary for, or incidental to, the carrying out of its functions under this Act.

(2) The provisions of the First Schedule apply to the Authority.

Functions of
Authority

5. (1) The functions of the Authority are to—

- (a) receive, respond to and make decisions on any notification and application, in consultation with the Scientific Advisory Committee, and in accordance 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, through the publication of guidance and other materials that explain and elaborate on the risk assessment, risk management and authorization processes;
- (d) establish and maintain a data base on genetically modified organisms and products of genetically modified organisms intended for direct use as food or feed, or for research and production processing and make available such information to the public;
- (e) prescribe criteria, standards and guidelines as may be necessary for the implementation of the provisions of this Act;
- (f) take into account the policy recommendations and other guidelines of the Scientific Advisory Committee in making decisions on the import, export, development, transit, research, contained use, release or placing on the market of any genetically modified organism or product of a genetically modified organism;

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- (g) to cause the establishment and appointment of members of institutional biosafety committees at relevant institutions and constitute any other organ of experts, as appropriate, as technical and scientific advisors on issues of biosafety;
 - (h) to keep any genetically modified organism or any product of any genetically modified organism under review and where the Authority has reasonable grounds to believe that the genetically modified organism or product thereof poses any risk to human and animal health, biological diversity or the environment, to ban its transit, import, export, development, research, use or release in Zambia;
 - (i) review or have made a risk assessment of any genetically modified organism or product of any genetically modified organism;
 - (j) take any measures to protect human and animal health, biological diversity and the environment from the risks that may be posed by any genetically modified organism or product of any genetically modified organism;
 - (k) designate inspectors and undertake inspection as well as any other control measures to ensure compliance with this Act; and
 - (l) carry out any other activity which is necessary or conducive to the performance of its functions under this Act.
- (2) The Authority shall serve as the National Biosafety Focal Point and receive, process and respond to information and notifications from the Secretariat of the Cartagena Protocol on Biosafety.
- (3) In furtherance of its functions under subsection (2), the Authority shall—
- (a) facilitate regional and international information exchange and sharing relating to genetically modified organisms or products of genetically modified organisms or any other matter connected therewith; and
 - (b) declare through the Secretariat of the Protocol that—
 - (i) any genetically modified organism or product of a genetically modified organism intended as food or feed or for processing shall be imported only after it is subjected to a full risk assessment in accordance with this Act; and

- (ii) any application to import a genetically modified organism or product of a genetically modified organism shall require a risk assessment any time a new genetically modified organism is posted in the Clearing House under the Protocol.

Scientific
Advisory
Committee

6. (1) There is hereby established a Scientific Advisory Committee for the purpose of conducting risk assessments and providing scientific and other technical advice and assistance to the Authority.

(2) The Authority shall appoint the members of the Scientific Advisory Committee.

(3) A member of the Scientific Advisory Committee shall hold office for a period of three years and may be re-appointed for a further like period.

(4) The office of a member becomes vacant—

- (a) upon the member's death;
- (b) if the member is adjudged bankrupt;
- (c) if the member is absent from three consecutive meetings of the Committee of which the member has had notice, without the prior approval of the Committee;
- (d) upon the expiry of one month's notice of the member's intention to resign from office, given by the member in writing to the Authority;
- (e) upon the expiry of one month's notice of the member's removal given to the member in writing by the Authority;
- (f) if the member becomes mentally or physically incapable of performing the duties of a member of the Committee;
- (g) if the member is convicted of an offence under this Act;
- (h) if the member is convicted of an offence under any other written law and sentenced therefor to imprisonment for a term of six months or more; or
- (i) if the member acquires any interest in a biotechnology enterprise or any commercial enterprise likely to benefit directly from biotechnology or its products.

Functions of
Scientific
Advisory
Committee

7. The Scientific Advisory Committee shall—

- (a) conduct risk assessments;
- (b) review risk assessment and risk management measures;
- (c) recommend containment measures, limitations on the duration of authorizations, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures;
- (d) provide policy recommendations and guidelines to the Authority; and
- (e) provide such other advice and assistance as the Authority may request.

8. (1) The Scientific Advisory Committee shall consist of nine scientific experts from any of the following fields:

Composition
of Scientific
Advisory
Committee

- (a) breeding and genetics;
- (b) agronomy;
- (c) weed science;
- (d) pathology;
- (e) molecular biology;
- (f) food science;
- (g) toxicology;
- (h) ecology;
- (i) entomology;
- (j) virology;
- (k) microbiology; and
- (l) pharmacology.

(2) The Chairperson of the Scientific Advisory Committee shall be elected by members of the Committee.

(3) The Committee may, for the purpose of performing its functions under this Act, constitute any sub-committees and designate chairpersons of the sub-committees, who shall be drawn from the members of the Scientific Advisory Committee.

(4) The Scientific Advisory Committee may appoint as members of any sub-committee constituted under sub-section (3) persons from any government agency, independent institution, research institute, university or any other academic institution.

(5) The Scientific Advisory Committee may recommend to the Authority the appointment of any additional members of any sub-committee as may be required for purposes of this Act.

(6) The Scientific Advisory Committee may recommend the appointment of any expert advisor from any relevant scientific discipline not otherwise adequately represented on the Scientific Advisory Committee or any sub-committee.

(7) A member or advisor of the Scientific Advisory Committee or any sub-committee, shall publicly disclose any actual or potential conflict of interest relating to any risk assessment or any other matter upon which the Scientific Advisory Committee or any sub-committee may be consulted by the Authority.

(8) Any person with any actual or potential interest with regard to a particular matter which is the subject of discussion or consideration by the Scientific Advisory Committee shall not participate in any risk assessment, discussion or deliberation concerning that matter and shall be removed from the Committee or sub-committee where any actual or potential conflict impair the person's ability to serve in an independent or impartial manner.

(9) The Minister may, by statutory instrument, make regulations for—

- (a) the rules of procedure and the operations of the Scientific Advisory Committee and any sub-committee;

- (b) any matter necessary for the effective and transparent operation of the Scientific Advisory Committee and any sub-committee;
- (c) the terms of reference and competence of the Scientific Advisory Committee;
- (d) the mechanisms and procedures for the appointment of members and chairpersons of the Scientific Advisory Committee and any sub-committee;
- (e) the manner of appointment of any advisor and the participation of any advisor in the deliberations and discussions of the Scientific Advisory Committee or any sub-committee;
- (f) the declaration and manner of dealing with any conflict of interest among the members or advisors of the Scientific Advisory Committee or any sub-committee;
- (g) the remuneration of the members or advisors of the Scientific Advisory Committee or any sub-committee; and
- (h) the protection of confidential information for purposes of this Act by any member or advisor of the Scientific Advisory Committee or any sub-committee.

Institutional
biosafety
committees

9. (1) Any institution that is involved in the import, development, research, transit, export, handling, contained use, release or placing on the market of any genetically modified organism or product of a genetically modified organism shall establish an institutional biosafety committee to institute and control safety mechanisms and approval procedures at the institutional level.

(2) Any institutional biosafety committee established under subsection (1) shall register with the Authority in such manner and upon payment of such fee as may be prescribed.

PART III

REGULATION OF ACTIVITIES RELATING TO GENETICALLY MODIFIED ORGANISMS

Prohibition
of import,
export,
transit, etc of
genetically
modified
organism or
product of
genetically
modified
organism

10. (1) A person shall not research on, develop, produce, import, export, transit, carry out any contained use, release or place on the market any genetically modified organism or any product of a genetically modified organism or deal in any manner with any genetically modified organism or a product of a genetically modified organism without the prior approval of the Authority.

(2) Sub-section (1) applies to any traditional breeding method which results in or is likely to result in any genetically modified variety.

(3) Any approval or authorisation of the Authority for any activity relating to any genetically modified organism or any product of any genetically modified organism shall be through the issuance of a permit.

(4) Any person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a term not exceeding ten years or to both.

11. (1) The Authority shall not grant any approval for the importation, development, production, release into the environment or placing on the market of any genetically modified organism or product of a genetically modified organism relating to any crop or livestock of strategic importance to national food security.

No permit on crop or live livestock of strategic importance

(2) The Minister may, for the purpose of sub-section (1), by statutory instrument make provision for a list of any strategic crop or livestock of national importance and food security.

12. A person shall not conduct the following activities:

Prohibition of certain work on genetically modified organisms

- (a) any gene therapy or somatic gene therapy for improving or enhancing any desired human characteristic for non-medical reasons; and
- (b) use of any genetically modified organism or a product of a genetically modified organism that does not accord with the public interest, morality or cultural and ethical values of the people of Zambia.

13. (1) Any person who intends to conduct research on, develop, apply, import, transit, release, place on the market or carry out any contained use of any genetically modified organism or product of any genetically modified organism shall submit an application in writing to the Authority for authorisation.

Notification procedure

(2) The application referred to under sub-section (1) shall include the following information:

- (a) the information set out in the Second Schedule, Third Schedule and any other information as may be prescribed under this Act;
- (b) an assessment report on risks that may be posed by the genetically modified organism or product of a genetically modified organism upon the environment, biological diversity or human health, non-genetically modified crop including the consequences of any unintentional release;
- (c) any information from any previous or current release of the genetically modified organism or product of a genetically modified organism in the country or in any other country;
- (d) information on any previous approvals or rejections of the genetically modified organism or any product of the genetically modified organism by any other country;

- (e) if the request for approval is for the purposes of research and development, the recommendations of the relevant institutional biosafety committee;
- (f) a clear and sequential description of the steps to be taken in the implementation of the project, and the monitoring and evaluation that will be made at the end of each step and the method of disposing off any waste;
- (g) the place where and the purpose for which the genetically modified organism or the product of a genetically modified organism is planned to be developed, used, kept, released or marketed, including detailed instructions for the use and a proposed labelling and packaging scheme in accordance with the provisions of this Act;
- (h) a declaration confirming that the information provided is correct including, where appropriate, an undertaking from the originator of such information affirming its accuracy and completeness; and
- (i) a clear environmental monitoring plan.

Public
consultation,
information
and
participation

14. (1) The Authority shall consult the public prior to the grant of any authorisation under this Part, in such manner and within such period as may be prescribed.

