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Arranged to provide for matters connected therewith.

Genetically Modified Organisms Amendment Act 23 of 2006

as amended by:

[Commissioned Date: 1 December 1999]

[Assented to: 20 May 1997]

(English text signed by the Acting President)
1. Definitions

[a] genericity modified organisms, means any person in control of research and activities involving genetic engineering of organisms or animal cells in order to have an immediate or delayed adverse impact on the environmental or human or animal health within the Republic or to have an immediate or delayed adverse impact on the environment of a Outsider involving an international environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment of Outsiders.

[b] In this Act, unless the context otherwise indicates,
"officer" means an officer as defined in section 1 of the Public Service Act 1974 (as replaced by section 1 of the Public Service Act 1979);

"recommendation" means the presentation to the Council of documents containing the information, written or oral, of the opinion of any person or the information provided to the Council by any person;

"monitoring" means the monitoring of regulatory surveillance over the chequing of the financial condition of a financial institution;

"Minister" means the Minister for Agriculture;

"Inspection" means any person appointed as an inspector in terms of section 12;

"measured" means in numeric proportion, compared or physically characterized or generally characterized by a numeric proportion of which the numerical value of the measured component or the measured material of which the measured component is a part, to its total numerical value or the measured material of which the measured component is a part;

"generic modification" shall have the meaning prescribed by the Act.

"biochemical" means the biochemical modification of a gene or other genetic material by genetic means in order to change the gene or other genetic material by genetic means to replace absent ones.

"general release" means the release of a genetically modified organism into the environment.

"extension permit" means a permit issued for activities relating to genetically modified organisms for which a permit has been issued previously.

"environmental impact assessment" means the process used to assess the potential impact of a proposed activity on the environment and includes the collection of information on such activities.

"extension permit" means the permit issued for activities relating to genetically modified organisms for which a permit has been issued previously.

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"Department-General" means the Department of Agriculture;

"Director-General" means the Director-General of Agriculture;

"General Act" means the General Act 1996;

"Council" means the Executive Council for Generally Modified Organisms established by this Act;

"Inspection" means to examine, regulate or direct any activity with a person's agreement.
This Act shall not apply to techniques -

(a) the use of gene therapy;

(b) the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and

(c) the general modification of organisms.

2. Application of Act

This Act includes the regulations:

(a) means the person appointed under section 4;

(b) means the release and general release;

(c) means release into the environment, and includes a final release, conditional general release or final release made under this Act;

(d) means the person appointed under section 2;

(e) means a protocol established by the Conference of the Parties for the purposes referred to in paragraph 12 of Annex II of the Convention, that has been approved by the parties to the Convention and adopted by the Parties to the Convention, according to the procedure referred to in the Convention.

3. Definitions

This Act includes the definitions:

(a) means a protocol referred to in section 2 and includes a written authority; and

(b) means a protocol established by the Conference of the Parties for the purposes referred to in paragraph 12 of Annex II of the Convention.
(a) the Department of Water Affairs and Forestry,

(vii) the Department of Arts and Culture; and

(viii) the Department of Trade and Industry;

(ix) the Department of Labour;

(x) the Department of Health;

(xi) the Department of Environmental Affairs and Tourism;

(xii) the Department of Science and Technology;


(iii) The Department of Agriculture;

shall be one officer of each of the following national departments of State:

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

[Subs. (1A) inserted by s. 2 of Act 21 of 2006]

member if such number is unable to attend an assembly, whom they appoint and vote at the meeting of the Council on behalf of the Executive Council on behalf of the

[Subs. (1) substituted by s. 2 of Act 24 of 2006]

Council of General or Genetically Modified Organisms with which the Council consists or more than 10 members.

There is hereby established a Judicial Person to be known as the Executive Council for

Executive Council of Genetically Modified Organisms

Section 3: Declared cases

(iii) in cell fusion (including protoplast fusion) of plant cells,

(ii) in the construction and use of somatic hybrids and

(i) in noneucaryotes;

- employed in polyphasic hybridisation;

- employed in conjugation, transduction, transformation or any other natural process;

(ii) in in vitro fertilisation in humans and animals;

- employed in which recombinant DNA molecules or Genetically modified organisms are not

(iii) involving human gene therapy;

(iv) involving human organs;
whether the user must re-apply for approval.

