

GENETICALLY MODIFIED ORGANISMS ACT 15 OF 1997

(English text signed by the Acting President)

[Assented To: 20 May 1997]

[Commencement Date: 1 December 1999]

as amended by:

Genetically Modified Organisms Amendment Act 23 of 2006

[with effect from 26 February 2010]

ACT

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to provide for an adequate level of protection during all activities involving genetically modified organisms that may have an adverse impact on the conservation and sustainable use of biological diversity, human and animal health; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for scientifically based risk assessments, environmental impact assessments, socio-economic considerations and risk management measures; to establish a Council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith.

[Long title substituted by s. 16 of Act 23/2006]

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1. Definitions

In this Act, unless the context otherwise indicates -

“accident” means any -

- (i) incident involving an unintentional environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment or on human or animal health within the Republic; or
- (ii) unintentional transboundary movement of genetically modified organisms that is likely to have an immediate or a delayed adverse impact on the environment or on human or animal health;

[Definition of “accident” substituted by s. 1 of Act 23/2006]

“activity” means any activity with genetically modified organisms but is not limited to the importation, exportation, transit, development, production, release, distribution, use, storage and application of genetically modified organisms only;

[Definition of “activity” inserted by s. 1 of Act 23/2006]

“appeal board” means an appeal board appointed in terms of section 19;

“applicant” means any person in control of facilities and activities involving genetic modification of organisms and includes “user”;

“biosafety” means the level of safety when risk management measures must be taken to avoid potential risk to human and animal health and safety and to the conservation of the environment, as a result of exposure to activities with genetically modified organisms, and “biological safety” shall have a corresponding meaning;

[Definition of “biosafety” inserted by s. 1 of Act 23/2006]

“Biosafety Clearing-House” means an information-sharing exchange mechanism established under Article 20 of the Protocol;

[Definition of “Biosafety Clearing-House” inserted by s. 1 of Act 23/2006]

“Committee” means the Advisory Committee established by section 10;

“commodity clearance” means the authorisation to use a genetically modified organism as a food or feed, or for processing, but excludes the planting of a genetically modified organism as a release into the environment;

[Definition of “commodity clearance” inserted by s. 1 of Act 23/2006]

“conditional general release” means a release of a genetically modified organism under specific imposed conditions to regulate or monitor the use of that genetically modified organism for a specified period of time;

[Definition of “conditional general release” inserted by s. 1 of Act 23/2006]

“contained use” means the development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both, that effectively limit contact of the genetically modified organisms with humans, animals and the external environment and their impact on humans, animals and the external environment;

[Definition of “contained use” substituted by s. 1 of Act 23/2006]

“Convention” means the Convention on Biological Diversity;
[Definition of “Convention” inserted by s. 1 of Act 23/2006]

“control” means to examine, regulate, manage or direct any activity within a person’s jurisdiction;

“Council” means the Executive Council for Genetically Modified Organisms established by section 3;

“department” means the Department of Agriculture;

“Director-General” means the Director-General: Department of Agriculture;

“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;

“environmental impact assessment” means the process used to assess the potential impact of an activity on the environment by collecting, organising, analysing, interpreting and communicating information on such activity;
[Definition of “environmental impact assessment” inserted by s. 1 of Act 23/2006]

“extension permit” means a permit issued for activities relating to genetically modified organisms for which a permit had been issued previously;
[Definition of “extension permit” inserted by s. 1 of Act 23/2006]

“general release” means the release of a genetically modified organism into the environment by whatever means, where the organism is no longer contained by any system of barriers;
[Definition of “general release” substituted by s. 1 of Act 23/2006]

“gene therapy” means a technique for delivering functional genes (to replace aberrant ones) into living cells by means of a genetically modified vector or by physical means in order to genetically alter the living cell;

“genetically modified organism” means an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and **“genetic modification”** shall have a corresponding meaning;

“hazard” means an intrinsic biological, chemical or physical characteristic of a genetically modified organism which could lead to an adverse impact on the environment;

“inspector” means any person appointed as an inspector in terms of section 15;

“Minister” means the Minister for Agriculture;

“monitoring” means the maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process;

“notification” means the presentation to the Council of documents containing the information required by the Council;