(2) The Authority shall for purposes of this Part, consult with any relevant institution responsible for the conservation, management or protection of the environment, human and animal health, and farming local communities.

(3) The Authority shall, upon receipt of an application and the information referred to in section thirteen, avail the information to the public and any relevant government institution.

(4) The public shall make comments on the application in 30 the manner and within such period as may be prescribed.

(5) The Authority shall, in making or reviewing its decision regarding any application, take into account the views or concerns of the public, any relevant institution or other stakeholder made in accordance with the provisions of this Act. 35

(6) The Authority shall inform the public on the following matters:

- (a) information on any genetically modified organism or any product of a genetically modified organism which has been granted or denied authorization for import, 40 transit, release, including the location of the release, placing on the market or contained use;

- (b) any risk assessment report relating to a genetically modified organism or product of a genetically modified organism; and
- (c) any report on the evaluation of the risk assessment.

15. The Minister may, by statutory instrument, in consultation with the Authority, make regulations providing for—

- (a) the procedure and manner of consulting or making information available to the members of the public for purposes of this Act;
- (b) the procedure and manner of submission of any comments or objections by members of the public under this Act;
- (c) the conduct of public hearings pursuant to this section;
- (d) the forms and procedure to be used for purposes of this section;
- (e) the period within which the public may make submissions to the Authority and decisions made relating to any application; and
- (f) any other matter to give effect to the provisions of this section for purposes of this Act.

Regulatory powers on public information, consultation and participation

16. (1) The Authority shall, within such period as may be prescribed, inform the applicant in writing and the public of its decision.

Decision-making procedure

(2) The Authority may approve or reject the application or approve the application on such terms and conditions as it may determine.

(3) The Authority may, prior to making a decision in relation to any application under this Part, request the applicant to submit further and additional information as the Authority may consider necessary for purposes of this Act.

(4) The Authority shall, where an applicant fails to submit any further or additional information requested under subsection (3), reject the application.

(5) The Authority shall, where it rejects an application give reasons to the applicant for the rejection.

17. (1) An approval for a permit shall require the holder to carry out the activity in a step-by-step sequence and to conduct an assessment of risks at each step.

Permit condition

(2) Any approval for the import, transit, placing on the market, release or contained use of a genetically modified organism or product of a genetically modified organism shall require the permit holder to carry out monitoring and evaluation of risks on a continuous basis for a period commensurate with the life cycle of the species as the Authority may determine.

(3) A permit holder shall, where any new information becomes available on any potential risks to human or animal health, biological diversity or the environment, notify the Authority within forty eight hours from the time the information becomes available.

(4) A permit issued under this Part shall be used solely by the person to whom it is issued and is not transferable to any other person.

Criteria for
decision
making

18. (1) No approval shall be given unless there is firm and sufficient evidence that the genetically modified organism or product of a genetically modified organism poses minimum risk to human and animal health, non-genetically modified crop, biological diversity or the environment.

(2) The Authority shall not give any approval for a permit where there is reason to believe that any harm or damage may be caused to human and animal health, non-genetically modified crop, biological diversity or the environment although there is lack of scientific evidence or certainty.

(3) Lack of scientific evidence shall not be used as a basis for not taking preventive measures where there is reason to suspect threats of any damage to socio-economic conditions, human and animal health, non-genetically modified crop, biological diversity or the environment.

(4) The Authority may reject an application under this Part on grounds of public interest.

(5) The Authority shall not grant any approval for a permit if—

- (a) the applicant fails to meet any condition precedent to the issue of the permit;
- (b) the applicant fails to submit the assessment results of the effect of the use of any genetically modified organism or product of a genetically modified organism on human and animal health, non-genetically modified crop, biological diversity or the environment;
- (c) any permit previously held by the applicant has been revoked by the Authority;
- (d) the applicant has been convicted of an offence under this Act;
- (e) the Authority is satisfied that in the interest of protecting human and animal health, non-genetically modified crop, biological diversity and the environment, the permit should not be issued; and
- (f) the applicant has been convicted of an offence relating to biosafety in another country or the applicant's permit was withdrawn by the relevant authority in that country.

(6) The Authority shall notify the applicant in writing of the refusal to issue the permit and shall state the reasons for the refusal.

19. (1) The Authority shall not grant any approval unless it considers that the import, transit, contained use, development, release or placing on the market of the genetically modified organism or the product of a genetically modified organism shall—

Socio-economic considerations

- (a) benefit the country without causing any risk to human and animal health, non-genetically modified crop, biological diversity or the environment;
- (b) contribute to sustainable development;
- (c) not have adverse socio-economic impacts; and
- (d) accord with the ethical values and concerns of communities and does not undermine community knowledge and technologies.

(2) The Authority shall, as a condition for approval, require an applicant to furnish evidence of insurance cover or other sufficient arrangement to meet its obligations under this Act.

20. (1) An applicant may, where the Authority refuses to grant a permit, not later than thirty days from the date of receipt of the notice of refusal, appeal in writing to the Tribunal against the refusal.

Appeal against refusal to grant permit

(2) The Minister shall appoint a Tribunal in accordance with Part XIV of this Act.

21. (1) The Authority may revoke a permit or subject it to conditions additional to those initially imposed where—

Revocation of permit

- (a) the Authority is satisfied that the holder of the permit has failed to comply with any conditions relating to the permit; or
- (b) in the opinion of the Authority, new information or a review of existing information about a genetically modified organism or any product of a genetically modified organism has established or is likely to establish any risk to human or animal health, non-genetically modified crop, biological diversity or the environment.

(2) The Authority shall, where it revokes a permit, notify the permit holder of the decision in writing within seven days of the revocation and shall state the reasons for the revocation.

40 (3) The Authority may, where it revokes a permit in accordance with sub-section (1), order the destruction of the genetically modified organism or product of a genetically modified organism or order compensation for the harm caused to human and animal health, non-genetically modified crop, biological diversity or the environment.

(4) The Authority shall, where the genetically modified organism or product of a genetically modified organism is a plant or seed, cause the sterilisation or decontamination of the soil, as the case may be.

Appeal
against
revocation

22. (1) A permit holder may, where the Authority revokes the permit, not later than thirty days from the date of receipt of the notice of revocation, appeal in writing to the Tribunal against the revocation.

(2) The decision of the Tribunal on any appeal under this section shall be subject to further appeal to the High Court.

Suspension,
cancellation
and
loss of permit

23. (1) The Authority may suspend, for any period, or cancel any permit issued under this Act, if in the opinion of the Authority, any genetically modified organism or product of a genetically modified organism to which the permit relates poses any risk to human or animal health, non-genetically modified crop, biological diversity or the environment.

(2) Upon the suspension of any permit under subsection (1), the Authority shall notify the holder, in writing, of the period of the suspension and, during that period, the permit so suspended shall be of no legal force or effect and shall be surrendered to the Authority.

(3) Upon the cancellation of any permit under sub-section (1), the Authority shall notify the holder in writing of such cancellation and, from the date of the notice, the permit so cancelled shall no longer be of any legal force or effect and shall forthwith be surrendered to the Authority.

(4) Upon the suspension or cancellation of any permit under sub-section (1), the holder may be refunded such proportion of the fee paid for the permit as the Authority may determine.

(5) Where any person loses a permit, the person shall inform the Authority within fourteen days of the loss and shall after a further period of fourteen days apply to the Authority for the issuance of a duplicate permit.

(6) On application under subsection (5), the Authority—

(a) may issue a duplicate permit on such terms and conditions as the Authority may determine; or

(b) reject the application and notify the holder in writing giving reasons for the refusal.

(7) Any person whose permit has been suspended or cancelled under subsection (1) or to whom the Authority has refused to issue a duplicate permit under subsection (6) may, not later than thirty days after the receipt of the notice given under subsection (2) or (3), or the notice of refusal to issue a duplicate permit under subsection (5), as the case may be, appeal in writing to the Tribunal against the suspension, cancellation or refusal.

(8) The decision of the Tribunal on any appeal under this section shall be subject to further appeal to the High Court.

PART IV
RISK ASSESSMENT

24. (1) An applicant shall carry out or cause to be carried out an assessment of any risk associated with a genetically modified organism or a product of a genetically modified organism in respect of which the application is being made.

Risk
Assessment

(2) The Authority shall not make any decision on any application to import, transit, make contained use of, develop, research on, release or place on the market a genetically modified organism or a product of a genetically modified organism unless an assessment of risk to human and animal health, non-genetically modified crop, biological diversity, the environment, socio-economic conditions and cultural norms is conducted.

(3) A risk assessment of a genetically modified organism or a product of a genetically modified organism shall be carried out by an applicant or the Scientific Advisory Committee, as the case may be in a scientifically sound manner, on a case by case basis, in accordance with the Fourth Schedule.

(4) The Authority may require an applicant to bear all the costs for evaluating a risk assessment report or carrying out the risk assessment, as the case may be.

(5) The Authority shall reject an application where an independent risk assessment cannot be undertaken or its independence verified.

25. (1) The Authority shall evaluate or cause the evaluation of any risk assessment report and consider the result of the evaluation in making a decision on any application to import, transit, develop, research, make contained use of, release or place on the market a genetically modified organism or a product of a genetically modified organism.

Evaluation of
risk
assessment

(2) The Authority shall, where an evaluation of a risk assessment shows that any risk cannot be avoided, reject the application for the import, transit, development, research, contained use of, release or placing on the market of a genetically modified organism or a product of a genetically modified organism.

(3) No person shall be involved in the evaluation of a risk assessment in respect of a subject matter in which the person has any direct or indirect interest of any kind, or if, for any reason, there is, or there is likely to be, a conflict of interest as a result of the person's participation in the evaluation process.

(4) A person with a conflict of interest shall declare the fact and withdraw from the evaluation process.

Effect of
refusal of
authorisation
on patents

26. Where the Authority rejects an application under subsection (2) of section *eighteen*, any patent or an application for a patent on the genetically modified organism or product of a genetically modified organism shall be revoked or rejected by the relevant authority.

PART V

RISK MANAGEMENT

Risk
management

27. (1) The Authority shall—

(a) develop, maintain and use as the need arises, a risk management strategy for protecting human and animal health, non-genetically modified crop, biological diversity or the environment from accidents in genetic engineering, the use of any genetically modified organism or any product of a genetically modified organism; and

(b) impose such measures as may be necessary to implement the Fifth Schedule and to avoid adverse effects on the environment, biological diversity and human and animal health, including on socio-economic conditions, arising from a genetically modified organism or a product of a genetically modified organism.