(iii) being notified by the user of any intended change,

was granted; and

an intentional change in the use of a facility or an activity for which approval

determined in the event of-

proposed risk management measures;

scientifically based risk assessments; and

in considering an application have regard to the following factors:

(a) in consultation with the Committee, decide whether to approve an application;

(b) and on assessment of the socio-economic considerations of such activities;

Management Act, 1998 (Act No. 107 of 1998), of the impact on the environment,

in accordance with the relevant provisions of the National Environment

applicable in addition to the Act, and any assessment in respect of generally

activities in respect of generally modified organisations determining whether their

where an application applies in the prescribed manner for a penalty to conduct

The Council shall.

Powers and duties of Council

section 6 of Act 2/2006

modified organisations, and ensure that such activities are performed in accordance with this Act.

The Council shall advise the Minister on all aspects concerning activities requiring to generally

Oppositions of Council

whenever the chairperson is unable to do so.

The deputy chairperson shall exercise all the powers and perform all the duties of the

members of the Council.

The Minister shall designate a chairperson and a deputy chairperson from among the

may include any other person.

shall include the chairperson of the Committee; and

exercise powers and regulations applicable within the sector.

with regard to the sector represented by the sector concerned, including any

who shall have knowledge of the implications of generally modified organisations

Page 6 of 20

generally modified organisations act
Committee shall, in consultation with the Minister, make recommendations to the Minister on the application of measures to be taken to secure that any education provided for the purposes of this Act is of a standard comparable with that of education provided for the purposes of any other Act.

Where the Committee has been informed by the Registrar that there is a reasonable suspicion that an activity is conducted in contravention of this Act or to a contravention of any other Act, the Committee may, if it considers that it is necessary to do so, require the Registrar to report to the Committee on the activity and any action taken to deal with it.

Committee shall, in consultation with the Minister, make recommendations to the Minister on the application of measures to be taken to secure that any education provided for the purposes of this Act is of a standard comparable with that of education provided for the purposes of any other Act.

The Committee shall, in making recommendations to the Minister, take into account the views of other education authorities and bodies, including any relevant professional bodies, and any other information that it considers relevant.

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cease to be an officer.

(9)

A vacancy in the Council shall occur when a member

6. Vacancies in Council

(8) Substituted by 9 of April 2006]

functions

subsection of any aspect of genetic modification which falls within the Council's

(1)

inure within 2 months from any person knowledgeable in a specific field of

necessary

(3)

Council in order to advise the Council on matters where the Council considers it

co-opt any person knowledgeable in a specific field of science to serve on the

(4)

It is

(6)

co-opted to subsection (1) (c) or paragraph (a) to co-opt one or more

sections conducted in terms of this Act, which may have an impact on the
council in the event of any new and relevant scientific or technological evidence about

(7)

qualified modelers and other such specialists available to the public;

with the consent of the Minister, approve and issue guidelines for activities with

(10)

or of persons and bodies;

promote co-operation between the Republic and any other country with regard to

(11)

such issues as the Council may consider necessary to come to a decision;

where an applicant applies for an extension permit, consult with the Committee on

(12)

in the event of an accidental release, notify the relevant authorities and prepare a panel to enquire into

(13)

impact of such activities;

the environmental impact assessment of

(14)

the potential socio-economic impact of such activities;

subsection (1) (c) or paragraph (a) to co-opt one or more qualified modelers and other such specialists available to the public;

(15)

of this Act, which may have an impact on the council in the event of any new and relevant scientific or technological evidence about

(16)

with the consent of the Minister, approve and issue guidelines for activities with

(17)

promote co-operation between the Republic and any other country with regard to

(18)

such issues as the Council may consider necessary to come to a decision;

where an applicant applies for an extension permit, consult with the Committee on

(19)

in the event of an accidental release, notify the relevant authorities and prepare a panel to enquire into

(20)

impact of such activities;

the environmental impact assessment of

(21)

the potential socio-economic impact of such activities;

section consider the following factors:

(a)

The Council may—

such activity may be removed and

a place of release where a genetically modified organism was released in such a

accidental or potentially affected by such activity.

modifying organism used in such activity or any material or substance used.