“officer” means an officer as defined in section 1 (1) of the Public Service Act, 1994 (Proclamation No. 103 of 1994), read with section 1 of the Public Service Amendment Act, 1996 (Act No. 13 of 1996);

“**organism**” means a biological entity, cellular or noncellular, capable of metabolism, replication, reproduction or of transferring genetic material and includes a micro-organism;

“**permit**” means a permit referred to in section 5 (a) and includes a written authority;

“**prescribed**” means prescribed by regulation;

“**Protocol**” means the Cartagena Protocol on Biosafety to the Convention, that has been negotiated and adopted by the Parties to the Convention, acceded to by the Republic on 14 August 2003; A copy of the Protocol is attached for information purposes in the Annexure;
[Definition of “Protocol” inserted by s. 1 of Act 23/2006]

“**registrar**” means the person appointed under section 8;

“**regulation**” means a regulation made under this Act;

“**release**” means release into the environment, and includes a trial release, conditional general release and general release;
[Definition of “release” inserted by s. 1 of Act 23/2006]

“**risk**” means the probability of causing or incurring a loss or damage or an adverse impact or a misfortune;

“**this Act**” includes the regulations;

“**transboundary movement**” means the movement of a genetically modified organism from the Republic to another country or from another country to the Republic;
[Definition of “transboundary movement” inserted by s. 1 of Act 23/2006]

“**trial release**” means the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organisms is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment;

“**user**” means a person who conducts an activity with a genetically modified organism;
[Definition of “user” substituted by s. 1 of Act 23/2006]

“**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 byproduct, emission, residue or remainder of any process or activity in connection with genetically modified organisms.

2. Application of Act

(1) This Act shall apply to -

- (a) the genetic modification of organisms;
- (b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and
- (c) the use of gene therapy.

(2) This Act shall not apply to techniques -

- (a) involving human gene therapy;
- (b) in which recombinant DNA molecules or genetically modified organisms are not employed -
 - (i) in *in vitro* fertilisation in humans and animals;
 - (ii) in conjugation, transduction, transformation or any other natural process; and
 - (iii) in polyploidy induction;
- (c) in which genetically modified organisms as recipient or parental organisms are not employed -
 - (i) in mutagenesis;
 - (ii) in the construction and use of somatic hybridoma cells; and
 - (iii) in cell fusion (including protoplast fusion) of plant cells.

(Section 3: Decided cases)

3. Executive Council of Genetically Modified Organisms

- (1) There is hereby established a juristic person to be known as the Executive Council for Genetically Modified Organisms, which shall consist of not more than 10 members appointed by the Minister.

[Subs. (1) substituted by s. 2 of Act 23/2006]

- (1A) For each member of the Council referred to in subsection (1), the Minister may appoint an alternate, who may attend and vote at the meeting of the Council on behalf of the member if that member is unable to attend.

[Subs. (1A) inserted by s. 2 of Act 23/2006]

- (2) The members referred to in subsection (1) -
 - (a) shall be one officer of each of the following national departments of State, nominated by the relevant department:
 - (i) The Department of Agriculture;
 - (ii) the Department of Science and Technology;
 - (iii) the Department of Environmental Affairs and Tourism;
 - (iv) the Department of Health;
 - (v) the Department of Labour;
 - (vi) the Department of Trade and Industry;
 - (vii) the Department of Arts and Culture; and
 - (viii) the Department of Water Affairs and Forestry,

who shall have knowledge of the implications of genetically modified organisms with regard to the sector represented by his or her department, including any existing policies and legislation applicable within that sector;
[Para. (a) substituted by s. 3 of Act 23/2006]

- (b) shall include the chairperson of the Committee; and
- (c) may include any other person.
- (3) The Minister shall designate a chairperson and a deputy chairperson from among the members of the Council.
- (4) The deputy chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.