(2) Without limiting the generality of the foregoing, the Authority may—

(a) require any genetically modified organism to undergo a period of observation commensurate with its life cycle or generation time, at the cost of the applicant, before and after it is put to its intended use;

(b) prohibit the import, development, research on, transit, contained use, release or placing on the market of any genetically modified organism or a product of a genetically modified organism, if it contains any characteristic or trait which poses any risk to human and animal health, non-genetically modified crop, the environment and biological diversity;

- (c) order the cessation of any activity, which is being undertaken in violation of any of the provisions of this Act or any decisions made under it;
- (d) order the cessation of any activity involving a genetically modified organism or a product of a genetically modified organism that is known to cause risks to human and animal health, non-genetically modified crop, the environment or biological diversity;
- (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 human and animal health, the environment, non-genetically modified crop, biological diversity or socio-economic conditions, to implement remedial measures or restore the environment to its previous state as far as is feasible;
- (f) undertake measures, as necessary, at the cost of the person responsible, in the event that the person responsible fails to undertake any safety measures prescribed by the Authority;
- (g) take measures, as necessary, in the case of imminent or serious danger to human and animal health, the environment, biological diversity, non-genetically modified crop, socio-economic conditions or order public caused by a genetically modified organism or a product of a genetically modified organism at the cost of the person responsible for causing the danger;
- (h) require an applicant to submit reports periodically in respect of any monitoring and evaluation of risks carried out after any approval of the import, research, transit, development, contained use, release or placing on the market of a genetically modified organism or a product of genetically modified organism;
- (i) restrict or prohibit the development, research, production, transit, import, release, contained use or placing on the market of any genetically modified organism or a product of a genetically modified organism; and
- (j) assess and prohibit the import, transit, research, development, production, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism that is being or is likely to be used for a hostile purpose.

(3) The Authority shall, where it has reasonable grounds to believe that any genetically modified organism or a product of a genetically modified organism has caused or is likely to cause serious danger or any adverse effect to human or animal health, non-genetically modified crop, biological diversity or the environment, and that immediate action or redress is required, take such measures as are necessary, without prior notice, to prevent or limit any harm to human or animal health, non-genetically modified crop, biological diversity or the environment and all the costs and expenses for such measures or remedial action shall be borne by, or be recoverable from, the person responsible for the harm.

PART VI
CO-EXISTENCE

Co-existence
of farming
practices

28. (1) A person who cultivates any genetically modified crop shall prevent any contamination or commingling of the genetically modified crop with any non-genetically modified crop.

(2) A person who keeps or owns genetically modified livestock shall prevent any cross-breeding between genetically modified and non-genetically modified livestock.

(3) Any person who contravenes subsections (1) or (2) commits an offence and is liable upon conviction to a fine not exceeding five hundred thousand penalty units or to imprisonment for a term not exceeding ten years, or to both.

(4) In addition to any penalty that may be imposed under subsection (3), any person responsible for the contamination or commingling of genetically modified crop with any non-genetically modified crop or cross-breeding between genetically modified livestock with non-genetically modified livestock shall compensate the person whose crop has been contaminated or livestock cross-bred as the case may be.

(5) The Minister may, by statutory instrument, provide for—

- (a) the management measures to ensure non-contamination of non-genetically modified crops by genetically modified crops;
- (b) the measures to be taken during cultivation, harvesting, transportation, storage and processing of any genetically modified crop;
- (c) the prevention and management of any accidental mixing of any genetically modified crop with non-genetically modified crop;

- (d) the prevention of cross pollination and commingling between any genetically modified crop and non-genetically modified crop;
 - (e) appropriate segregation, certification, identification and labelling practices and measures;
 - (f) the restriction of cultivation of a certain type of crop in any area;
 - (g) the skill and qualifications of persons involved in the cultivation, storage, handling, harvesting, transportation and processing of any genetically modified crop; and
 - (h) generally, the co-existence of any farming practices and systems.
- (5) The regulations made under subsection (4) may make provision for measures specific to different types of crop, taking into account any local or national factors.
- (6) Subsections (4) and (5) apply with necessary modifications to livestock.

PART VII

IDENTIFICATION AND LABELING

- 29.** (1) Any genetically modified organism or product of a genetically modified organism shall be clearly identified and labeled as such in accordance with this Act or any regulations enacted thereunder.
- (2) The identification required for purposes of subsection (1) shall specify the relevant traits and characteristics given in sufficient detail for purposes of traceability.
- (3) Any genetically modified organism or any product of a genetically modified organism shall be clearly labeled and packaged in the manner provided for in paragraph C of the Third Schedule.
- (4) The Minister may, in consultation with the Authority, by statutory instrument, make provision for—
- (a) the manner of labeling, identification and packaging of any genetically modified organism or a product of a genetically modified organism;
 - (b) the manner of indicating any genetically modified organism that may or is likely to cause allergies or pose any other risk to human or animal health, non-genetically modified crop, biological diversity or the environment;

Packaging,
identification
and
labelling

- (c) the measures to be taken by a producer, researcher, importer, exporter or any other person dealing with any genetically modified organism so as to protect consumers;
- (d) the prevention of fraudulent practices in the packaging, identification and labeling of any genetically modified organism or product of a genetically modified organism;
- (e) the segregation of genetically modified organisms from non-genetically modified organisms;
- (f) the threshold level for purposes of identification of any genetically modified organism or a product of a genetically modified organism; and
- (g) any other matter necessary to give effect to the provisions of this Part.

PART VIII

EXPORT

Procedure
for export

30. (1) Any person who intends to export a genetically modified organism or a product of a genetically modified organism shall provide to the Authority a written advance informed agreement or approval of the competent authority of the importing country.

(2) The presentation of the advance informed agreement by an exporter does not in any manner absolve the exporter from complying with any other laws governing foreign trade.

(3) There shall be no authorization for the re-export of a genetically modified organism or product of a genetically modified organism that is banned by the laws of the exporting country.

(4) An exporter shall —

- (a) package any genetically modified organism or a product of a genetically modified organism in the prescribed manner so as to prevent any unintentional release in transit; and
- (b) comply with any other requirements imposed by the competent authority of the importer as to labeling or other relevant measures to protect human and animal health, non-genetically modified crops, biological diversity or the environment from any risk or adverse effect from any genetically modified organism or a product of a genetically modified organism.

PART IX

REQUIREMENTS FOR GENETICALLY MODIFIED ORGANISMS IN TRANSIT

31. (1) A person shall not make any transboundary movement of a genetically modified organism or a product of a genetically modified organism otherwise than with the written consent of the Authority.

Requirements for genetically modified organism in transit

(2) A person shall not transport or transit any genetically modified organism or a product of any genetically modified organism through Zambia without authorization from the Authority.

(3) Any person who contravenes this section commits an offence and is liable, upon conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a period not exceeding ten years, or to both.

32. The Minister may, by statutory instrument, in consultation with the Authority, provide for—

Regulatory powers

(a) the packaging, handling and transportation of any genetically modified organism or a product of any genetically modified organism in transit; and

(b) the conditions to be met and measures to be taken by any person responsible for the transit of any genetically modified organism or a product of a genetically modified organism.

PART X

UNINTENTIONAL RELEASE AND EMERGENCY MEASURES

33. (1) The Authority shall, for purposes of managing any unintentional release or emergency arising from an accident with a genetically modified organism or a product of a genetically modified organism—

Emergency response plan

(a) require a permit holder to prepare an emergency plan for the protection of human and animal health, non-genetically modified crops, biological diversity and the environment outside the area of release or contained use in the event of an accident;

(b) require the notification of any hazards in writing by a permit holder of any appropriate emergency services;

(c) require a permit holder to inform any persons likely to be affected by the accident on safety measures and procedures; and

- (d) require the update periodically by a permit holder of any information relating to safety measures and the making available of the information to the general public.
- (2) A permit holder shall inform the Authority immediately of any accident and provide the following information:
- (a) the circumstances of the accident;
 - (b) the identity and quantity of any genetically modified organism released unintentionally;
 - (c) any measure necessary to assess the effects of any accident on human and animal health, biological diversity and in general, the environment; and
 - (d) the emergency measures taken or to be taken.
- (3) The Authority shall, upon receipt of any information under subsection (2)—
- (a) ensure that a permit holder responsible for any accident takes measures to neutralise risks to human and animal health, non-genetically modified crop, biological diversity and the environment; and
 - (b) inform relevant government and non-governmental organisations in countries likely to be affected and the Biosafety Clearing House.

PART XI

CONFIDENTIAL BUSINESS INFORMATION

Protection of
certain
business
information

- 34.** (1) A person shall apply to the Authority in the prescribed manner upon payment of a prescribed fee, for the treatment of any information as confidential for business purposes.
- (2) The Authority shall, after consultation with the applicant, determine the information which may be kept confidential and shall inform the applicant of its decision and the reasons therefor.
- (3) The following information shall not be kept confidential:
- (a) any description of a genetically modified organism or a product of a genetically modified organism;
 - (b) the name, address or other particulars of the applicant;
 - (c) the purpose and location of the import, transit, development, research, production, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism;

- (d) any methods and plans for monitoring of a genetically modified organism or a product of a genetically modified organism and for any emergency response; and
- (e) the evaluation of any foreseeable effects, in particular any pathogenic or ecologically disruptive effects.
- (4) A person shall not disclose any confidential information.
- (5) Any person who contravenes subsection (4) commits an offence and is liable, upon conviction to a fine not exceeding two hundred thousand penalty units or to imprisonment for a term not exceeding five years, or to both.
- (6) The Authority shall not, where an applicant withdraws an application before approval, disclose any confidential information relating to the application.
- (7) The Authority may, where it determines that it is in the public interest to do so, make available to the public any information referred to under section *thirteen* notwithstanding that it may be commercially confidential.

35. Notwithstanding subsection (3) of section *thirty-four*, the Authority shall, where it is satisfied on the basis of evidence submitted to it by the applicant and, after consultation with the applicant, that it is necessary to withhold for a specified time, some of the information specified in subsection (3) in order to protect the applicant's intellectual property rights, withhold that information to the extent and for so long as it is necessary to protect the rights.

