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GENERAL NOTICE

NOTICE 100 OF 1996

DEPARTMENT OF AGRICULTURE

DRAFT GENETICALLY MODIFIED ORGANISMS BILL, 1996

The Draft Genetically Modified Organisms Bill, 1996, is hereby published for comment.

The background to and the proposed operation of the Draft Bill are stated hereunder in an explanatory memorandum.

Interested persons are hereby invited to furnish written comments and representations concerning the Draft Bill to the Director-General, Department of Agriculture, Dirk Uys Building, Hamilton Street, Pretoria or Private Bag X258, Pretoria, 0001, marked for the attention of Mr D. S. Aucamp, Subdirectorate: Legal Services, **before or on 15 March 1996.**

An Afrikaans version of the Draft Bill is available on request to the above-mentioned address or Telephone No. (012) 319-6265.

D. P. KEETCH
Chairperson: Working Group for Legislation on GMO's

BILL

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all operations 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 and agricultural production; to give attention to the prevention of accidents and the safe disposal of wastes; to establish common measures for the evaluation and reduction of the potential risks arising out of operations 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; to establish appropriate procedures for the notification of specific operations involving the use of genetically modified organisms; and to provide for matters incidental thereto.

BE IT ENACTED by the President and the Parliament of the Republic of South Africa, as follows:—

Definitions

1. In this Act, unless the context otherwise indicates—

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

"agricultural production" means the rearing of crops or livestock by farming for the production of food and other useful products;

"appeal board" means an appeal board appointed in terms of section 19;

"contained use" means any operation 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 a combination of physical barriers together with chemical or biological barriers, are used to limit their contact with the environment;

"control" means to examine, regulate and direct activities within a person's jurisdiction;

"control measure" means a control measure contemplated in section 20;

"department" means the Department of Agriculture in the national government of the Republic of South Africa;

"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;

"executive officer" means an officer designated in terms of section 3;

"Executive Council" means the council established by section 5;

"genetically modified organism" means an organism whose genes or genetic material have been modified in a way that does not occur naturally by mating or natural recombination or both, and "genetic modification" shall have a corresponding meaning;

"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 for the purpose of treatment of disease or to correct a genetic disorder;

"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, such that the organism is likely to survive and be disseminated;

"germ-line gene therapy" means gene therapy directed at germ-line cells which are destined to become gametes;

"hazard" means a characteristic (biological, chemical or physical) of a genetically modified organism which could lead to an unplanned adverse impact on the environment;

"importation" means to introduce genetically modified organisms into the Republic of South Africa or to bring about the introduction of such genetically modified organisms into the Republic;

"inspector" means any person designated as inspector in terms of section 16;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including animal or plant cell cultures;

"Minister" means the Minister of Agriculture in the national government of the Republic of South Africa;

"monitoring" means to maintain regular surveillance over, to check, to warn about or to record a situation or operation;

"negligible risk" means where the risk of causing an adverse impact is reasonably estimated to be effectively zero;

"non-viable organism" means an entity which cannot metabolise, replicate or reproduce itself in any environment. This group includes naked DNA and plasmids because they are themselves not capable of transferring or replicating genetic material;

"notification" means the presentation to the Executive Council of documents containing the information required by the Executive Council;

"officer" means an officer or employee as defined in section 1 of the Public Service Act, 1994 (Proclamation No. 103 of 1994);

"order" means an order contemplated in section 3;

"organism" means biological entity, cellular or non-cellular, capable of metabolism, replication or of transferring genetic material and includes a micro-organism;

"permit" means a permit mentioned in section 4;

"port of entry" means any international airport, seaport, post office and border post to be specified by the executive officer;

"prescribed" means prescribed by regulation;

"regulation" means a regulation made under this Act;

"risk" means the probability of incurring or causing a loss, an adverse impact or a misfortune;

"SAGENE" means the South African Committee for Genetic Experimentation;

"self-cloning" means the removal of nucleic acid from a cell or organism, followed by the re-insertion of all or part of that nucleic acid with or without further enzymatic, chemical or mechanical steps—into the same cell type (or cell line) or into a phylogenetically closely related species which can naturally exchange genetic material with the donor species;