4. Objectives of Council

The Council shall advise the Minister on all aspects concerning activities relating to genetically modified organisms, and ensure that such activities are performed in accordance with this Act.
[S. 4 substituted by s. 3 of Act 23/2006]

5. Powers and duties of Council

(1) The Council shall-

- (a) where an applicant applies in the prescribed manner for a permit to conduct activities in respect of genetically modified organisms determine whether that applicant must, in addition to his or her application, submit an assessment in accordance with the relevant provisions of the National Environmental Management Act, 1998 (Act No. 107 of 1998), of the impact on the environment and an assessment of the socio-economic considerations of such activities;
- (b) in consultation with the Committee, decide whether to approve an application-
 - (i) for the use of facilities to conduct activities in respect of genetically modified organisms; or
 - (ii) to conduct any activity, except an activity for which an extension permit is required;
- (c) in considering an application have regard to the following factors:
 - (i) Scientifically based risk assessments; and
 - (ii) proposed risk management measures;
- (d) determine, in the event of-
 - (i) an intentional change in the use of a facility or an activity for which approval was granted; and
 - (ii) being notified by the user of any intended change,whether that user must re-apply for approval;

- (e) evaluate whether the user implemented the prescribed notification procedures in accordance with article 8 of the Protocol;
- (f) in the event of an accident, determine the manner of notification and the information to be submitted by a user as required in terms of this Act;
- (g) advise the Minister on ways to avoid accidents in the future and on measures to minimise any adverse impact on the conservation and sustainable use of biological diversity including risks to human and animal health;
- (h) implement appropriate measures regarding the manner of notification that must be given to an affected or potentially affected State, the Biosafety Clearing-House and, where appropriate, any relevant international organisations, of an unintentional transboundary movement that is likely to have an adverse impact on-
 - (i) the conservation and the sustainable use of biological diversity; or
 - (ii) human and animal health,in such an affected or potentially affected State;
- (i) provide an affected or potentially affected State with the prescribed information in the notification referred to in paragraph (h);
- (j) consult with an affected or potentially affected State immediately after notifying that State of an unintentional transboundary movement referred to in paragraph (h), to enable that State to take the necessary actions, including emergency measures;
- (k) satisfy itself prior to the Republic entering into a bilateral, regional or multilateral agreement or arrangement, including an agreement or arrangement on contingency plans regarding unintentional transboundary movements, that the level of protection of human and animal health and the environment is not lower than the level of protection provided for in the Protocol, and shall advise the Minister accordingly;
- (l) inform the Minister-
 - (i) of any approval to conduct an activity contemplated in this Act and to exercise control over such an activity;
 - (ii) of any notification received of an unintentional transboundary movement, and any relevant information on such transboundary movement;
 - (iii) in the event of an accident, of the proposed control measures to be implemented to contain that accident; and
 - (iv) of any other matter with regard to genetically modified organisms;
- (m) make recommendations to the Minister on the appointment of members to the Committee;
- (n) where the Council has been informed by the registrar that there is a reasonable suspicion that an activity is conducted contrary to this Act or to a condition contained in a permit issued under this Act, determine-

- (i) a place or facility whereto a genetically modified organism used in such a activity or any material or substance used, affected or potentially affected by such activity must be removed; and
- (ii) appropriate measures for the disposal or repatriation of any genetically modified organism used in such activity or any material or substance used, affected or potentially affected by such activity.

(2) The Council may-

- (a) before making a decision regarding an application submitted in terms of this section consider the following factors:
 - (i) Public input;
 - (ii) the environmental impact assessment; or
 - (iii) the potential socio-economic impact of such activities;
- (b) if the Council is satisfied that the application conforms with the factors in subsection (1)(c) or paragraph (a), authorise the registrar, in writing, to issue a permit on such terms and conditions as the Council considers necessary;
- (c) in the event of an accident, instruct the registrar to appoint a panel to enquire into and report on the causes of such accident;
- (d) where an applicant applies for an extension permit, consult with the Committee on such issues as the Council may consider necessary to come to a decision;
- (e) promote co-operation between the Republic and any other country with regard to research, development and technology transfer in the field of genetic modification of organisms and biosafety;
- (f) with the consent of the Minister, approve and issue guidelines for activities with genetically modified organisms and make such guidelines available to the public;
- (g) if the Council receives new and relevant scientific or technological evidence about activities conducted in terms of this Act, which may have an impact on the factors referred to in subsection (1)(c) or paragraph (a), reconsider any decision taken by it;
- (h) co-opt any person knowledgeable in a specific field of science to serve on the Council in order to advise the Council on matters where the Council considers it necessary;
- (i) invite written comments from any person knowledgeable in a specific field of science on any aspect of genetic modification which falls within the Council's functions.