Protection of intellectual property rights

PART XII

LIABILITY AND REDRESS

36. (1) A person who imports, arranges transit, develops, makes contained use of, releases or places on the market a genetically modified organism or product of a genetically modified organism shall be strictly liable for any harm caused by the genetically modified organism or product of the genetically modified organism and shall compensate any person to whom the harm is caused.

Liability and redress

(2) Liability shall attach to the person responsible for the activity, which results in the damage, injury or loss as well as to the provider, supplier or developer of the genetically modified organism or of the product of a genetically modified organism.

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

(4) Where any harm is caused to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which are incurred and where applicable, the costs of preventive measures.

(5) Liability shall also extend to—

- (a) any harm or damage caused directly or indirectly by any genetically modified organism or a product of a genetically modified organism to the economy or social cultural conditions;
- (b) any negative impacts on the livelihood or indigenous knowledge systems or technologies of any community;
- (c) any damage or destruction arising from any incidents of public disorder triggered by any genetically modified organism or a product of a genetically modified organism;
- (d) any disruption or damage to any production or agricultural system;
- (e) any reduction in yields of the local community;
- (f) any soil contamination or damage to biological diversity;
- (g) any damage to the economy of an area or community; or
- (h) any other consequential disorder.

(6) The right to bring any action in respect of harm caused by a genetically modified organism or product of a genetically modified organism shall lapse 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 take to correlate the harm with the genetically modified organism or product of a genetically modified organism, having regard to the situation or circumstance of the person or community affected.

(7) Any person, group of persons or any private or state organisation may bring a claim and seek redress in respect of the breach or threatened breach of any provision relating to damage to the environment, non-genetically modified crop, biological diversity, human and animal health or to socio economic conditions:

- (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 person whose interests are affected;
- (d) in the public interest; and
- (e) in the interest of protecting the environment or biological diversity.

(8) No costs shall be awarded against any of the persons specified under subsection (7) who fail in any action if the action was instituted reasonably out of concern for the public interest or in the interest of protecting human health, biological diversity and in general, the environment.

(9) Where any harm is caused to human and animal health by a genetically modified organism or a product of a genetically modified organism, compensation shall include—

- (a) any costs and medical expenses;
- (b) compensation for any disability suffered; and
- (c) compensation for loss of life.

PART XIII

INSPECTORATE

37. (1) The Authority shall appoint such number of competent persons to exercise and perform the powers and functions of inspector as it may consider necessary.

Appointment
of
inspectors

(2) The Authority shall provide an inspector with an identification card that shall be prima facie evidence of the inspector's appointment as such.

(3) An inspector shall, at the request of any person affected by the exercise, or the performance by an inspector, of any power or function under this Act, produce for inspection by the person the identification card referred to under subsection (2).

38. (1) Subject to subsection (2), an inspector may seize and destroy, without compensation, any genetically modified organism or a product of a genetically modified organism that—

- (a) is not accompanied at the time of importation, transit, exportation, release, placing on the market or otherwise, by a permit or other prescribed document;

Seizure,
disposal and
destruction
of genet-
ically
modified
organism or
product illeg-
ally
imported,
exported, etc.

(b) is accompanied by a permit that is incorrect in a material particular;

(c) is imported, in transit, exported, released, placed on the market or otherwise dealt with contrary to the conditions of a permit issued in terms of this Act; and

(d) is imported, exported, in transit, released, placed on the market or otherwise dealt with, in contravention of the provisions of this Act.

(2) An inspector shall not seize or destroy any genetically modified organism or a product of a genetically modified organism unlawfully imported, in transit or exported unless the inspector gives notice to the importer or exporter of the seizure or destruction of the genetically modified organism or product of a genetically modified organism and the reasons therefor.

(3) An inspector shall, where the inspector has reasonable grounds to believe that any seized genetically modified organism or product of a genetically modified organism presents a risk to human and animal health, non-genetically modified crop, biological diversity or the environment, order the importer, exporter or person having any custody or control of the genetically modified organism or product to destroy the goods at the importer's, exporter's or person's cost.

Disposal of abandoned consignment

39. The Authority may, where, after its entry into Zambia, any genetically modified organism or product of a genetically modified organism is not claimed or abandoned at a port of entry within a period of fourteen days from the date of entry into Zambia, dispose of it by sale or destroy it.

Costs for sterilisation, removal, destruction, etc

40. (1) The costs and responsibility for the destruction, re-exportation, remediation, sterilization, disposal or any action taken under this Act shall be borne by the person responsible for the harm or damage or person who is in contravention of the provisions of this Act or conditions and terms of a permit, except where the Authority determines that it should take responsibility for the associated costs.

(2) Where the person responsible for any harm or damage or in contravention of the provisions of this Act or the terms and conditions of a permit does not pay for any cost or fee for inspection, disposal, remediation or other measure required under this Act, the genetically modified organism or product of a genetically modified organism shall be forfeited to the Authority and disposed of as the Authority may determine.

(3) The assumption by the Authority of any financial responsibility under sub-section (1) is without prejudice to its recovering the costs as a debt.

(4) The costs charged for purposes of this section shall be done in the prescribed manner.

(5) The Authority shall not bear any liability for the destruction or disposal of any genetically modified organism or product of a genetically modified organism dealt with in contravention of this Act.

41. (1) An inspector may—

Powers of
inspectors

- (a) with a warrant, at any reasonable time, enter upon and inspect any land, building or premises on or in which the inspector has reasonable grounds to believe that a genetically modified organism or product of a genetically modified organism likely to cause any harm to human and animal health, non-genetically modified crop, biological diversity or the environment may be found or in which an activity is being carried out contrary to the provisions of this Act;
- (b) inspect any operation or process undertaken or carried out on any land, building or premises in connection with matters provided for in this Act;
- (c) inspect and take any sample of any plant under cultivation, in storage or in transit, for the purpose of detecting any genetically modified organism or product of a genetically modified organism likely to pose any risk to human and animal health, non-genetically modified crop, biological diversity or the environment or cultivated, stored or carried in contravention of the provisions of this Act;
- (d) open and examine any container, conveyance, package or wrapping reasonably suspected to contain a genetically modified organism or product of a genetically modified organism likely to pose any risk to human and animal health, non-genetically modified crop, biological diversity or the environment or carried, stored, kept or packaged in contravention of this Act;
- (e) in collaboration with the relevant government agencies, inspect any consignment of plants, plant products or regulated articles destined for import into or export from Zambia to determine whether the consignment is in compliance with the provisions of this Act;

- (f) inspect and examine any vehicle, carriage or other conveyance in or upon which the inspector has reasonable grounds to believe a genetically modified organism or a product of a genetically modified organism is being or has been transported;
- (g) with warrant, search any person whom the inspector has reasonable grounds to believe is harbouring any genetically modified organism or carrying out activities contrary to this Act;
- (h) order the application of measures which are reasonably necessary or prescribed for purposes of this Act within a specified period;
- (i) order the destruction at any time of any genetically modified crop which is growing on land or used contrary to the provisions of this Act;
- (j) order the cessation of any activity or operation carried out in contravention of this Act, any permit condition or any regulations;
- (k) order the adoption of measures prescribed for the purpose of protecting human and animal health, non-genetically modified crop, biological diversity or the environment from any risk posed by a genetically modified organism or product of a genetically modified organism; and
- (l) restrict areas in which any genetically modified crop may be cultivated.

(2) An owner or occupier of any land, building or premises or conveyance and the owner's servants and agents shall afford an inspector access thereto and shall give such information and provide such reasonable assistance as the inspector may require for the purposes of carrying out an inspection.

(3) An inspector may, in the performance of any functions under this section, be accompanied and assisted by a police officer, wildlife officer, forestry officer, fisheries or other relevant officer.

(4) Subject to subsection (5), an inspector may, in the course of an inspection carried out under this section—

- (a) seize, destroy, detain, treat or otherwise dispose of any plant, plant product, material, substance, appliance, equipment or document, or order that any such action be taken, at the expense of the owner;
- (b) obtain any sample of any plant, substance or product as the inspector considers necessary; and

(c) order an owner, occupier, person in charge or control to produce for inspection, or for purposes of obtaining extracts or copies, any book, document or other information concerning any matter relevant to the administration of this Act.

(5) An inspector shall not detain, treat, dispose of or destroy anything in exercise of powers under this Act unless the inspector, as soon as is practicable, notifies in writing, the Authority and the owner or person in possession of the genetically modified organism, plant, plant product, substance, material or other article of the steps required or taken and the reasons therefor.

(6) The Authority may following a notice issued by an inspector under subsection (5) authorise the inspector to detain, treat, dispose off or destroy the genetically modified organism, plant, plant product, substance, material or other article as the case may be under such conditions as the Authority may determine.

42. (1) A person commits an offence if the person—

(a) wilfully delays or obstructs an inspector in the carrying out of duties or functions under this Act; or

(b) knowingly or negligently gives an inspector false or misleading information orally, in writing or otherwise.

Obstruction
of inspector

(2) Any person convicted of an offence under subsection (1) shall be liable, upon conviction, to a fine not exceeding twenty thousand five hundred penalty units or to imprisonment for a term not exceeding five years or to both.

43. (1) Subject to subsection (2), any person aggrieved with any decision made by an inspector in terms of this Act may, within seven days of the date of the decision, lodge with the Minister a notice of that person's intention to appeal against the order.

Appeals
against
orders of
destruction

(2) There shall be no right of appeal against—

(a) an order for the destruction of a genetically modified organism or product of a genetically modified organism likely to pose any risk to human and animal health, non-genetically modified crop, biological diversity or the environment; or

(b) an order of destruction of any crop grown on land contrary to the provisions of this Act or any other law.

(3) A notice of intention to appeal lodged in terms of subsection (1) shall be in writing and shall specify in detail the grounds upon which it is given.

(4) The Minister shall transmit to a tribunal board constituted under section *forty-four* a notice lodged in terms of subsection (1).