"somatic gene therapy" means gene therapy directed at cells of the body other than those destined to become gametes;

"this Act" includes the regulations;

"trial release" means the deliberate release of genetically modified organisms into the environment as a result of research and development trials conducted in the open under conditions where the degree of dissemination of the genetically modified organism is limited by chemical or physical barriers or by built-in barriers which prevent its survival in the environment;

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

Application of Act

2. The provisions of this Act shall apply to—

(a) the use of organisms including viruses and bacteriophages;

(b) the genetic modification of organisms; and

(c) the use of gene therapy.

Persons charged with the administration of the Act

3. (1) The Minister shall designate as many officers of the Department as he or she may deem necessary as executive officers, who shall subject to the instructions of the Minister exercise the powers and perform the duties confirmed or imposed upon an executive officer in terms of section 11 of this Act.

(2) An executive officer may delegate any power confirmed upon him or her by or under this Act to an officer.

(3) Any decision or order of such an officer may at any given time be withdrawn or amended by the Minister or the executive officer concerned, as the case may be, and shall, until it has been so amended or withdrawn be deemed to be a decision or order of the Minister or such executive officer.

Powers of an executive officer

4. An executive officer shall, subject to the conditions laid down by the Executive Council—

(a) issue a permit or written authority;

(b) where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms have been imported or locally produced contrary to the provisions of this Act or conditions of a permit or written authority, serve an order upon any person by whom or on whose behalf genetically modified organisms have been so imported or produced in the Republic of South Africa for the removal of the genetically modified organisms to a place or premises and in such a manner designated by the Executive Council;

(c) destroy or cause to be destroyed, such genetically modified organisms as mentioned in paragraph *(b)* after having given the person by whom or on whose behalf those genetically modified organisms have been imported or produced in the Republic of South Africa or the person in possession or in charge of those genetically modified organisms, notice of his or her intention to do so, at least seven days beforehand: Provided that where in the opinion of such executive officer the destruction of the goods is urgently required or the giving of notice is impracticable, notice need not be given; and

(d) amend or withdraw the provisions or conditions of a permit, written authority for removal, order or notice in terms of this Act.

Executive Council for Genetically Modified Organisms

5. (1) There shall be a council to be known as the Executive Council for Genetically Modified Organisms, which shall consist of nine members appointed by the Minister for such period the Minister deems necessary, but not exceeding five years, of whom—

(a) six shall be members with knowledge of genetically modified organisms, one nominated from each of the following national government departments:

(i) Department of Agriculture;

(ii) Department of Arts, Culture, Science and Technology;

(iii) Department of Environmental Affairs and Tourism;

(iv) Department of Health;

(v) Department of Labour; and

(vi) Department of Trade and Industry.

(b) two members shall be from the general public and shall be nominated by the Minister; and

(c) the chairperson or person nominated by the South African Committee for Genetic Experimentation.

(2) The Minister shall designate any member of the council as chairperson and any other member as deputy chairperson.

(3) 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) The members of the Executive Council who are not members of any of the departments referred to in paragraph *(a)* of subsection (1), shall be appointed for a period not exceeding five years at such salary or other remuneration and on such conditions as the Minister may from time to time, with the concurrence of the Minister of Finance, determine.

(5) A member of the Executive Council whose period of office has expired, shall be eligible for reappointment.

(6) A member of the Executive Council shall vacate his or her office if he or she—

(a) is declared insolvent or assigns his or her estate in favour of his or her creditors;

(b) is convicted of an offence and sentenced to imprisonment without an option of a fine;

(c) is absent from more than three consecutive meetings of the Executive Council without leave of the chairperson;

(d) resigns as a member; or

(e) is removed from the office under subsection (7).

(7) The Minister may at any time remove a member of the Executive Council from office if he or she is of the opinion that such member is incompetent to fulfil his or her office or that he or she has misconducted himself or herself.

(8) If a member dies or in terms of subsection (6) ceases to be a member, the Minister may, subject to the provisions of subsection (1), appoint a competent person in his or her place for the unexpired period of such former member's term of office, or for such shorter term as the Minister determines.

