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## **THE PRESIDENCY**

No. 347

17 April 2007

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:—

**No. 23 of 2006: Genetically Modified Organisms Amendment, 2006**



**AIDS HELPLINE: 0800-123-22 Prevention is the cure**

## GENERAL EXPLANATORY NOTE:

- [ ] Words in bold type in square brackets indicate omissions from existing enactments.
- Words underlined with a solid line indicate insertions in existing enactments.

*(English text signed by the President.)*  
*(Assented to 11 April 2007.)*

## ACT

To amend the Genetically Modified Organisms Act, 1997, ~~so as to give effect to the Protocol pertaining to genetically modified organism? to which South Africa is party; to amend certain definitions and to add new definitions: to amend the composition and remuneration of members of the Committee and Council: to amplify the powers and duties of the Council and the Committee and the functions of the registrar; to clarify the procedure relating to the application for and issuing of permits; to provide for risk assessments and liability determinations: to amend the information requirements contemplated in the confidentiality clause; to lay down criteria with regard to offences; to provide for certain procedures during an appeal process; and to provide for matters connected therewith.~~

**B**E IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

## Amendment of section 1 of Act 15 of 1997

1. Section 1 of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). (hereinafter referred to as the principal Act). is hereby amended—

(a) by the substitution for the definition of "accident" of the following definition:

"'accident' means any—

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

(b) by the insertion after the definition of "accident" of the following definition:

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

(c) by the insertion after the definition of "applicant" of the following definition:

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

- (d) by the insertion after the definition of "biosafety" of the following definition:  
 " **'Biosafety Clearing-House'** means an information-sharing exchange mechanism established under Article 20 of the Protocol;"
- (e) by the insertion after the definition of "Committee" of the following definitions: 5  
 " **'commodity clearance'** means the authorisation to use a genetically modified organism as a food or feed, or for processing, but excludes the planting of a genetically modified organism as a release into the environment;  
 " **'conditional general release'** means a release of a genetically modified organism under specific imposed conditions to regulate or monitor the use of that genetically modified organism for a specified period of time;" 10
- (f) by the substitution for the definition of "contained use" of the following definition: 15  
 " **'contained use'** means [any activity in which organisms are genetically modified or in which such] the development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms [are cultured, stored, used, transported, destroyed or disposed of and for which] within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both [are used to limit], that effectively limit contact [thereof] of the genetically modified organisms with humans, animals and the external environment and their impact on humans, animals and the external environment;" 20 25
- (g) by the insertion after the definition of "contained use" of the following definition:  
 " **'Convention'** means the Convention on Biological Diversity;" 30
- (h) by the insertion after the definition of "environment" of the following definitions:  
 " **'environmental impact assessment'** means the process used to assess the potential impact of an activity on the environment by collecting, organising, analysing, interpreting and communicating information on such activity; 35  
 " **'extension permit'** means a permit issued for activities relating to genetically modified organism; for which a permit had been issued previously;"
- (i) by the substitution for the definition of "general release" of the following definition: 40  
 " **'general release'** means the [introduction] release of a genetically modified [organisms] organism into the environment by whatever means, where the [organisms are] organism is 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];" 45
- (j) by the insertion after the definition of "prescribed" of the following definition:  
 " **'Protocol'** means the Cartagena Protocol on Biosafety to the Convention, that has been negotiated and adopted by the Parties to the Convention, acceded to by the Republic on 14 August 2003; A copy of the Protocol is attached for information purposes in the Annexure;" 50
- (k) by the insertion after the definition of "regulation" of the following definition:  
 " **'release'** means release into the environment, and includes a trial release, conditional general release and general release;" and 55
- (l) by the insertion after the definition of "this Act" of the following definition:  
 " **'transboundary movement'** means the movement of a genetically modified organism from the Republic to another country or from another country to the Republic;"
- (m) by the substitution for the definition of "user" of the following definition: 60  
 " **'user'** means a person who conducts an activity with a genetically modified organism,"