Appropriate measures for the disposal of seed or any genetically

modifying organism used in such activity.

Appropriate measures for the disposal of seed or any genetically

modifying organism used in such activity.
(5) The Council may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

In the event of an accident occurring in section 3(1)(f).

(6) On receipt of a written request signed by at least two members of the Council, the Chairperson shall call the Council by the Chairperson.

(7) On receipt of a written request by the Minister.

(8) The Council shall convene a special meeting at such time and place and on such dates as determined by the Chairperson.


If the event that the Council fails to reach consensus on a decision such decision shall be determined by the Chairperson.

(4) A decision of the Council shall be reached on the basis of consensus by all members of the Council.

(2) The quorum for any meeting of the Council shall be a majority of the members.

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 Chairperson.

7. Meetings of Council

Subject to the provisions of this Act, the Council may, by general resolution, determine the time, place, and manner of conducting its meetings, including the quorum required for such meetings. The Chairperson shall ensure that all members of the Council are notified of the time and place of meetings in accordance with the procedures established by the Council.

Whenever the Minister is satisfied that any member of the Council is prevented by illness from attending a meeting of the Council, the Minister may by general resolution, determine the time, place, and manner of conducting the meeting, including the quorum required for such meetings.

(3) A vacancy in the Council shall be filled as soon as practicable in accordance with section 3.

(4) An officer of the Council may resign from the office in terms of subsection (2).

(5) The Minister may by general resolution, remove a member of the Council from office if the Minister is of the opinion that such member is no longer competent to hold the office of member of the Council.

(6) is removed from the office in terms of subsection (2).

(7) The Minister may by general resolution, remove a member of the Council from office if the Minister is of the opinion that such member is no longer competent to hold the office of member of the Council.

(8) The Minister may by general resolution, remove a member of the Council from office if the Minister is of the opinion that such member is no longer competent to hold the office of member of the Council.
accord to any other matter with regard to business of generally modelfed

with generally modelfed organisation

the environment and human and animal health during the exercise of any activity

subject himself or herself to all users apply the applicable measures to protect

a warrant or withdraw a warrant or an extension permit issued under this Act

issue a warrant or an extension permit in the manner prescribed;

evaluate whether an application conforms to the requirements of this act;

The Register shall, subject to the inscriptions of end conditions laid down by the

Council.

9. Functions of Register

of the Register

necessary to assist the Register in the exercise of his or her powers and the performance

1994 (Proclamation No. 103 of 1994) and as may be of the Department as may be

The Director-General shall designate subject to the provisions of the Public Service Act

Any action of the Register may at any time be withdrawn or amended by the Minister

appended to the Register in the exercise of his or her powers and the performance

of the Department in terms of sub-section (a) and that number has while so

so a Register is appointed in terms of subsection (1), and that number has while so

Register. For any reason absent of unable to perform his or her functions,

defeated or suspended in terms of subsection (1) or any other matter this Act by the Council

may exercise such powers and perform such duties as may be conferred upon or

is charged with the administration of this Act;

Register.

he duties satisfactorily,

may be recommenced by the Minister if the Register does not perform his or

small remuneration for the continuation of the Register's services.

An appointment under paragraphs (a).

Appointed and experienced person as Register.

recommend the Minister shall, after consultation with the Council, appoint a qualified and experienced person as Register;

as soon as possible after the composition of the Council and whenever necessary

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

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

................................

.............................
The Committee shall, after the recommendation of the Council, designate any member of the General Assembly of Organisations on Human and Animal Health.

The Council shall, in recommending the number, for appointment to the Committee, ensure that it is reflected in the number of person shall be from the public sector, of which one person shall have knowledge of scientific matters and genetically modified organisms, and the other knowledge of regulatory matters and genetically modified organisms.

The Committee shall, after the recommendation of the Council, designate any member of the General Assembly of Organisations on Human and Animal Health.