(9) Whenever the Minister is satisfied that any member of the Executive Council is prevented by illness, absence or any other cause 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 he or she is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member on whose stead he or she has been appointed so to act: Provided that a person appointed as the deputy of the chairperson or the acting chairperson or the deputy chairperson, shall perform only the duties of an ordinary member unless the Minister otherwise directs.

Meetings of the Executive Council

6. (1) The meetings of the Executive Council shall be held at such times and places as the chairperson may determine from time to time.

(2) The quorum for a meeting of the Executive Council shall be two thirds of the members thereof.

(3) A decision of the majority of the members present at any meeting of the Executive Council shall be the decision of the Executive Council: Provided that in the event of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to his or her deliberative vote.

(4) The Executive Council will be entitled to co-opt other knowledgeable persons to serve on the Executive Council in order to advise the Executive Council in special circumstances.

Objectives of the Executive Council

7. The Executive Council shall, in addition to its functions in terms of this Act, advise the Minister on all aspects concerning the use, research and development of genetically modified organisms, to ensure that all operations are carried out in accordance with the provisions of this Act.

Functions, powers and duties of the Executive Council

8. In order to achieve its objectives, the Executive Council shall—

(a) approve premises for activities involving genetic modification;

(b) require notification of the intention to use premises for activities involving genetic modification for the first time, or of any change in the type of work being undertaken at such premises;

(c) recommend to the Minister the inspection by an inspector of such approved premises as may be deemed necessary but at least once every five years;

(d) arrange for the inspection of all activities it deems necessary, including large-scale contained use, trial release and general release, and shall ensure that all conditions are complied with;

(e) require that it be immediately notified of any accident involving a genetically modified organism and be supplied with information on the circumstances of the accident, the identity and quantity of genetically modified organisms released, any information necessary to assess the impact of the accident on the environment, and the emergency measures taken;

(f) appoint a panel to make a full analysis of an accident and make recommendations to the Minister with a view to avoid similar accidents in the future and with a view to limiting the adverse impacts of such accidents;

(g) examine the conformity of the notifications, the accuracy and completeness of the information furnished by the user, the correctness of the classification and, where appropriate, the adequacy of the waste management, safety and emergency response measures described by the applicant;

(h) maintain a register of all premises as well as all persons involved in such work;

(i) require the cessation of any genetic modification work at premises where the conditions of authorisation have not been or are not being complied with;

(j) ensure that appropriate emergency measures are undertaken at all times with a view to the protection of the environment;

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

(l) purchase or otherwise acquire or possess or hire movable or immovable property and alienates or let such property;

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

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

(o) at the end of each financial year submit a budget to the Minister for his or her approval, which budget shall also make provision for the funding of SAGENE;

(p) annually submit an audited report on its activities, income and expenditure to the Minister;

(q) receive and disburse fees, grants or donations;

(r) approve and publish guidelines for risk assessment and risk management related to the introduction of genetically modified organisms into the environment;

(s) advise the Minister on—

(i) prohibitions;

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

(iii) authorisation or notification of contained uses;

(iv) authorisation of trial or general releases; and

(v) control measures to be taken where an accident occurs,

with regard to genetically modified organisms.

Administrative work of Executive Council

9. The Director-General shall designate, subject to the provisions of the Public Service Act, 1994, as many officers and employees of the Department as may be necessary to assist the Executive Council and any committee thereof in the administrative work connected with the performance of the functions of such council or committee: Provided that, with the approval of the Minister, such administrative work may be performed by any person other than such officer or employee at the remuneration and allowances which the Minister with the concurrence of the Minister of Finance may determine.

