

GENETICALLY MODIFIED ORGANISMS ACT 15 OF 1997[/SAPL4]

[ASSENTED TO 20 MAY 1997] [DATE OF COMMENCEMENT: 1 DECEMBER 1999]

(English text signed by the Acting President)

ACT

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment; 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 risk assessments; 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.

1 Definitions

In this Act, unless the context otherwise indicates-

'accident' means any incident involving an unintended general release of genetically modified organisms which could have an immediate or delayed impact on the environment;

'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';

'Committee' means the Advisory Committee established by section 10;

'contained use' means any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or in a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment;

'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;

'general release' means the introduction of genetically modified organisms into the environment by whatever means, where the organisms are no longer contained by any system of barriers and are no longer under any person's control, so that the organism is likely to survive and be disseminated;

'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 103 of 1994), read with section 1 of the Public Service Amendment Act, 1996 (Act 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;

'registrar' means the person appointed under section 8;

'regulation' means a regulation made under this Act;

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

'this Act' includes the regulations;

'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 any natural or legal person or institution responsible for the use of genetically modified organisms and includes an end-user or consumer;

'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 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 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.

3 Executive Council of Genetically Modified Organisms

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

(2) The members referred to in subsection (1)-

- (a) shall be one officer of each of the following national departments of State:
 - (i) The Department of Agriculture;
 - (ii) the Department of Arts, Culture, Science and Technology;
 - (iii) the Department of Environmental Affairs and Tourism;
 - (iv) the Department of Health;
 - (v) the Department of Labour; and
 - (vi) the Department of Trade and Industry,

who shall have knowledge of the implications of genetically modified organisms with regard to the sector represented by his or her department;

- (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 the development, production, use, application and release of genetically modified organisms, and to ensure that all activities with regard to the development, production, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act.

5 Powers and duties of Council

In order to achieve its objectives, the Council may-

(a) require any applicant for a permit to use facilities for the development, production, use or application of genetically modified organisms or to release such organisms into the environment, to submit to the Council through the registrar, an assessment of the risk and, where required, an assessment of the impact on the environment of such development, production, use, application or release, as the case may be;

(b) require the registrar to examine the conformity of an application to the requirements of this Act;

(c) require the registrar to maintain a register of all facilities involved in the contained use or the trial release of genetically modified organisms as well as the names and addresses of persons concerned with such contained use or trial release of genetically modified organisms;

(d) require notification by the applicant of any intended change in the type of activities or release involving genetic modification of organisms being undertaken at facilities for which approval was granted in terms of paragraph (g), in which case the Council may require the applicant to apply for a new permit;

(e) require the registrar to arrange for the inspection by an inspector of facilities where activities with or the release of genetically modified organisms are being undertaken;

(f) require the registrar to arrange for the inspection of all activities as he or she may deem necessary, including contained use, trial release and general release to ensure that all terms and conditions attached to a permit issued under this Act are complied with;

(g) after consideration of the risk assessment and, where required, the environmental impact assessment referred to in paragraph (a), and in consultation with the Committee, approve, subject to the provisions of this Act and any other law and in accordance with such terms and conditions as the Council may deem necessary, the use of the facilities concerned for the purpose for which the application was made, or the release of genetically modified organisms into the environment, and authorise the registrar to issue a permit accordingly;

(h) (i) require that the user immediately notify the registrar both orally and in writing of any accident involving genetically modified organisms and require that the registrar be supplied with information on the circumstances of the accident, the identity and quantity of genetically modified organisms releases, any information necessary to assess the impact of the accident on the

environment and the emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment;

(ii) require the registrar to appoint a panel to enquire into and report on the causes of an accident, and to make recommendations to the Minister with a view to avoiding similar accidents in the future and with a view to limiting the adverse impact of such accidents;

(i) inform any other country of any accident that may have an impact on that country's environment;

(j) co-operate or enter into agreements with any person or institution upon such conditions as the Council and the person or institution concerned may agree upon;

(k) promote co-operation between the Republic and any other country with regard to research, development and technology transfer in the field of the genetic modification of organisms;

(l) with the consent of the Minister approve and publish guidelines for all uses of genetically modified organisms;

(m) advise the Minister on-

(i) prohibitions;

(ii) the authorisation and exercise of the necessary control of imports;

(iii) the development, production, use, application, release and distribution of genetically modified organisms;

(iv) the authorisation or notification of contained uses;

(v) the authorisation of trial or general releases;

(vi) the control measures to be taken in the event of an accident;

(vii) any other matter with regard to genetically modified organisms;

(n) make recommendations to the Minister on the appointment of members to the Committee.

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 meeting 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 decision of the Council shall be reached on the basis of consensus.

(4) The Council may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

(5) The Council may co-opt other knowledgeable persons to serve on the Council in order to advise the Council whenever the Council deems it necessary.

(6) The Council may invite written comment from knowledgeable persons on any aspect of genetic modification which lies within the Council's brief.

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 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

The registrar shall, subject to the instructions of and the conditions laid down by the Council-

- (a) issue a permit as required or prescribed under this Act;
- (b) where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder-
 - (i) serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in the Republic for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the Council; and
 - (ii) authorise an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in this Act;
- (c) amend or withdraw a permit issued under this Act;
- (d) furnish an inspector with a certificate of appointment;
- (e) require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and
- (f) ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the environment from hazards.

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 and shall have knowledge of ecological matters and genetically modified organisms.

(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, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them-

(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) invite written comments from knowledgeable persons on any aspect of the genetic modifications of organisms which lies within the Committee's brief.

(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 member referred to in section 3 (2) (c) shall be paid such remuneration as the Minister, with the concurrence of the Minister of Finance, may determine.

(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 or document and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act; and

(d) to give notice to the owner of any material, substance, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under subparagraph (c) to remove the seized items at such person's own cost within a period and to a place specified in such notice.

(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 which may arise from the use of genetically modified organisms.

(2) The liability for damage caused by the use or release of 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 use or release 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.

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;
- (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 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;
- (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 evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.

(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.

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 consist of the person or persons who, in the opinion of the Minister, has or have expert knowledge and who is or are otherwise suitable to decide on the issues of the appeal concerned.

(b) If an appeal board consisting of more than one person is appointed, the Minister shall designate one of the members as a chairperson of that appeal board.

(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 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;

or

(c) make such other order as it may deem fit.

(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 decision of an appeal board, together with the reasons therefor, shall be reduced to writing, and copies thereof shall be furnished to the Minister, whereupon the Minister may take such further action as he or she may deem necessary.

20 Regulations

(1) The Minister may make regulations-

- (a) regarding the applications for and the issue of permits in terms of this Act;
- (b) prescribing the procedure to be followed by an applicant for the purpose of drawing up risk assessments and environmental impact assessments for submission to the Council in terms of this Act;
- (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
- (q) 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 any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;

(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 ability to a question lawfully demanded from or put to him or her by any inspector in the performance of his or her functions in terms of this Act, or furnished information, an explanation or a reply to any inspector which is false or misleading, knowing that it is false or misleading; or

(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.