[S. 5 substituted by s. 4 of Act 23/2006]

6. Vacancies in Council

- (1) A vacancy in the Council shall occur when a member -
 - (a) ceases to be an officer;

- (b) is absent without leave from more than three consecutive meetings of the Council;
 - (c) resigns;
 - (d) is removed from the office in terms of subsection (2);
 - (e) dies.
- (2) The Minister may at any time remove a member of the Council from office if the Minister is of the opinion that such member is no longer competent to fill his or her office or that he or she has misconducted himself or herself.
- (3) A vacancy in the Council shall be filled as soon as practicable in accordance with section 3.
- (4) Whenever the Minister is satisfied that any member of the Council is prevented by illness or any other reason from performing the duties of his or her office, the Minister may appoint any other person whom he or she considers suitable to act as the deputy of that member while such member is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member in whose stead he or she has been appointed so to act: Provided that a person appointed as the deputy of the chairperson or the deputy chairperson shall only perform the duties of an ordinary member, unless the Minister otherwise directs.

7. Meetings of Council

- (1) Meetings of the Council shall be held at such times and places as the chairperson may determine from time to time: Provided that the first meeting shall be held at a time and place determined by the Minister.
- (2) The quorum for any meeting of the Council shall be a majority of the members.
- (3) (a) A decision of the Council shall be reached on the basis of consensus by all members of the Council.
- (b) In the event that the Council fails to reach consensus on a decision such decision shall be considered as having been refused.
[Subs. (3) substituted by s. 5 of Act 23/2006]
- (3A) The Council shall convene a special meeting at such time and place and on such date as determined by the chairperson-
- (a) on receipt of a written request by the Minister;
 - (b) on receipt of a written request signed by at least two members; or
 - (c) in the event of an accident contemplated in section 5(1)(f),
[Subs. (3A) inserted by s. 5 of Act 23/2006]
- (4) The Council may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

(5)

[Subs. (5) deleted by s. 5 of Act 23/2006]

(6)

[Subs. (6) deleted by s. 5 of Act 23/2006]

8. Appointment of registrar

- (1) (a) As soon as possible after the composition of the Council and whenever necessary thereafter the Minister shall, after consultation with the Council, appoint a suitably qualified and experienced person as registrar.
- (b) An appointment under paragraph (a) -
 - (i) shall terminate if the person resigns as registrar;
 - (ii) may be terminated by the Minister if the registrar does not perform his or her duties satisfactorily.
- (2) The registrar -
 - (a) is charged with the administration of this Act;
 - (b) may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by or under this Act or by the Council.
- (3) Whenever the registrar is for any reason absent or unable to perform his or her functions, or whenever a vacancy in the office of the registrar occurs, the Council may designate a member of its staff to act in that capacity until the registrar resumes his or her functions, or a registrar is appointed in terms of subsection (1), and that member has, while so acting, such powers and shall perform such duties of the registrar as may be delegated or assigned to him or her by the Council.
- (4) Any action of the registrar may at any time be withdrawn or amended by the Minister.
- (5) The Director-General shall designate, subject to the provisions of the Public Service Act, 1994 (Proclamation No. 103 of 1994), as many officers of the department as may be necessary to assist the registrar in the exercise of his or her powers and the performance of his or her duties.

9. Functions of registrar

- (1) The registrar shall, subject to the instructions of and conditions laid down by the Council-
 - (a) examine whether an application conforms to the requirements of this Act;
 - (b) issue a permit or an extension permit in the manner prescribed;
 - (c) amend or withdraw a permit or an extension permit issued under this Act;
 - (d) satisfy himself or herself that all users apply the appropriate measures to protect the environment and human and animal health during the exercise of any activity with genetically modified organisms; and
 - (e) attend to any other matter with regard to biosafety of genetically modified

organisms.