Advisory Committee

10. (1) There shall be an Advisory Committee to be known as SAGENE which shall consist of a chairperson and eleven other members appointed by the Executive Council for a period not exceeding five years and of whom—

(a) nine members shall be—

(i) molecular biologists of international standing, active in training or research in the genetic modification of organisms; or

(ii) experts in population biology or ecology and the ability of introduced organisms to survive in the environment; or

(iii) experts in human health and disease and have a knowledge of human gene therapy; or

(iv) knowledgeable about the genetic engineering of crop plants; or

(v) knowledgeable about veterinary science;

(b) one member shall be a representative of the business community or industry and who shall have knowledge of genetically modified organisms; and

(c) one member shall be from the non-government sector and who shall have knowledge of ecological matters and genetically modified organisms.

(2) The provisions of section 5 shall *mutatis mutandis* apply to SAGENE.

(3) SAGENE will be entitled to co-opt any knowledgeable person to serve on SAGENE in order to advise SAGENE in special circumstances.

(4) SAGENE will be entitled to form subcommittees to deal with specific matters as required.

(5) A member of SAGENE whose period of office has expired, shall be eligible for reappointment.

Functions, powers and duties of SAGENE

11. SAGENE shall—

(a) act as the national advisory body on the genetic modification of organisms;

(b) advise the Executive Council, the Minister and other Ministries and bodies as appropriate, on the genetic modification of organisms;

(c) advise on all aspects of human and environmental health and safety of the introduction into the South African environment of genetically modified organisms;

(d) advise on proposals for specific activities or projects concerning the genetic modification of organisms;

(e) advise on all aspects concerning the contained use of genetically modified organisms;

(f) advise on the importation and exportation of genetically modified organisms;

(g) advise on proposed regulations and written guidelines; and

(h) liaise, through the department with the relevant international groups or organisations concerned with biosafety.

Funding of SAGENE

12. The members of SAGENE shall be paid such remuneration as the Minister, with the concurrence of the Minister of Finance, may determine.

Conflict of interest

13. In the event of any conflict of interest arising in the case of any matter to be advised on by SAGENE, such conflict of interest must be declared by the member(s) concerned and such member must recuse himself or herself from consideration of the matter.

Prohibition of certain classes of work on genetically modified organisms

14. The Minister may by notice in the *Gazette* and on such conditions as he or she may specify in the notice—

(a) prohibit certain classes of activities with regard to the issue of human germ-line gene therapy and of somatic gene therapy for improving or enhancing certain desired human characteristics for non-medical reasons; and

(b) prohibit certain activities involving genetically modified organisms.

Exclusion of certain techniques in genetic modification

15. The following techniques are excluded from this Act:

(a) Where recombinant DNA molecules or genetically modified organisms are not used—

(i) *in vitro* fertilisation;

(ii) conjugation, transduction, transformation or any other natural process; and

(iii) polyploidy induction.

(b) Where genetically modified organisms as recipient or parental organisms are not used—

(i) in mutagenesis;

(ii) in the construction and use of somatic hybridoma cells; and

(iii) in cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods.

Inspections

16. (1) The Minister may designate a person (hereinafter referred to as an inspector) to exercise and perform the powers and functions mentioned in subsection (4).

(2) An inspector shall be furnished with a certificate signed by the Executive Officer stating that the said person has been designated as inspector under this Act.

(3) An inspector shall, at the request of any person affected by the exercising, or the performance by such an inspector, of a power or function referred to in subsection (4), exhibit the certificate referred to in subsection (2) to such a person.

(4) An inspector may conduct an investigation to determine whether the provisions of this Act or the regulations are being or have been complied with, and may for that purpose at all reasonable times and without giving prior notice—

(a) enter any place or premises in respect of which he or she has reason to believe that a contravention of the provisions of this Act or regulations is taking place;

(b) inspect any operation or process carried out in or upon such premises in connection with any activity referred to in this Act;

(c) demand any information regarding such operation or process from the owner or person in charge of such premises or from any person carrying out or in charge of the carrying out of such operation or process;

(d) seize any material, substance, appliance, book, statement or document or other object which appears to provide proof of a contravention of any provision of this Act or regulations;

(e) take samples of and remove such material or substance concerned to a place he or she determines; and

(f) direct the owner of such material or the person who had control over it before any seizure under subparagraph *(d)* to remove it at his or her own cost and within a period specified in such notice to a place the inspector determines.