**Amendment of section 3 of Act 15 of 1997****2. Section 3 of the principal Act is hereby amended—**

(a) by the substitution for subsection (1) of the following subsection:

“(1) There is hereby established a **[council]** juristic person to be known as the Executive Council for Genetically Modified Organisms, which shall consist of not more than **[eight]** 10 members appointed by the Minister.”;

(b) by the insertion of the following subsection:

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

(c) by the substitution for paragraph (a) of subsection (2) of the following paragraph:

“(a) shall be one officer of each of the following national departments of State, nominated by the relevant department:

- (i) The Department of Agriculture;
  - (ii) the Department of **[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;
  - (vii) the Department of **Arts and Culture**; and
  - (viii) the Department of Water Affairs and Forestry,
- who shall have knowledge of the implications of genetically modified organism? with regard to the sector represented by his or her department, including any existing policies and legislation applicable within that sector.”

**Substitution of section 4 of Act 15 of 1997**

3. The following section is hereby substituted for section 4 of the principal Act: 30

**“Objectives of Council**

4. The Council shall advise the Minister on all aspects concerning **[the development, production, use, application and release of]** activities relating to genetically modified organisms, and [to] ensure that [all activities with regard to the development, production, use, application and release of] such activities [genetically modified organisms] are performed in accordance with [the provisions of] this Act.”

**Substitution of section 5 of Act 15 of 1997**

4. The following section is hereby substituted for section 5 of the principal Act:

**“Powers and duties of Council**

5. (1) The Council shall—

- (a) where an applicant applies in the prescribed manner for a permit to conduct activities in respect of genetically modified organisms determine whether that applicant must, in addition to his or her

- application, submit an assessment in accordance with the relevant provisions of the National Environmental Management Act, 1998 (Act No. 107 of 1998), of the impact on the environment and an assessment of the socio-economic considerations of such activities;
- (b) in consultation with the Committee, decide whether to approve an application — 5
- (i) for the use of facilities to conduct activities in respect of genetically modified organisms; or
- (ii) to conduct any activity, except an activity for which an extension permit is required; 10
- (c) in considering an application have regard to the following factors
- (i) Scientifically based risk assessments; and
- (ii) proposed risk management measures;
- (d) determine, in the event of — 15
- (i) an intentional change in the use of a facility or an activity for which approval was granted; and
- (ii) being notified by the user of any intended change, whether that user must re-apply for approval;
- (e) evaluate whether the user implemented the prescribed notification procedures in accordance with article 8 of the Protocol; 20
- (f) in the event of an accident, determine the manner of notification and the information to be submitted by a user as required in terms of this Act;
- (g) advise the Minister on ways to avoid accidents in the future and on measures to minimise any adverse impact on the conservation and sustainable use of biological diversity including risks to human and animal health; 25
- (h) implement appropriate measures regarding the manner of notification that must be given to an affected or potentially affected State, the Biosafety Clearing-House and, where appropriate, any relevant international organisations, of an unintentional transboundary movement that is likely to have an adverse impact on — 30
- (i) the conservation and the sustainable use of biological diversity; or
- (ii) human and animal health, 35
- in such an affected or potentially affected State;
- (i) provide an affected or potentially affected State with the prescribed information in the notification referred to in paragraph (h);
- (j) consult with an affected or potentially affected State immediately after notifying that State of an unintentional transboundary movement referred to in paragraph (h), to enable that State to take the necessary actions, including emergency measures: 40
- (k) satisfy itself prior to the Republic entering into a bilateral, regional or multilateral agreement or arrangement, including an agreement or arrangement on contingency plans regarding unintentional transboundary movements, that the level of protection of human and animal health and the environment is not lower than the level of protection provided for in the Protocol, and shall advise the Minister accordingly; 45
- (l) inform the Minister — 50
- (i) of any approval to conduct an activity contemplated in this Act and to exercise control over such an activity;
- (ii) of any notification received of an unintentional transboundary movement, and any relevant information on such transboundary movement: 55
- (iii) in the event of an accident, of the proposed control measures to be implemented to contain that accident; and