(2) The registrar shall-

- (a) having regard to section 18, maintain a register of-
 - (i) all the facilities that are used for contained use;
 - (ii) all the trial release sites; and
 - (iii) the names and addresses of the persons involved with such contained use or trial release;
 - (b) arrange for an inspection by an inspector, in the manner contemplated in section 15, of any activities or facilities where such activities are undertaken;
 - (c) where the registrar has ascertained or suspects on reasonable grounds that an activity is conducted contrary to this Act or to a condition contained in a permit or an extension permit issued under this Act require the cessation of any such activity;
 - (d) submit to the Council the application for a permit together with all the prescribed documents and any other documentation the Council may require to make its decision; and
 - (e) communicate to the Biosafety Clearing-House the information specified in the regulations.
- (3) The registrar may, subject to such terms and conditions laid down by the Council, issue an extension permit for an activity in respect of genetically modified organisms for which a permit had been issued previously.
[S. 9 substituted by s. 6 of Act 23/2006]

10. Advisory Committee

- (1) There is hereby established an Advisory Committee which shall consist of not more than ten persons appointed by the Minister after the recommendation of the council for a period not exceeding five years of whom -
- (a) not more than eight members shall be knowledgeable persons in those fields of science applicable to the development and release of genetically modified organisms;
 - (b) two persons shall be from the public sector, of which one person shall have knowledge of ecological matters and genetically modified organisms, and the other person shall have knowledge of the potential impact of genetically modified organisms on human and animal health.
[Subs. (b) substituted by s. 7 of Act 23/2006]
- (2) The Council shall, in recommending members for appointment to the Committee, endeavour to achieve representation from all the fields of expertise involved with genetically modified organisms.
- (3) The Minister shall, after the recommendation of the Council, designate any member of the Committee as chairperson.

- (4) In the absence of the chairperson the remaining members of the Committee shall elect an acting chairperson from their number.
- (5) The acting chairperson shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to do so.
- (6) A member of the Committee whose period of office has expired shall be eligible for reappointment.

11. Functions of committee

- (1) The Committee shall -
 - (a) act as the national advisory body on all matters concerning or related to the genetic modification of organisms;
 - (b) advise, on request or of its own accord, the Minister, the Council, the registrar, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, *inter alia*, advise them -
[Words preceding para. (i) substituted by s. 11 of Act 23/2006]
 - (i) on all aspects relating to the introduction of genetically modified organisms into the environment;
 - (ii) on proposals for specific activities or projects concerning the genetic modification of organisms;
 - (iii) on all aspects concerning the contained use of genetically modified organisms;
 - (iv) on the importation and exportation of genetically modified organisms; and
 - (v) on proposed regulations and written guidelines;
 - (c) liaise, through the relevant national departments, with international groups or organisations concerned with biosafety; and
 - (d) co-opt or invite written comments from knowledgeable persons in specific fields of science on any aspect of the genetic modification of organisms which lies within the Committee's brief, to assist the Committee in performing its functions.
[Para. (d) substituted by s. 11 of Act 23/2006]
- (2) The Committee may appoint subcommittees to deal with specific matters as required.

12. Funding

- (1) To members of the Committee, subcommittee members and the members referred to in sections 3(2)(c), 5(2)(h) and 11(d) shall be paid such remuneration as the Minister, with the concurrence of the Minister of Finance, may determine.
[Subs. (1) substituted by s. 9 of Act 23/2006]
- (2) The Committee shall annually and in accordance with the departmental budgetary programme submit a budget to the Council.

13. Conflict of interest

A person appointed to the Committee shall immediately recuse himself or herself as a member of the Committee if a subject matter is in issue in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings of the Committee.

14. Prohibition of activities concerning genetically modified organisms

The Minister may, on the recommendation of the Council, by notice in the *Gazette* prohibit any activity involving genetically modified organisms.