PART XIV

APPEALS

Appeals
tribunal

44. (1) Subject to subsection (2), any person making an appeal under this Act shall lodge the appeal with the Minister and the Minister shall for the purpose of hearing and determining an appeal against any refusal to grant a permit or authorisation, revoke a permit or authorisation or an order of destruction, appoint a tribunal consisting of three members of whom—

(a) one member, who shall be the chairperson, shall be a legal practitioner or magistrate; and

(b) two other members which persons shall be experts with not less than five years experience and knowledge in matters relevant to this Act.

(2) The Minister shall not appoint a tribunal unless the appellant deposits with the Minister such sum as the Minister considers will be sufficient to pay the costs, including the allowances payable to the members of the tribunal, likely to be incurred in connection with the appeal.

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(3) The powers, rights and privileges of a tribunal shall be the same as those conferred upon commissioners by the Inquiries Act, and the provisions of that Act shall, with the necessary modifications apply in relation to the hearing and determination of an appeal by the tribunal in terms of this section and to a person summoned to give evidence before a tribunal.

(4) The Minister shall, on the determination of an appeal refund to the appellant the sum deposited by the appellant in terms of subsection (2) less the amount of the costs, if any, payable by the appellant in terms of subsection (5).

(5) If an appeal is dismissed, the tribunal may order the appellant to pay to the Government the costs incurred by the Government in connection with the appeal.

(6) A member of a tribunal shall be paid out of moneys appropriated for the purpose by Parliament, such allowances to meet the reasonable expenses incurred by the member in connection with an appeal as the Minister may prescribe.

(7) The Minister shall where an appeal is lodged, take all reasonable steps to stay the destruction, disposal or treatment of the articles pending a determination of the appeal by the tribunal, except where in the opinion of the Minister, any delay would create a risk of harm to the environment, biological diversity, human and animal health.

(8) The tribunal shall, within fourteen days of determining the appeal, inform the appellant and the Authority in writing of its decision and the reasons therefor.

(9) A determination by a tribunal under sub-section (2) shall not prejudice the right of any aggrieved party to seek recourse in a court of competent jurisdiction within thirty days of the determination.

PART XV

OFFENCES AND PENALTIES

- 45.** (1) Any person commits an offence who—
- Offences and penalties
- (a) researches, develops, imports, releases, places on the market or makes contained use of any genetically modified organism or product of a genetically modified organism without the written approval of the Authority;
 - (b) violates any conditions attached to the grant of approval under this Act;
 - (c) fails to furnish any information as required by the provisions of this Act;
 - (d) withholds information that has become available to that person after the approval of the person's application, and that could change the evaluation of the risk posed by that person's project;
 - (e) provides false, misleading or deceptive information under this Act in order to secure an approval;
 - (f) does not label, package or identify any genetically modified organism or a product of a genetically modified organism in accordance with this Act or with any conditions imposed under this Act;
 - (g) labels, packages or identifies any genetically modified organism or product of a genetically modified organism in a manner that is false, misleading or deceptive or in contravention of any regulation made under this Act;
 - (h) exports a genetically modified organism or a product of a genetically modified organism without the advance informed agreement of the importing country;
 - (i) participates in proceedings related to decision taking in respect of a subject matter covered by this Act in which that person has direct or indirect interest of any kind;
 - (j) violates any other provision of this Act or any condition or requirement imposed under this Act;
 - (k) fails to declare any conflict of interest arising in the Authority or Institutional Biosafety committee of which

the person is a member, or in the evaluation of a risk assessment in which that person is involved and fails to withdraw from its activities in relation to that case; and

- (l) uses a genetically modified organism or a product of a genetically modified organism for hostile purposes;
- (m) obstructs or fails to assist the Authority or other authorised officers in the performance of their duties under this Act; or
- (n) fails to inform the Authority of an accident or emergency involving a genetically modified organism or a product of a genetically modified organism.

(2) Any person who commits an offence under subsection (1) is liable, on conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a term not exceeding fifteen years, or to both.

(3) The court may, where a person is convicted of an offence under paragraphs (a), (b), (c) or (d) of subsection (1), prohibit the person from carrying out any activities permissible under this Act, connected or related therewith.

(4) Where an offence is committed by a corporation, and the court is of the view that a custodial sentence ought to be imposed, every person concerned in the management of the corporation at the time the offence was committed shall be liable to imprisonment unless the person shows—

- (a) that the offence was committed without the person's connivance or consent; and
- (b) the person took necessary steps to prevent the offence from being committed.

PART XVI Miscellaneous

Regulations

46. (1) The Minister may, in consultation with the Authority, by statutory instrument, prescribe all matters which by this Act are required or permitted to be prescribed, or which are necessary to be prescribed for carrying out or giving effect to the provisions of this Act.

(2) Without derogating from the generality of subsection (1), the Minister may, in regulations, orders or notices made or issued in terms of this Act, provide for—

-
- (a) the form and manner in which applications for registration, permits, certificates and licences are to be made and the information to be supplied in connection therewith;
 - (b) the form of permits or certificates, the conditions to be contained in permits, certificates and licences and the periods for which permits and licences shall remain in force;
 - (c) the persons by whom, the circumstances in which and the conditions subject to which permits, certificates and licences shall be issued;
 - (d) the circumstances in which and the conditions, including the payment of a fee, subject to which copies of permits, certificates and licences may be obtained;
 - (e) the cancellation, suspension and amendment of permits, certificates and licences and the surrender or delivery of permits, certificates and licences for those purposes;
 - (f) the procedures to be followed by inspectors in the exercise of their powers under this Act;
 - (g) conditions for the import, export, development, transit, carriage, packaging, labeling, release, contained use or placing on the market of any genetically modified organism or product of a genetically modified organism;
 - (h) the ports of entry for the import and export of genetically modified organisms or products of genetically modified organisms;
 - (i) the fees payable and procedure in respect of any application, appeal, matter or document;
 - (j) the classification and types of genetically modified organisms and products of genetically modified organisms;
 - (k) the requirements for contained use of genetically modified organisms and products of genetically modified organisms;
 - (l) the requirements for laboratory development of genetically modified organisms and products of genetically modified organisms;
 - (m) the requirements for trial release of genetically modified organisms and products of genetically modified organisms;

- (n) the requirements for general release and marketing of genetically modified organisms and products of genetically modified organisms;
- (o) the registration of a place or premises where work on genetically modified organisms and products of any genetically modified organism is to be undertaken;
- (p) the control measures which shall be complied with or carried out by a user; and
- (q) any other matter necessary for the proper implementation and to give effect to the provisions of this Act.

(3) The Minister may, on the advice of the Authority, in any regulation made under this section, prescribe in respect of the contravention of any provision of the regulations—

- (a) for a penalty not exceeding a fine of two hundred thousand penalty units or a term of imprisonment for a period not exceeding five years, or to both;
- (b) the forfeiture of anything which is the subject matter of the contravention or with which the offence was committed or which was used in, or for the purpose of, in relation to, or in connection with, the commission of the contravention; and
- (c) in the case of a continuing offence, an additional penalty not exceeding a fine of five thousand penalty units on each count.

Transitional
Provisions

47. (1) Any person who, on the commencement of this Act, carries out any research, import, release, placing on the market, transit or contained use of a genetically modified organism or product of a genetically modified organism, shall within three months of the coming into force of this Act apply for a permit to the Authority in the manner prescribed under this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable, upon conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a term not exceeding five years, or to both.

FIRST SCHEDULE
(Section 4)

PART I

ADMINISTRATION OF AUTHORITY

1. (1) The Authority shall consist of thirteen part-time members appointed by the Minister. Composition of Authority

(2) The members referred to in subparagraph (1) shall include the following:

(a) one representative each from the ministries responsible for—

- (i) science and technology;
- (ii) environment and natural resources;
- (iii) agriculture;
- (iv) health;
- (v) commerce, trade and industry;
- (vi) information; and
- (vii) justice

(b) one person each from the following groups:

- (i) consumers;
- (ii) religious;
- (iii) farmers; and
- (iv) traditional authorities and;

(c) two other persons.

(3) The Chairperson and Vice-Chairperson shall be appointed by the Minister from amongst the members.

(4) A person shall not be appointed as a member of the Authority if the person—

- (a) is an undischarged bankrupt;
- (b) has been convicted of an offence under any law in force or this Act;
- (c) has been convicted of any other offence and sentenced to a term of imprisonment of not less than six months; or
- (d) has any financial, contractual or other interest in any biotechnology enterprise likely to benefit directly or indirectly from biotechnology or its products.

2. (1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Secretary. Seal of Authority

(2) The affixing of the seal shall be authenticated by the Chairperson or the Vice-Chairperson and the Secretary or one other person authorised in that behalf by a resolution of the Authority.

(3) Any contract or instrument which, if entered into or executed by a person not being a body corporate, would not be required to be under seal, may be entered into or executed without seal on behalf of the Secretary by the Secretary or any other person generally or specifically authorised by the Authority in that behalf.

(4) Any document purporting to be a document under the seal of the Authority or issued on behalf of the Authority shall be received in evidence and shall be executed or issued, as the case may be, without any further proof, unless the contrary is proved.

Tenure of
office of
member and
vacancy

3. (1) Subject to the other provisions of this Act, a member of the Authority shall hold office for a period of three years from the date of appointment and may be re-appointed for a further like period.

(2) The office of a member becomes vacant—

- (a) upon the member's death;
- (b) if the member is adjudged bankrupt;
- (c) if the member is absent from three consecutive meetings of the Authority of which the member has had notice, without the prior approval of the Authority;
- (d) upon the expiry of one month's notice of the member's intention to resign from office, given by the member in writing to the Authority;
- (e) if the member becomes mentally or physically incapable of performing the duties of a member of the Authority;
- (f) if the member is convicted of an offence under this Act;
- (g) if the member is convicted of an offence under any other written law and sentenced therefor to imprisonment for a term of six months or more; or
- (h) if a member acquires any interest in a biotechnology enterprise or any commercial enterprise likely to benefit directly from biotechnology or its products.

Proceedings
of Authority

4. (1) Subject to the other provisions of this Act, the Authority may regulate its own procedure.

(2) The Authority shall meet for the transaction of business as often as is necessary or expedient for the conduct of its business at such places and times as the Authority may determine.