Determination of risks and liability

17. (1) Users shall ensure that all appropriate measures are taken to avoid adverse impacts on the environment which might arise from the use of genetically modified organisms.

(2) Users shall carry out a prior assessment of the uses as regards the risk to the environment in accordance with protocols approved by the Executive Council.

(3) A record of the assessment referred to in subsection (2) shall be kept by the user and made available on request to the Executive Council.

(4) If the user becomes aware of relevant new information or modifies the use in a way which would have significant consequences for the risks posed by the use, or if the category of genetically modified organism used is changed, the user shall inform the Executive Council immediately.

(5) The liability for any damage caused by the use or release of a genetically modified organism shall be borne by the user concerned.

Secrecy

18. (1) No person shall disclose any information acquired by him or her through the exercising of his or her powers or the performing of his or her duties in terms of this Act, except—

(a) as 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 required to do so by any competent court; or

(d) if he or she is authorised thereto by the Minister.

(2) The Executive 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) description of the genetically modified organisms, name and address of the applicant, purpose of the contained use or release and location of use;

(b) methods and plans for monitoring of the genetically modified organisms and for emergency response; and

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

(3) Notwithstanding the provisions of subsection (2), where the Executive Council is satisfied on the basis of detailed evidence submitted to it by the applicant and where appropriate, after consultation with the applicant that it is necessary to withhold for the time being, certain of the information specified in subsection (2) in order to protect his or her intellectual property rights, the Executive Council shall withhold that information to the extent and for so long as it is necessary to protect those rights.

(4) If, for whatever reasons, the applicant withdraws the application, the Executive Council must respect the confidentiality of the information supplied.

(5) *(a)* The intended general release of any genetically modified organism shall be made known by the applicant by way of a notice in the press or a journal concerning all matters applicable to the genetically modified organisms.

(b) A statement shall include—

(i) a description of the organism but should not prejudice any intellectual property rights pertaining to the genetically modified organism;

(ii) a request that interested parties shall submit objections, if any, in connection with the intended release within the period stated in the statement, which period shall not be fewer than 30 days after the date of the statement; and

(iii) the address to which such comments shall be submitted.

Appeals

19. (1) A person who feels aggrieved by any decision or action taken by the Executive Council, the executive officer or an inspector in terms of this Act may, within the period and in the manner prescribed and upon the payment of the prescribed fees, appeal to the Minister against the decision or action in question.

(2) *(a)* The Minister shall refer the appeal for investigation and decision to a board, the members of which shall be appointed by the Minister for the purpose of the appeal concerned, and which shall consist of—

(i) one person designated as chairperson on account of his or her knowledge of law; and

(ii) at least two persons who in the opinion of the Minister have expert knowledge of the subject of the appeal.

(b) A person appointed under subparagraph (ii) of paragraph *(a)* shall recuse himself or herself as a member of the board if he or she has any direct or indirect personal interest in the subject matter of the appeal.

(3) If a person appointed under subsection (2)—

(a) dies or is incapacitated during the investigation of the appeal or so soon before the commencement of the investigation that the vacancy cannot be filled;

(b) is unable to act and another person cannot for any valid reason be appointed; or

(c) is, after the investigation has commenced, unable for any valid reason to continue therewith,

the parties to the appeal may agree that the investigation be continued by the remaining members, in which event, where the member who has died or has become incapacitated was or is the chairperson of the board, the Minister shall designate one of the remaining members to act as chairperson.

(4) If the parties to the appeal do not agree under subsection (3), the investigation shall be adjourned in order that the Minister may appoint a member in accordance with the requirements of subsection (2), in the place of the member who has died or has become incapacitated.

(5) All the members of an appeal board in question shall constitute a quorum for a meeting of that appeal board, and if an appeal board consists of more than one member—

(a) the decision of the majority of the members thereof shall be the decision of the appeal board; and

(b) the chairperson of that appeal board shall, in the case of an equality of votes, have a casting vote in addition to his or her deliberate vote.