15. Inspectors

- (1) The registrar may appoint any officer, or with the approval of the Minister, any person who is not an officer, as an inspector to exercise and perform the functions referred to in subsection (4) and in section 16.
- (2) Every inspector shall be furnished with a certificate signed by the registrar stating that he or she has been appointed as inspector under this Act.
- (3) An inspector shall, at the request of any person affected by the exercise or performance of a function by such an inspector, exhibit the certificate referred to in subsection (2) to such a person.
- (4) An inspector may, on the authority of a warrant issued in terms of subsection (5), conduct an investigation to determine whether the provisions of this Act are being or have been complied with, and may, for that purpose during normal office hours and without giving prior notice, enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of this Act is taking place—
 - (a) to inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;
 - (b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;
 - (c) to seize any appliance, book, statement, document or genetically modified organism and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act.
[Para. (c) substituted by s. 10 of Act 23/2006]
 - (d) to give notice to the owner of any material, substance, genetically modified organism, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under paragraph (c) to remove the seized items at such person's own cost within a period and to a place specified in such notice;
[Para. (d) substituted by s. 10 of Act 23/2006]
 - (e) to dispose of or repatriate any genetically modified organism used or any material or substance used, affected or potentially affected if such activity has an adverse impact on the environment or human and animal health.
[Para. (e) added by s. 10 of Act 23/2006]
- (5) (a) A warrant referred to in subsection (4) shall be issued by a magistrate who has

jurisdiction in the area in which the place or facility in question is situated, and shall only be issued if it appears from information on oath that there are reasonable grounds to believe that any material, substance, appliance, book, statement or document that may relate to a contravention of this Act, is upon or in such place or facility.

- (b) A warrant issued in terms of this section shall be executed with strict regard to decency and order.
- (6) (a) If no criminal proceedings are instituted in connection with any item referred to in subsection (5) (a), seized in terms of subsection (4), or if it appears that such item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.
- (b) After the conclusion of criminal proceedings any item seized in terms of subsection (4) and which served as an exhibit in proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the registrar.

16. Routine inspections by inspectors

An inspector may during office hours, without warrant, enter any place or facility registered in terms of this Act in order to -

- (a) open any container found in or upon such place or facility and which the inspector believes on reasonable grounds to contain material of any genetically modified organism;
- (b) examine the material of any genetically modified organism and take samples thereof;
- (c) inspect any activity or process carried out in or upon the place or facility in connection with genetically modified organisms; and
- (d) require the owner or occupier thereof to produce for inspection or for the purpose of obtaining copies or extracts, thereof or therefrom any book, label, shipping bill, bill of lading or other document with respect to the administration of this Act.

17. Determination of risks and liability

- (1) Users shall ensure that appropriate measures are taken to avoid an adverse impact on the environment and human and animal health which may arise from the use of genetically modified organisms.

[Subs. (1) substituted by s. 11 of Act 23/2006]

- (1A) In the event of damage, a user shall immediately inform the registrar of the damage and in consultation with the registrar investigate, assess and evaluate the damage caused by the activity on the environment and human and animal health and implement measures including but not limited to-

- (a) cease, modify or control any act, activity or process causing the damage;
- (b) minimise, contain or prevent the movement of any genetically modified organisms causing the damage in the event that an activity cannot reasonably be avoided or stopped;
- (c) eliminate any source of the damage; or

- (d) remedy the effects of the damage caused by the activity.
[Subs. (1A) inserted by s. 11 of Act 23/2006]
- (2) The liability for damage caused by activities relating to a genetically modified organism shall be borne by the user concerned: Provided that when such an organism was in the possession of an inspector as set out in section 15(4), the user concerned at the time of such activity shall not be held liable for any damage unless such user foresaw or should have foreseen such damage and could or should have prevented the damage but failed to take reasonable action to prevent such damage.
[Subs. (2) substituted by s. 11 of Act 23/2006]

- (3) If a person fails or inadequately implements the measures contemplated in subsection (1A), the Council may take any reasonable measures to remedy the situation.
[Subs. (3) substituted by s. 11 of Act 23/2006]

17A. Recovery of costs

- (1) Subject to subsection (2), the Council may recover all costs incurred as a result of it acting under section 17(3) or section 5(1)(n).
- (2) The Council may in respect of the recovery of costs under subsection (1), claim proportionally from any other person who benefited from the measures undertaken under section 17(3) or section 5(1)(n).
- (3) The costs claimed under subsections (1) and (2) must be reasonable and may include, without being limited to, labour, administrative and overhead costs.
- (4) If more than one person is liable under subsection (2), the Council must, at the request of any of those persons, and after having given the others an opportunity to be heard, apportion the liability, but such apportionment does not relieve any of them of their joint and several liabilities for the full amount of the costs.
- (5) Any order referred to in subsections (1) and (2) shall have the effect of civil judgment in a magistrate's court.
- (6) Any person affected by an order for costs awarded under this section may lodge an appeal to the appeal board in the manner contemplated in section 19.
[S. 17A inserted by s. 12 of Act 23/2006]