(3) Upon giving notice of not less than fourteen days, a meeting of the Authority may be called by the Chairperson and shall be called if not less than one third of the members so request in writing:

Provided that if the urgency of any particular matter does not permit the giving of such notice, a special meeting may be called upon a shorter notice given by three members of the Authority.

(4) The quorum at any meeting of the Authority shall be five of the members.

(5) There shall preside at any meeting of the Authority—

(a) the chairperson;

(b) in the absence of the chairperson, the vice-chairperson; and

(c) in the absence of both the chairperson and the vice-chairperson, such member as the members present may elect from amongst themselves for the purpose of that meeting.

(6) A decision of the Authority on any question shall be by a majority of votes of the members present and voting at the meeting and, in the event of an equality of votes, the person presiding at the meeting shall have, in addition to a deliberative vote, a casting vote.

(7) Where a member is for any reasonable cause unable to attend any meeting of the Authority, the member may, in writing, nominate another person from the same

organisation to attend such meeting in that member's stead and such person shall be deemed to be a member for the purpose of such meeting.

(8) The Authority may invite any person whose presence in its opinion is desirable to attend and to participate in the deliberations of a meeting of the Authority but such person shall have no vote.

(9) The validity of any proceedings, act or decision of the Authority shall not be affected by any vacancy in the membership of the Authority or by any defect in the appointment of any member or by reason that any person not entitled so to do, took part in the proceedings.

(10) The Authority shall cause minutes to be kept of the proceedings of every meeting of the Authority and every meeting of any committee established by the Authority.

5. (1) The Authority may, for the purpose of performing its functions under this Act, constitute any committee and may delegate to any such committee such of its functions as it thinks fit.

Committees
of Authority

(2) The Authority may appoint as members of a committee constituted under sub-paragraph (1), persons who are or are not members of the Authority and such persons shall hold office for such period as the Authority may determine.

Allowances
of members

6. There shall be paid to members of the Authority or any committee of the Authority such allowances as the Authority may, with the approval of the Minister, determine.

Disclosure of
interest

7. (1) A person who is present at a meeting of the Authority or any committee of the Authority and who is directly or indirectly interested in a matter that is the subject of consideration at the meeting shall, as soon as is practicable after the commencement of the meeting, disclose the interest and shall not, unless the Authority or the committee otherwise directs, take part in any consideration or discussion of, or vote on, any question relating to the matter.

(2) A disclosure of interest made under this paragraph shall be recorded in the minutes of the meeting at which it is made.

Registrar
and staff of
Authority

8. (1) The Authority shall appoint a suitably qualified and experienced person as Registrar of the Authority who shall be the chief executive officer of the Authority and who, subject to the general or special direction of the Authority, shall be responsible for the carrying out of the provisions of this Act, and shall be responsible for the administration of the Act.

(2) The Authority shall, with the approval of the Minister, determine the terms and conditions of service of the Registrar.

(3) The Registrar shall be an *ex-officio* member and Secretary of the Authority.

(4) Where the Registrar is for any reason absent or unable to perform the functions of office, or where a vacancy occurs in the office of Registrar, the Authority shall designate a member of staff to act in that capacity for the duration of the absence until the Registrar resumes functions of office or until another Registrar is appointed in terms of sub-paragraph (1), and that person has, while so acting, such powers and shall perform such duties as may be delegated or assigned by the Authority.

(5) The Authority may appoint, on such terms and conditions as the Authority may with the approval of the Minister determine, such other staff as it considers necessary for the performance of its functions under this Act.

9. (1) A person shall not, without the consent in writing given by or on behalf of the Authority, publish or disclose to any unauthorized person, otherwise than in the course of duties of that person, the contents of any document, communication or information whatsoever, which relates to or which has come to the knowledge of that person in the course of that person's duties under this Act.

Prohibition of publication of, or disclosure of information to unauthorized persons

(2) Any person who contravenes the provisions of sub-paragraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding ten thousand penalty units or to imprisonment for a term not exceeding two years, or to both.

(3) If any person, having any information which to the knowledge of that person has been published or disclosed in contravention of sub-paragraph (1), unlawfully publishes or communicates any such information to any other person, the person commits an offence and is liable, upon conviction, to a fine not exceeding ten thousand penalty units or to imprisonment for a term not exceeding two years or to both.

10. No action or other proceeding shall lie or be instituted against any member of the Authority or a committee of the Authority, or any member of the staff of the Authority, for or in respect of any act or thing done or omitted to be done in good faith in the exercise or performance, or purported exercise or performance, of any of the powers or functions conferred under this Act.

Immunity of members of Authority and staff

PART II

FINANCIAL PROVISIONS

11. (1) The funds of the Authority shall consist of such moneys as may—

- (a) be appropriated by Parliament for the purpose of the Authority;
- (b) be paid to the Authority by way of fees, levy, grants or donations; and
- (c) vest in or accrue to the Authority.

(2) The Authority may—

- (a) accept moneys by way of grants or donations from any source in Zambia and subject to the approval of the Minister, from any source outside Zambia;
- (b) subject to the approval of the Minister, raise by way of loans or otherwise, such moneys as it may require for the discharge of its functions; and

(c) in accordance with the regulations made under this Act, charge and collect fees for services provided by the Authority.

(3) There shall be paid from the funds of the Authority—

(a) such monies as may be necessary for the performance of its functions under the Act;

(b) salaries, allowances and loans of the staff of the Authority;

(c) such reasonable travelling, transport and subsistence allowances for members or the members of any committee of the Authority when engaged in the business of the Authority, at such rates as the Minister may determine; and

(d) any other expenses incurred by the Authority in the performance of its function.

(4) The Authority may, subject to the approval of the Minister, invest in such manner as it thinks fit such of its funds as it does not immediately require for the performance of its functions.

Financial
year

12. The financial year of the Authority shall be the period of twelve months ending on 31st December, in each year.

Accounts

13. The Authority shall cause to be kept proper books of accounts and other records relating to its accounts.

Annual
report

14. (1) As soon as practicable, but not later than six months after the expiry of each financial year, the Authority shall submit to the Minister a report concerning its activities during the financial year.

(2) The report referred to in sub-paragraph (1) shall include information on the financial affairs of the Authority and there shall be appended thereto—

(a) an audited balance sheet;

(b) an audited statement of income and expenditure; and

(c) such other information as the Minister may require.

(3) The Minister shall, not later than thirty days after the first sitting of the National Assembly next after the receipt of the report

referred to in sub-paragraph (1), lay it before the National Assembly.

SECOND SCHEDULE

(Section 13)

INFORMATION REQUIRED FOR THE APPLICATION

I General Information

A. Name and address of the applicant

B. Information on personnel and training

1. Name of person(s) responsible for the planning and carrying out the release, including those responsible for supervision, monitoring and safety, in particular, name and qualification(s) of the responsible scientist.
2. Information on training and qualification(s) of personnel involved in carrying out the release.

II. Information Relating to the Genetically Modified Organism(s) or Products thereof

A *Characteristics of -*

(a) the donor;

(b) the recipient; or

(c) (where appropriate) parental organism(s)

1. Scientific name.
2. Taxonomy.
3. Other names (usual name, strain name, cultivars name, local name etc.).
4. Phenotypic and genetic markers.
5. Degree of relatedness between donor and recipient or parental organisms.
6. Description of identification and detection techniques.
7. Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
8. Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts.
9. Potential for genetic transfer and exchange with other organisms.
10. Verification of the genetic stability of the organisms and factors affecting it, taking into account the relevance of the laboratory experiments undertaken for the authentic

ecological conditions under which the organisms live or are used.

11. Pathological, ecological and physiological traits:

- (a) classification of hazard according to existing national rules concerning the protection of human and animal health and/or the environment;
- (b) generation time in natural ecosystem, sexual and asexual reproductive cycle;
- (c) information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia;
- (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
- (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for therapy and prophylaxis;
- (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:

- (a) Sequence;
- (b) Frequency of mobilisation;
- (c) Specificity;
- (d) Presence of genes, which confer resistance.

13. History of previous modifications.

B. Characteristics of the Vector

1. Nature and source of the vector.
2. Sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organism (s) and products thereof and to make the introduced vector and insert function in the genetically modified organism (s) and products thereof.
3. Frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination.
4. Information on the degree to which the vector is limited to the DNA required to perform the intended function.

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5. Factors (chemical, biological, climatic, etc.) influencing the functional level of the promoter / enhancer, and how the functional level is changed.
- C. *Characteristics of the genetically modified organism (s) and Products thereof*
1. Information relating to the genetic modification:
 - (a) method used for the modification;
 - (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
 - (c) description of the insert and / or vector construction;
 - (d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
 - (e) number of intact and truncated vector inserts. Sequence, functions identity and location of the altered /inserted/deleted nucleic acid segment(s) in question with particular reference to any known sequence; and
 - (f) sequence and methylation pattern of the recipient DNA as far as 100 kbp up and down stream from all DNA inserts.
 2. Information on the final genetically modified organism (s) and products thereof:
 - (a) description of the genetic trait(s) of phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
 - (b) structure and amount of any vector and / or donor nucleic acid remaining in the final construction of the genetically modified organism (s) and products thereof;
 - (c) stability of the organism in terms of genetic traits;
 - (d) rate and level of expression of the new genetic material. Methods and sensitivity of measurement;
 - (e) activity of the expressed protein(s);
 - (f) expression levels for the recipient's genes situated as far as 100 kbp up and down stream from all DNA inserts;

- (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
- (h) history of previous releases or uses of the genetically modified organism (s) or products thereof;
- (i) health considerations:
 - (i) toxic or allergenic effects of the viable or non-viable genetically modified organism (s) or product thereof or their metabolic products;
 - (ii) product hazards;
 - (iii) comparison of the genetically modified organism (s) or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
 - (iv) capacity for colonisation;
 - (v) if the organisms is pathogenic to humans who are immuno competent:
 - (a) disease caused and mechanism of pathogenicity including invasiveness and virulence;
 - (b) communicability;
 - (c) infective dose;
 - (d) host range, possibility of alteration;
 - (e) possibility of survival outside human;
 - (f) presence of vectors or means of dissemination;
 - (g) biological stability;
 - (h) antibiotic resistance patterns;
 - (i) allergenicity;
 - (j) availability of appropriate therapies.