(6) There may be paid to a member of an appeal board who is not in the full-time employment of the State, from moneys appropriated by Parliament for this purpose, such remunerations or allowances as may be determined by the Minister, with the concurrence of the Minister of Finance, in general or in any particular case.

(7) Such appeal board may—

(a) confirm, set aside or amend the decision or direction concerned which is the subject of the appeal;

(b) refer the relevant matter back to the executive officer or inspector for reconsideration; or

(c) make any other order in connection therewith as it may deem fit.

(8) The decision of an appeal board together with the reasons therefore shall be in writing, and copies thereof shall be furnished to the Minister, the appellant and the Executive Council, as the case may be.

Regulations

20. (1) The Minister may make regulations—

(a) prescribing the fees payable in respect of any application, matter or document;

(b) regarding the classification and types of genetically modified organisms;

(c) regarding requirements for contained use of genetically modified organisms;

(d) regarding requirements for laboratory development of genetically modified organisms;

(e) regarding requirements for trial release of genetically modified organisms;

(f) regarding requirements for general release and marketing of genetically modified organisms;

(g) regarding the import and export of genetically modified organisms;

(h) regarding the issue of permits in terms of this Act;

(i) regarding the registration of a place or premises where work on genetically modified organisms is to be undertaken;

(j) prescribing the fees payable, the manner and time in which such an appeal may be lodged;

(k) regarding the procedure of proceedings of an appeal board;

(l) regarding the period within which an appeal board shall decide on an appeal;

(m) prescribing control measures which shall be complied with or carried out by a user; and

(n) concerning, generally, any matter which he or she considers necessary or expedient to prescribe in order that the objects and purposes 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 imprisonment or to both that fine and that imprisonment.

Offences and penalties

21. (1) Any person who—

(a) contravenes or fails to comply with a condition, restriction, prohibition, reservation or directive imposed under section 14;

(b) obstructs or hinders any inspector in the exercise of his or her powers or performance of his or her duties under this Act;

(c) refuses or fails to furnish information or give an explanation or to answer 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 exercise of his or her powers or the carrying out of his or her duties in terms of this Act, or furnishes information, an explanation or an answer to any inspector which is false or misleading, knowing that it is false or misleading; or

(d) falsely holds himself of herself out to be an inspector designated in terms of this Act,

shall be guilty of an offence.

(2) Any person who is convicted of an offence under this Act, shall—

(a) in the case of a first conviction of an offence referred to in subsection (1), be liable to a fine or to imprisonment or to both that fine and that imprisonment; and

(b) in the case of a second or subsequent conviction of an offence mentioned in paragraph *(a)*, whether it be the same or some other offence mentioned in that paragraph, be liable to a fine or to imprisonment or to both that fine and that imprisonment.

(3) Notwithstanding anything to the contrary in any other law contained, a magistrate's court shall be competent to impose any penalty or make any order prescribed by this Act.

Presumptions

22. In any prosecution for any offence under this Act if it is proven that any person made a false statement or furnished false information, it shall be presumed, unless the contrary is proven, that such person has made that statement or furnished that information knowing it to be false.

Delegation of powers

23. The Minister may, subject to such conditions as he or she may determine, in writing delegate any power conferred on him or her by this Act, excluding 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.

Short title and commencement

24. (1) This Act shall be called the **Genetically Modified Organisms Act, 1996,** and shall come into operation on a date to be fixed by the President by proclamation in the *Gazette*.

(2) Different dates may be so fixed in respect of different provisions of this Act.

EXPLANATORY MEMORANDUM

DRAFT GENETICALLY MODIFIED ORGANISMS BILL, 1996

1. AIM

The Draft Bill should apply to viable organisms (those that can replicate themselves) including viruses and bacteriophages. Non-viable organisms or extracts from such organisms should not be included in the Act.

The Draft Bill also needs to cover the genetic modification of plants, micro-organisms, animals, humans and live genetically modified organisms vaccines.

2. INTRODUCTION

Recognising the potential of genetically modified organisms to provide enhanced quality of product, expansion of employment opportunities and products and services impossible and unforseen previously, this Draft Bill is intended to ensure prompt, efficient, ethical and safe deployment of these technologies throughout South Africa and the Southern African region.