(Section 18: Decided cases) 18. Confidentiality

- (1) No person shall disclose any information acquired by him or her through the exercise of his or her powers or the performance of his or her duties in terms of this Act, except -
 - (a) in so far as it is necessary for the proper application of the provisions of this Act;
 - (b) for the purposes of any legal proceedings under this Act;
- (Section 18(1)(c): Decided cases)
 - (c) when ordered to do so by any competent court; or
 - (d) if he or she is authorised to do so by the Minister.

- (2) The Council shall decide, after consultation with the applicant, which information will be kept confidential and shall inform the applicant of its decision: Provided that the following information shall not be kept confidential -
- (a) the general description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use;
[Para. (a) substituted by s. 12 of Act 23/2006]
 - (b) the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and
 - (c) the summary of the scientifically based risk assessment of the impact on the environment and human and animal health.
[Para. (c) substituted by s. 12 of Act 23/2006]
- (3) Notwithstanding the provisions of subsection (2), the Council may after consultation with the applicant and if the Council is satisfied on the grounds of information furnished by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold such information for the period needed to protect such rights.
- (4) If, for whatever reasons, the applicant withdraws an application, any party who has knowledge of the details of the application must respect the confidentiality of the information supplied.

(Section 19: Decided cases)

19. Appeals

- (1) A person who feels aggrieved by any decision or action taken by the Council, the registrar or an inspector in terms of this Act may, within the period and in the manner prescribed and upon the payment of the prescribed fee, appeal against such decision or action to the Minister, who shall appoint an appeal board for the purpose of the appeal concerned.
- (2)
- (a) An appeal board shall be appointed within 60 days from the date of receipt of the appeal by the registrar, provided that the Minister may, if he or she considers it necessary, extend the period by another 30 days and shall consist of persons who, in the opinion of the Minister, have expert knowledge of the matter on appeal and who are otherwise suitable to make a decision on the appeal concerned.
[Para. (a) substituted by s. 13 of Act 23/2006]
 - (b) The Minister shall designate one of the members of the appeal board as chairperson of that appeal board.
[Para. (b) substituted by s. 13 of Act 23/2006]
 - (c) A person appointed under paragraph (a), shall recuse himself or herself as a member of the appeal board if he or she has any direct or indirect interest in the subject matter of the appeal or if, for any other reason, there is or there is likely to be a conflict of interests as a result of his or her participation in the proceedings of the appeal board.
- (3) There may be paid to a member of an appeal board who is not in the full-time employment of the State, from money appropriated by Parliament for such purpose, such

remuneration or allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

(4) An appeal board may -

- (a) confirm, set aside, substitute or amend the decision or action concerned, which is the subject of the appeal;
- (b) refer the relevant matter back to the registrar for reconsideration by the Council;
- (c) after due consideration of the potential risks and potential benefits related to the matter of appeal, make such other order as it may consider fit in order to minimise a significant negative impact on the environment or human and animal health;
- (d) in making a decision -
 - (i) only follow the prescribed procedures; and
 - (ii) consider new scientific or technical evidence or any other information that is, in the opinion of the appeal board, directly applicable to the appeal.

[Subs. (4) substituted by s. 13 of Act 23/2006]

(5) If a decision or action which is the subject of an appeal -

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

(6) The full decision of an appeal board, together with the reasons therefor, shall be reduced to writing and furnished to the Minister, the registrar and all parties directly involved in the appeal, and made available to the public, within 30 days after the final decision has been taken: Provided that the Minister may take such further action as he or she may consider necessary.