III Information Relating to the conditions of release and the receiving Environment.

A. Information on the Release

1. Description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. Preparation of site prior to the release;

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4. Size of the site;
 5. Method(s) to be used for the release;
 6. Quantities of genetically modified organism(s) or products thereof to be released;
 7. Disturbance on the site (type and method of cultivation, mining, irrigation or other activities);
 8. Workers protection measures taken during the release;
 9. Post-release treatment of the site;
 10. Techniques foreseen for elimination or inactivation of the genetically modified organism (s) or products thereof at the end of the experiment;
 11. Information on, and results of, previous releases of the genetically modified organism (s) or products thereof, especially at different scales and in different ecosystems.
- B. Information of the environment (both on site and in the wider environment)*
1. Geographical location and grid reference of the site(s) (in case of notification the site(s) of release will be the foreseen areas of use of the product).
 2. Physical and biological proximity to humans and other significant biota.
 3. Proximity to significant biotopes or protected areas.
 4. Size of local population.
 5. Economic activities of local populations which are based on the natural resources of the area.
 6. Distance to closest areas protected for drinking water and/or environmental purposes.
 7. Climatic characteristics of the region(s) likely to be affected.
 8. Geographical, geological and pedological characteristics.
 9. Flora and fauna, including crops, livestock and migratory species.
 10. Description of target and non-target ecosystems likely to be affected.
 11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release.
 12. Any known planned developments or changes in land use in the region, which could influence the environmental impact of the release.

IV Information relating to the interactions between the genetically modified Organism(s) or Products thereof and the Environment**A. Characteristics and factors affecting survival, multiplication, gene expression and dissemination**

1. Biological features which affect survival, multiplication and dispersal.
2. Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals and others, etc.).
3. Sensitivity to specific agents.

B. Interactions with the Environment

1. Predicted habitat of the genetically modified organism (s) or products thereof.
2. Studies of the behaviour and characteristics of the genetically modified organism (s) or products thereof and their ecological impact carried out in simulated natural environments, such as microorganisms, growth rooms, green houses.
3. Genetic transfer capability:
 - (a) post-release transfer of genetic material from genetically modified organism (s) or products thereof into organisms in affected ecosystems;
 - (b) post-release transfer of genetic material from indigenous organisms to the genetically modified organism (s) or products thereof;
4. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organism (s) or products thereof.
5. Measures employed to ensure and verify genetic stability. Description of genetic traits, which may prevent or minimise dispersal or genetic material. Methods to verify stability.
6. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.
7. Description of ecosystems to which the genetically modified organism (s) or products thereof could be disseminated.

C. Potential Environmental Impact

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1. Potentials for excessive population increase in the environment.
 2. Competitive advantage of the genetically modified organism (s) or products thereof in relation to the unmodified recipient or parental organism(s).
 3. Identification and description of the target organisms.
 4. Anticipated mechanism and result of interaction between the released genetically modified organism (s) or products thereof and the target organism.
 5. Identification and description on non-target organisms, which may be affected unwittingly.
 6. Likelihood of post release shifts in biological, or in host range.
 7. Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens.
 8. Known or predicted involvement in biogeochemical processes.
 9. Other potentially significant interactions with the environment.
- V. Information on monitoring, control, waste treatment and emergency response plans**
- A. Monitoring Techniques*
1. Methods for tracing the genetically modified organism (s) or products thereof, and for monitoring their effects.
 2. Specificity (to identify the genetically modified organism (s) or products thereof, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.
 3. Techniques for detecting transfer of the donated genetic material to other organisms.
 4. Methods to detect aberrant gene expression.
- B. Control of the Release*
1. Methods and procedures to avoid and/or minimise the spread of the genetically modified organism (s) or products thereof beyond the site of release or the designated area for use.
 2. Methods and procedures to protect the site from intrusion by unauthorised individuals.
 3. Methods and procedures to prevent other

organisms from entering the site.

C. *Waste Treatment*

1. Type of waste generated;
2. Expected amount of waste;
3. Possible risks;
4. Description of treatment envisaged.

D. *Emergency Response Plan*

1. Methods and procedures for controlling the genetically modified organism (s) or products thereof in case of unexpected spread.
2. Methods for decontamination of the areas affected, e.g. eradication of the genetically modified organism (s) or products thereof.
3. Methods for disposal or sanitation of plants, animals, soils, etc. that was exposed during or after the spread.
4. Methods for the isolation of the area affected by the spread.
5. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

THIRD SCHEDULE

(Section 29)

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR
PLACING ON THE MARKET

A. *The following information shall be provided in the notification for placing on the market products, in addition to that of Annex I:*

1. Name of the product and name(s) of genetically modified organism (s) contained therein.
2. Name of the manufacturer or distributor and his address, including address in the country;
3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical areas(s) of the country for which the product is suited.
4. Type of expected use: industry, agriculture and skilled trades, consumers use by public at large.

B. *The following additional information shall be provided when required/relevant:*

1. Measures to take in case of unintended release or misuse.

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2. Specific instructions or recommendations for storage and handling.
 3. Estimated production in and/or imports to the country.
 4. Proposed packaging. This must be appropriate so as to avoid unintended release of the genetically modified organism (s) during storage, or at a later stage proposed labelling. This must include, at least in summarised form, the information referred to in points A.1, A.2, A.3, B.1 and B.2.
- C. *The following information concerning labelling of products thereof shall be provided on a label and/or in accompanying documents:*
1. The words “This product contains genetically modified organism (s)” whenever there is evidence of the presence of genetically modified organism (s) in the product.
 2. The words “This product may contain genetically modified organism (s)” where the presence of genetically modified organism (s) in a product cannot be excluded but there is no evidence of any presence of genetically modified organism (s).
 3. The words “This product may cause [specify the particular reactions, allergies or other side effects]” where it is known that a particular reaction, allergy or other side effect may be caused by the product.
 4. Where applicable, further or as a qualification to C.1 or C.2, the words “This product contains genetic material (nucleic acids) from genetically modified organism (s)” or this product is based on raw materials from genetically modified organism”.
 5. The identification and labelling shall specify the relevant traits and characteristics in sufficient detail for purposes of traceability and to facilitate verification by both importing and transiting countries.

FOURTH SCHEDULE

(section 24)

RISK ASSESSMENT

The risk assessment shall take the following parameters into consideration:

A. *General Principles*

1. The guiding principle of risk assessment is the precautionary approach. Where the transboundary movement, or use or handling of genetically modified organism(s) or products thereof may cause, or has a proven or theoretical potential (or based on reasonable scientific theory of hazards based on deductive, circumstantial as well as inductive evidence) to cause harm to biodiversity, ecosystems, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.
2. The risk assessment should take into account, inter alia, all relevant scientific theory, evidence and experience, including previous risk assessments. This enables the risk assessment to evolve in the light of new evidence and knowledge; a genetically modified organism or product thereof previously considered acceptable may no longer be acceptable, and vice versa.
3. It shall be accepted as a principle underlying the risk assessment that every transgenic line is different because of random insertion, even if they are made with the same vector system, the same gene constructs and the same variety, and that it has to be well characterised to be stable for at least five generations under a reasonable range of environmental conditions that it may encounter.
4. The risk assessment should take into account, inter alia:
 - (a) all relevant scientific theory, evidence and experience;
 - (b) The general characteristics of both the genetically modified organism or product thereof and the parent organisms, the vector(s) used, the genetic modifications and the novel trait(s), including marker traits(s) and other sequences even when not expressed;
 - (c) the naive environments or host range of the recipient organism and donor organisms;
 - (d) the intended use(s) of the genetically modified organism or product thereof and the nature of the receiving and surrounding environments;
 - (e) potential impact of the genetically modified organism or product thereof on the environment, including long-term direct and indirect ecological impacts, particularly on centres of origin and areas with high genetic diversity of taxa related to the genetically modified organism or product thereof;

- (f) effects, long term and direct or indirect, of the genetically modified organism or product thereof on human, plant and animal health;
- (g) socio-economic impacts;
- (h) conformity with ethical norms;
- (i) details of risk assessments completed elsewhere.

B. Specific Information Requirements

The information required for risk assessment should include the following:

1. Characteristics of donor and recipient organisms or parental organisms:
 - (a) scientific name and taxonomy;
 - (b) strain, cultivar or other name;
 - (c) species it is related to and degree of relatedness;
 - (d) the degree of relatedness between the donor and recipient organisms, or between the parental organisms;
 - (e) all sites from where the donor and recipient organisms or parental organisms were collected, if known;
 - (f) information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;
 - (g) history of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
 - (h) phenotypic and genetic markers of interest;
 - (i) description of identification and detection techniques for the organisms, and the sensitivities of these techniques;
 - (j) geographic distribution and natural predators, prey, parasites, competitors, symbionts and hosts;
 - (k) climatic characteristics of original habitats;
 - (l) ability of the organisms to survive and colonise the environment to which release is intended or otherwise;
 - (m) genetic stability of the organisms, and factors affecting the stability;
 - (n) the presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;
 - (o) the potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;
 - (p) pathogenicity to humans or animals, if any;
 - (q) if pathogenic, their virulence, infectivity, toxicity and modes of transmission;

- (r) known allergenicity and/or toxicity of biochemical and metabolic products;
 - (s) availability of appropriate therapies for pathogenicity, allergenicity and toxicity.
2. Characteristics of the Vector(s):
- (a) nature and source of the vector(s);
 - (b) genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non coding sequences affecting the expression of the introduced gene(s), and marker gene(s);
 - (c) ability of the vector(s) to mobilise and transfer genes by integration and methods for determining the presence of the vector(s);
 - (d) complete nucleotide sequence of the vector(s);
 - (e) history of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;
 - (f) potential for pathogenicity and virulence;
 - (g) natural and host range of vectors;
 - (h) natural habitat and geographic distribution of natural and potential hosts;
 - (i) potential impacts on human and animal health and the environment
 - (j) measures for counteracting adverse impacts;
 - (k) potential to survive and multiply in the environment, or to form genetic recombinants; and
 - (l) genetic stability of vector(s), such as hypermutability.
3. Characteristics of the genetically modified organism or Product thereof:
- (a) the description of the modifications made using gene technology;
 - (b) the function of the genetic modifications and/or the new insert, including any marker gene(s);
 - (c) purpose of the modification and intended use in relation to need or benefit;
 - (d) method of modification and, in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;
 - (e) whether introduced gene(s) are integrated or extra chromosomal;
 - (f) number of insert(s) and its/their structure(s), for example, the copy number, the number of