To this end, a Competent Authority is hereby established, responsible for the collation and dissemination of applicable information and advice regarding the implementation of these technologies and the evaluation and control of safety aspects of all work in this field.

As exotic and novel organisms may well stray beyond national boundaries, the Competent Authority will need to foster relationships with neighbouring National or regional biosafety organisation(s) with the aim of developing complementary and comparable policies. In addition all local policies shall be in accord with the developing trends throughout the world.

The drafting of the Bill is seen as most relevant and applicable, especially in view of the progress made with regard to gene therapy. Somatic gene therapy is already in an experimental stage in various countries, and is seen as a practical and acceptable medical procedure. It is expected to be introduced into South Africa in the foreseeable future.

In general, germ-line gene therapy is considered to be unacceptable and should be banned or prohibited. It needs to be emphasised that gene therapy will only be permissible for medical purposes (treating of patients, alleviating suffering, etc) but not for improving or enhancing certain desired characteristics in healthy individuals.

For the purposes of this Draft Bill, genetically modified organisms shall be classified as follows:

Group 1: These organisms are composed of vector, inserted genes and recipient organisms (or those genetically rearranged in a manner) which can reasonably be assessed as having a negligible risk potential and to be safe to man or the environment as the recipient or parental organism.

In the case of micro-organisms (including viruses, viroids, cell and tissue cultures, bacteria, micro-algae, protozoa and fungi)—

(i) the recipient or parental organism should be—

- non-pathogenic
- contain no adventitious agents
- have a proven and extended history of safe use or built-in biological barriers which confer limited survivability and replicability without adverse consequences in the environment;

(ii) the vector/insert should be—

- well characterised and free from known harmful sequences;
- limited in size as much as possible to the genetic sequences required to perform the intended function;
- should not increase the stability of the construct in the environment, unless that is a requirement of the intended function;
- should be poorly mobilisable;
- should not transfer any resistance markers to organisms not known to acquire them naturally, if such acquisition could compromise the use of drugs to control disease agents;

(iii) genetically modified micro-organisms should be:

- as safe to man and the environment as the recipient or parental strains.

Group 2: These are all genetically modified organisms which do not fall into Group 1. Group 2 organisms are those which may have a non-negligible risk potential. These will include combinations where the donor/s, vector or recipient organism has a known pathogenic or pest characteristic, or are poorly characterised in this regard.

3. For the purpose of this Draft Bill the identification of types of activity with genetically modified organisms are as follows:

Type A operation: means any activity involving genetically modified organisms for the purposes of teaching, research or development, or for non-industrial or non-commercial purposes on a scale at which the practices and conditions of the operation relative to the culture volume and numbers of organisms involved are such that—

- the system used to keep the organisms under control reflects good laboratory practice and good occupational safety and hygiene;
- it is possible to easily render the organisms inactive by standard laboratory decontamination techniques.

Type B operation: means any activity involving genetically modified organisms which is not a Type A operation.

4. This Draft Bill also furthers the Government's policy of privatisation since authorisation is proposed that will *inter alia* enable the enforcement of certain control measures by private institutions. Clause 3 authorises the appointment of an executive officer and the possible appointment of other institutions or persons in order to exercise certain of the powers and perform certain of the duties of the executive officer, subject to the directions of the said officer.

5. Technological advances in a rapidly changing society require the regulation of technical aspects of matters dealt with by this Draft Bill in subordinate legislation in order to restrict to the minimum any possible shortcomings resulting from further technological development.

6. This Draft Bill was compiled by a working group constituted of representatives from the following instances:

- ★ Department of Agriculture
- ★ Department of Environmental Affairs and Tourism
- ★ Department of Manpower

- ★ Department of Health:
  - Directorate of Food and Chemicals
  - Directorate of Forensic and Research Services
- ★ Environmental Law Consultancy
- ★ SA Vaccine Producers
- ★ University of Pretoria: Department of Plant Production and Soil Science
- ★ SANSOR Working Group on Biotechnology
- ★ SAGENE (SA Committee for Genetic Experimentation)

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