[Subs. (6) substituted by s. 13 of Act 23/2006]

(Section 20: Decided cases)

20. Regulations

(1) The Minister may make regulations -

- (a) regarding the applications for and the period within which a decision on an application must be taken in terms of this Act;
[Para. (a) substituted by s. 14 of Act 23/2006]
- (b) prescribing the procedure to be followed by an applicant for the purpose of drawing up scientifically based risk assessments, environmental impact assessments, socio-economic considerations and risk management measures, for submission to the Council in terms of this Act;

[Para. (b) substituted by s. 14 of Act 23/2006]

- (c) prescribing the fees payable in respect of any application, matter or document;
- (d) regarding the classification and types of genetically modified organisms;

- (e) regarding requirements for the contained use of genetically modified organisms;
- (f) regarding requirements for laboratory development of genetically modified organisms;
- (g) regarding the standards to which facilities for activities involving genetically modified organisms should conform;
- (h) regarding requirements for trial release of genetically modified organisms;
- (i) regarding requirements for the effective management of waste;
- (j) regarding information to be submitted to the Council in the case of a notification in terms of this Act;
- (k) regarding requirements for the general release and marketing of genetically modified organisms;
- (l) regarding the importation and exportation of genetically modified organisms;
- (m) regarding the registration of a place or facility where activities concerning genetically modified organisms are undertaken;
- (n) prescribing -
 - (i) the manner in which and period within which an appeal under section 18 should be lodged;
 - (ii) the fee payable in respect of such an appeal;
 - (iii) the procedure at the proceedings of an appeal board; and
 - (iv) the period within which an appeal board shall decide on an appeal;
- (o) prescribing control measures which shall be complied with by a user;
- (p) regarding classes of genetically modified organisms exempted from control under this Act; and
- (pA) regarding the content of the information that a user, in the event of any accident involving genetically modified organisms, is required to supply to the registrar;
[Para. (pA) inserted by s. 14 of Act 23/2006]
- (pB) regarding the manner and content of the information that must be contained in the notification contemplated in section 5(1)(h);
[Para. (pB) inserted by s. 14 of Act 23/2006]
- (pC) regarding matters concerning the Biosafety Clearing-House;
[Para. (pC) inserted by s. 14 of Act 23/2006]
- (pD) regarding the manner and content of the notification procedures contemplated in section 5(1)(e).
[Para. (pD) inserted by s. 14 of Act 23/2006]

- (g) concerning, generally, any matter which he or she considers necessary or expedient to prescribe in order that the objects of this Act may be better achieved, the generality of the powers conferred by this paragraph not being limited by the provisions of the preceding paragraphs.

- (2) Any regulations made under subsection (1) may provide that any person who contravenes or fails to comply with a provision thereof, shall be guilty of an offence and liable on conviction to a fine, or to imprisonment for a period not exceeding two years.

21. Offences and penalties

- (1) Any person who -
 - (a) contravenes or fails to comply with this Act, any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;
[Para. (a) substituted by s. 15 of Act 23/2006]
 - (b) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties in terms of this Act or refuses to furnish information as required in terms of this Act to the registrar;
 - (c) refuses or fails to furnish information or give an explanation or to reply to the best of his or her knowledge to a question lawfully demanded from or put to him or her by the registrar, Committee, Council or any inspector in the performance of his or her functions in terms of this Act, or furnishes information, an explanation or a reply to the registrar, Committee, Council or any inspector which is false or misleading, knowing that it is false or misleading; or
[Para. (c) substituted by s. 15 of Act 23/2006]
 - (d) falsely holds himself or herself out to be an inspector or any other officer appointed in terms of this Act,

shall be guilty of an offence.
- (2) Any person convicted of an offence under this Act, shall -
 - (a) on a first conviction be liable to a fine, or to imprisonment for a period not exceeding two years; and
 - (b) on a second or subsequent conviction be liable to a fine, or to imprisonment for a period not exceeding four years.
- (3) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty or make any order prescribed by this Act.

22. Delegation of powers

The Minister may, subject to such conditions as he or she may determine, in writing delegate any power conferred upon him or her by this Act, other than a power referred to in section 20, to an officer employed by the department, but shall not be divested of any power so delegated and may amend or set aside any decision of the delegate made in the exercise of such power.

23. Short title and commencement

This Act shall be called the Genetically Modified Organisms Act, 1997, and shall come into

operation on a date to be fixed by the President by proclamation in the *Gazette*.

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