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- truncated or fragmented inserts, whether in tandem or other types of repeats and the position of each insert;
- (g) nucleotide sequence of each insert, including at least 100 kbp up and down stream from the insert;
 - (h) products of the transferred gene(s), levels of expression and integration;
 - (i) stability of the introduced gene(s) in terms of expression and integration;
 - (j) biochemical and metabolic differences of the genetically modified organism or product thereof compared with unmodified organism;
 - (k) probability of vertical or horizontal gene transfer to other species;
 - (l) probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;
 - (m) allergenicities, toxicities, pathogenicities and unintended effects;
 - (n) autecology of the genetically modified organism or product thereof compared with that of the unmodified organism
 - (o) susceptibility of the genetically modified organism or product thereof to diseases and pests compared with the unmodified organism;
 - (p) detailed information on past used including results on all experiments leading to previous releases
4. Characteristics of resuscitated organisms and gene(s) and fossil DNA sequences:
- Resuscitated Organism
- (a) scientific name and taxonomy;
 - (b) identify of nearest species and their characteristics which are of relevance to the intended use;
 - (c) site at which it was found;
 - (d) method used for resuscitation;
 - (e) purpose of introducing the organism and benefits, if any;
 - (f) impacts on human and animal health and the environment;
 - (g) measures for counteracting adverse impacts;

- (h) length of time the organisms has been in use;
- (i) genetic stability;
- (j) likelihood of gene transfer to other organisms;
- (k) fossil and living nearest relative species;
- (l) biological and biochemical differences from related living species;
- (m) information on previous uses since resuscitation.

DNA sequences from fossils or from resuscitated organism

- (a) scientific name and taxonomy of the species whether resuscitated or a fossil;
- (b) site of origin of the fossil;
- (c) site of the gene in the resuscitated genome, if known;
- (d) base sequence of the extracted gene;
- (e) method used in extracting the gene;
- (f) function of gene, if known;
- (g) purpose of use and benefits, if any;
- (h) environment in which it lived before fossilisation;
- (i) fossil species related to the species from which the gene was taken;
- (j) living species related to the species from which the gene was taken;

5. Safety Considerations for Human and Animal Health:

Information on the genetically modified organism or product and information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:

- (a) capacity for colonisation
- (b) if the genetically modified organism or product thereof is pathogenic to humans or animals the following information is required:
 - (i) disease caused and mechanisms of pathogenicity, including invasiveness and virulence, and property of virulence;
 - (ii) communicability;
 - (iii) infective dose;
 - (iv) host range and possibilities of alteration;
 - (v) ability to survive outside of the human or animal host;

- (vi) the existence of vectors or other means of transmission;
- (vii) biological stability;
- (viii) allergenicity and
- (ix) availability of appropriate therapies.

6. Environmental Considerations:

Information on the genetically modified organism or product thereof and information on the donor and recipient organism as well as the vector before it was disarmed or disabled where it has been disarmed or disabled, regarding:

- (a) factors affecting the survival, reproduction and spread of the genetically modified organism or product thereof in the environment;
- (b) available techniques for detection, identification and monitoring of the genetically modified organism or product thereof;
- (c) available techniques for detecting transmission of genes from the genetically modified organism or product thereof to other organisms;
- (d) known and predicated habitats of the genetically modified organism or product thereof;
- (e) description of the ecosystems which could be affected by accidental release of the genetically modified organism or product thereof;
- (f) possible interaction between the genetically modified organism or product thereof and other organisms in the ecosystem which might be affected by accidental release;
- (g) known or predicted effect on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonisation;
- (h) possible involvement in biogeochemical processes;
- (i) availability of methods for decontamination of the area in case of accidental releases;
- (j) effects of agricultural practices with possible undesirable impacts on the environment.

7. Socio-economic Considerations:

- (a) anticipated changes in the existing social and economic patterns resulting from the introduction

- of the genetically modified organism or product thereof;
- (b) possible threats to biological diversity, traditional crops or other products and, in particular, farmer's varieties and sustainable agriculture;
 - (c) impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;
 - (d) anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the genetically modified organism or product thereof;
 - (e) possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;
 - (f) possible effects, which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the genetically modified organism or product thereof.

FIFTH SCHEDULE

(Section 27)

RISK MANAGEMENT SCHEMES

The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the genetically modified organism or the product of a genetically modified organism, to its intended use or commercialisation.

1. Imported products of genetically modified organisms used for human or animal health (for example, antibodies, drugs and hormones):
 - (a) observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant;
 - (b) such observation can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in areas other than the State of import.
2. Imported microbial genetically modified organisms for human and animal health:

Besides the limited observation specified in 1, experiments shall be carried out to evaluate viability and risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.

3. Imported genetically modified organisms for contained use:
 - (a) the products of genetically modified organisms will be treated as in 1 above.
 - (b) experiments will be made in complete laboratory containment to determine:
 - (i) longevity of the genetically modified organism in cases of unintended release in the premises and in the surrounding environment; and
 - (ii) genetic transfer into other micro-organisms and implications thereof on human and animal health and the environment; and
 - (d) methods for counteracting adverse impacts resulting from unintended releases should be specified.
4. Products of genetically modified organism made locally:
 - (a) trial on experimental animals will be made when the product of the genetically modified organisms is intended to be used on humans;
 - (b) in all other cases, trials will be made on species for which the product of the genetically modified organism has been designed.
5. Genetically modified organisms made locally for use as human or animal vaccines:
 - (a) initial molecular, tissue culture, serological and other related studies in the laboratory in complete containment;
 - (b) trials with experimental animals under strict containment;
 - (c) experiments in complete containment to evaluate the extent of transfer of the genes of the vector introduced or of other genes through the agency of the vector to the genetically modified organism or to other species which will be found in association with the genetically modified organism to ensure that virulence is not acquired by the

genetically modified organism in question or by other micro-organisms;

- (d) trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the genetically modified organism has been made; and
- (e) statistically valid trials in conditions in which the vaccinated individuals live in their communities.

6. Imported plant or microbial genetically modified organism for release:

- (a) the reports from releases in areas other than the State of Import shall be thoroughly evaluated by the Authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
- (b) if the regulations mentioned in (a) have not been found adequate, the Authority shall decide at which step in item 8 the observations should begin;
- (c) if it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;
- (d) the observations will include the health of the genetically modified organism, the health of the organism within the area of limited release, and the biological diversity and the ecology of the area; and
- (e) nationally approved limited field releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

7. Imported animal genetically modified organism for lease:

- (a) the reports from releases in areas other than Zambia shall be thoroughly evaluated by the Authority. Particular emphasis shall be given to whether the

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- applicable regulations in the previous release have been adequate to ensure safety;
- (b) if the regulations mentioned in (a) have not been found adequate, the Authority shall decide at which step in item 9 the observations should begin;
- (c) if it is decided that the regulations used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;
- (d) when the results have met the stated requirements, then a trial release may be authorised with adequate emergency plans put in place to deal with cases of escape.
8. Plant or microbial genetically modified organisms produced locally for eventual release:
- (a) laboratory biomolecular experiments on transformation or resuscitation and other phenomena will be carried out in complete containment;
- (b) tissue culture experiments to develop the genetically modified organism, when required, will be carried out in complete containment;
- (c) observations aimed at understanding the nature of the genetically modified organism shall be carried out in complete containment;
- (d) experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the area of intended release, will be carried out in complete containment;
- (e) complete observations of the interactions of the genetically modified organism with the environment (soil including micro-organisms and terrestrial communities) will be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified micro-organisms may be use on an experimental basis, otherwise they shall be destroyed;
- (f) the product from the genetically modified organism shall be subjected to the procedure in 4;

(g) the monitoring of the spread and behaviour of any released plant or micro-organism, genetically modified organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of annuals and micro-organisms, the duration for perennials which live shorter than trees being in between. The user who is responsible for releasing the genetically modified organisms or its successor shall provide annual reports to the Authority.

9. Animal genetically modified organism produced locally for eventual release:

(a) laboratory biomolecular experiments on transformation (or resuscitation if it is possible) and other phenomena will be carried out in complete containment;

(b) methods of incubating the transformed generative cell or the resuscitated animal will be carried out in complete containment;

(c) the rearing of and observations on the genetically modified organism will be carried out under complete containment;

(d) the genetically modified organism shall be observed under complete containment in an experimental environment which simulates the intended area of release in climatic, microbial, animal and plant communities. The observations shall include the condition of the transgenic animal and those of its micro-organisms especially in the context of gene transfer and those of the microbial, plant and animal communities in the experiment, again including gene transfer;

(e) a limited release will be carried out in an area with appropriate enclosure and emergency measures put in place to prevent escape. Observations will include the condition of the genetically modified organism, its micro-organism focusing on gene transfer, and the ecology of the microbial, plant and animal communities in the area, again including gene transfer;

- (f) if the animal is intended to yield a product, the regulation of the product will follow the procedure in item 4;
- (g) the monitoring of the spread and behaviour of any released animal genetically modified organism will continue for at least 30 years.

10. General Requirements:

- (a) all trials, experiments or observations specified in all the above cases (1-9) are put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the lower institutional and higher national level bodies, namely the institutional biosafety committees or the subcommittees or the Scientific Advisory Committee and the Authority;
- (b) experiments starting from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of genetically modified organisms or products thereof shall be subject to approval by the institutional biosafety committee or by the Authority as the case may be. All experiments outside of strict laboratory isolation and initial experiments involving imported genetically modified organisms or products thereof shall be subject to approval by the Authority. All final approval for the use of genetically modified organisms or products thereof shall be made by the Authority;
- (c) once approval from the Authority is obtained at the completion of the final stage of trials, experiments or observations, the genetically modified organism in question or the product thereof can be employed for its intended use. The Authority shall notify its decision in writing to the competent authority.
- (d) whenever there is need to dispose of the genetically modified organism or the product thereof upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.
- (e) the release of genetically modified organisms or products thereof shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.