No more than eight members shall be knowledgeable persons in whose fields of science applicable to the development and release of genetically modified persons in the scientific community, including persons in whose field of science applicable to the development and release of genetically modified persons in those fields of science applicable to the development and release of genetically modified persons in the scientific community.

The Registrar may, subject to such terms and conditions laid down by the Council, issue regulations in the regulations to List the Biotechnology Organisations. These regulations include

- the names and addresses of the persons involved with such activities and
- all the real release sites and
- all the release sites that are used for controlled use.

The Registrar shall keep a register of such activities under this Act, together with all the prescribed documentation, and any other documentation the Council may require to make his decision and shall provide or a part of the information specified in the regulations.
12. Funding

The Committee may appropriate subcommittees, in accordance with specific members' requirements.


The Committee's role is to advise the Minister on the funding of relevant national departments, which has within it the power to allocate funding to relevant national departments, with the advice of the Minister.

The Committee shall, subject to the approval of the Minister, allocate funding to relevant national departments, with the advice of the Minister.

The Committee shall determine the amount of funding that shall be allocated to each relevant national department, and shall, subject to the approval of the Minister, allocate funding to relevant national departments, with the advice of the Minister.

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14. Prohibition of activities concerning generally modelled organisations

The Minister may, on the recommendation of the Council, by notice in the Gazette prohibit any activity involving generally modelled organisations.

15. Inspectors

15.1 Inspectors

An inspector of an inspectorate is appointed by the Minister, by notice in the Gazette.
c. eliminate any source of the damage;

(d) \[ \text{(e) eliminate any source of the damage;} \]

7. Penalty.

The penalty for violation of any activity carried on by a person shall be a fine of not more than $1,000,000, or imprisonment for not more than 5 years, or both.

8. Appeal.

Any person aggrieved by an order under this Act may appeal to the court of competent jurisdiction within 30 days from the date of the order.


Inspectors are authorized to enter any place where they suspect the violation of any provisions of this Act, and to conduct any necessary investigation.

10. Violation of Order.

Any person who violates any order made under this Act shall be liable to a fine of not more than $500,000, or imprisonment for not more than 2 years, or both.
(p) if the Act is authorised to do so by the Minister.

(e) when so ordered by or any court.

SECTION 18 (Decision by Court)

For the purposes of any legal proceedings under this Act,

(q) in so far as is necessary for the proper application of the provisions of this Act, except

No person shall disclose any information acquired by him or her through the exercise of

18. Confidentiality

[Section 18 (Decided cases)]

Appeal to the Appeal Board in the manner contemplated in Section 19

Any appeal instituted by an order for costs awarded under this section may be heard

(1) in a magistrates' court.

Any order referred to in subsections (1) and (2) shall have the effect of an order in

and several liquidations for the full amount of the costs.

and several liquidations for the full amount of the costs. Approval of the decision by the Court does not relieve any of them of their joint and several liabilities for the full amount of the costs.

If more than one person is liable under subsection (2), the Court may make an order

without being limited to damages, administrative and overheads.

The Court may award under subsection (1) and (2) and may make reasonable and may include,

The costs incurred under subsections (1) and (2) of section 18(b) of section 18 of section 18.

Subject to subsection (2), the Court may award all costs incurred as a result of

17A. Recovery of costs

In subsection (1) of section 17A of section 3(4)(e), any other provision of the Act to the

(1) the Court may order any reasonable measure to remedy the situation

(2) a person fails to immediately implement the measures contemplated in subsection

[Subs. (2) substituted by s. 11 of Act 22/2006]

(2) the inability to remove any reasonable measure to remedy the situation

[Subs. (3) substituted by s. 11 of Act 22/2006]

(3) if a person fails to immediately implement the measures contemplated in subsection

[Subs. (5) substituted by s. 5 of Act 22/2005]

(5) a reasonable measure to remedy the situation

[Subs. (5) substituted by s. 11 of Act 22/2006]

(5) if a person fails to immediately implement the measures contemplated in subsection

(d) the inability to remove any reasonable measure to remedy the situation

(e) if the Act is authorised to do so by the Minister.

(f) when so ordered by or any court.
empowered to decide whether or not to proceed to the full-time
appeal board.

(3) Appeal Board.

the appeal board shall be appointed under paragraphs (a) or (b)

include matters of the appeal or other matters, if any, which are

affected by the decision of the appeal board, the reasons for the decision

appeal board shall not be held to be a breach of confidence if so decided by

appeal board shall not be held to be a breach of confidence if so decided by

Appeals

Information supplied.

If for whatever reason, the Appeals Board refuses to accept the
application, the Council shall where possible provide a detailed
statement of the reasons for refusal

(1) A person who is refused by any decision of action taken by the Council, the

(2) The Council shall, after consultation with the applicant, provide the
information which will be

(3) Following information shall not be kept confidential:

- The full name of the applicant and the address of the application, and
- The general description of the genetically modified organism, the name and
- The summary of the scientifically based risk assessment of the impact on the}

(4) Provided such notice:

and forconjunctiveneuropsychotherapeutics in the case of an accidental and

(5) The methods and plans for the monitoring of the genetically modified organism,

(6) The scientific description of the genetically modified organism.

(7) The Council shall, after consultation with the applicant, provide the

(8) Following information shall not be kept confidential:

- The full name of the applicant and the address of the application, and
- The general description of the genetically modified organism, the name and
- The summary of the scientifically based risk assessment of the impact on the
regarding the classification and type of genetically modified organisms;

(b) presenting the fees payable in respect of any application made or document;

[Para (b) substituted by s. 14 of Act 2/2000]

(c) presentation to the Council in terms of this Act;

[Para (c) substituted by s. 15 of Act 2/2000]

(d) socio-economic considerations and risk management measures, for determining the procedure to be followed by an applicant for the purpose of application must be taken in terms of this Act;

(e) referring the applications for the period within which a decision on an application may be made regulations.

(f) The Minister may make regulations

(Section 20: Deemed cases)

[Subs. (6) substituted by s. 13 of Act 2/2000]

consider necessary.

The full decision of an appeal board, together with the reasons the Minister, shall be reduced to the applicant concerned may determine, shall be refunded to the applicant concerned or, in a decision of action which is the subject of an appeal, if a decision of action which is the subject of any appeal, in the opinion of the Appeal Board, directly applicable to the appeal, consider new scientific or technical evidence or any other information that only follow the prescribed procedures, and

- in making a decision

- after the consideration of or potential risks and potential benefits related to the subject of the appeal;

- if the relevant matter back to the Registrar for reconsideration by the Council;

- if an appeal board may determine.

- confirmation, set aside, substantive or amended the decision or action concerned, which is reformation of all variations as the Minister, with the concurrence of the Minister of Finance,
This Act shall be called the ‘Generically Modified Organisms Act, 1997’, and shall come into force on the date notified in this behalf by the Central Government in the Ministry of Science and Technology, Government of India.

22. Delegation of powers

The Minister may, subject to such conditions as he may determine, in writing delegate any power conferred by this Act to be exercised by an officer appointed by the Central Government in the Ministry of Science and Technology, Government of India.

Any power so delegated shall be exercisable subject to the following conditions, namely:

1. The officer shall be an officer not below the rank of an Inspector or any other officer empowered in this behalf by the Central Government in the Ministry of Science and Technology, Government of India.
2. The period of delegation of powers shall not exceed two years.
3. Any officer so notified shall be entitled to compensation for the loss of office for a period of not more than a year for which such officer is entitled to compensation for the loss of office for a period not exceeding four years.
4. Any person convicted of an offence under this Act shall, in addition to any other punishment, be liable to a fine or imprisonment for a period not exceeding two years.
5. Any officer so notified shall, in addition to any other punishment, be liable to a fine or imprisonment for a period not exceeding two years.
6. A person notified under this section shall be entitled to compensation for the loss of office for a period not exceeding four years.
7. The provisions of the Generically Modified Organisms Act, 1997, shall apply to the powers so delegated.

23. Short title and commencement

This Act shall come into force on the date notified in this behalf by the Central Government in the Ministry of Science and Technology, Government of India.