

NOTICE 2166 OF 2004**DEPARTMENT OF AGRICULTURE****PUBLICATION OF GENETICALLY MODIFIED ORGANISMS AMENDMENT BILL FOR COMMENTS**

I, Angela Thokozile Didiza, Minister of Agriculture hereby publish the Genetically Modified Organisms Amendment Bill, 2004, for comment by the general public. Comments must be submitted in writing within 30 days of publication of this notice to:

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GENETICALLY MODIFIED ORGANISMS AMENDMENT BILL

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

BILL

To amend the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) so as to incorporate the provisions of the Cartagena Protocol on Biosafety, to make amendments and additions to the definitions and scope of the Act, to amend the activities relating to genetically modified organisms, to amend the composition of the Committee and Council, to amend the functions of the Registrar, Committee and Council, to amend the determination of risks and liability, the confidentiality clause and procedures during an appeal.

BE 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 principal Act is hereby amended -
 - (a) by the substitution for the definition of "accident" of the following definition:

"accident" means any incident involving an unintended general release of genetically modified organisms, including any unintentional transboundary movement, which could have an immediate or delayed impact on the environment;
 - (b) by the insertion after the definition of "accident" of the following definition:

"activity" means any act with regard to, but not limited to, the importation, exportation, development, production, use, distribution, storage and application of genetically modified organisms;
 - (c) by the insertion after the definition of "applicant" of the following definition:

"Biosafety Clearing House" means a clearing house mechanism as established under article 18 (3) of the Convention;
 - (d) by the insertion after the definition of "committee" of the following definition:

"commodity clearance" means the authorization to use a the genetically modified organism as food, feed and during processing;
 - (e) by the substitution for the definition of "contained use" of the following definition:

"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, and their impact on the external environment;
 - (f) by the insertion after the definition of "contained use" of the following definition:

"convention" means the Convention on Biological Diversity;
 - (g) by the insertion after the definition of "environment" of the following definition:

"extension permit" means a permit issued for activities relating to genetically

modified organisms for which a permit had been previously issued."

- (h) by the insertion after the definition of "prescribed" of the following definition:
"protocol" means the Cartagena Protocol on Biosafety";
- (g) by the insertion after the definition of "this Act" of the following definition:
"transboundary movement" means the movement of a genetically modified organism from one Party to another Party, including movement between Parties and non-Parties to the Protocol".

Amendment of section 2 of Act 15 of 1997

2. Section 2 of the principal Act is hereby amended –
 (a) by the substitution in subsection (2) for paragraph (a) of the following paragraph:
"(a) involving [human gene therapy] germline modification"

Amendment of section 3 of Act 15 of 1997

3. Section 3 of the principal Act is hereby amended –
 (a) by the substitution of subsection (1) of the following paragraph:
"(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] ~~ten~~ members appointed by the Minister.;"
- (b) by the substitution of subsection (2) for paragraph (a) of the following paragraph:
"(a) shall be one officer of each of the following national departments of State, nominated by the relevant departments:
 (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 organisms with regard to the sector represented by his or her department, including any existing legislation applicable within the sector."

Substitution of section 4 of Act 15 of 1997

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

The Council shall advise the Minister on all aspects concerning all activities relating to genetically modified organisms, and to ensure that such activities are performed in accordance with the provisions of this Act."

Amendment of section 5 of Act 15 of 1997

5. Section 5 of the principal Act is hereby amended –
 (a) by the substitution of subsection (1) for paragraphs (a) and (g) of the following paragraphs respectively:
"(a) require any applicant for a permit, including an extension permit where required, to **[use facilities for the development, production, use or application] conduct activities relating to [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] activities;**

(g) after consideration of the risk assessment, risk management and, where required, public input, the environmental impact assessment referred to in paragraph (a) and the potential socio-economic impact, 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 authorize the registrar to issue a permit accordingly;

(b) by the insertion after paragraph (g) of the following paragraph:

"(h) require the registrar to communicate a decision taken in terms of paragraph (g) to the Biosafety Clearing House;"

(c) by the substitution of paragraph (h) of the following paragraph:

[h] (l) (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 release[s]d, 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;

(d) by the substitution of paragraphs (i) and (j) of the following paragraphs respectively:

"[(i)] (j) inform any other country of any accident directly or through the Biosafety Clearing House, that may have an impact on that country's environment;

[(j)] (k) 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, provided that such agreements do not result in a lower level of protection of the environment than that provided for in the Act;"

(e) by the insertion after paragraph (j) of the following paragraph:

"(l) advise on South Africa's entering into any bilateral, regional and multilateral agreements and arrangements with any other Party of the Protocol, provided that such agreements and arrangements do not result in a lower level of protection of the environment than that provided for in the Act;"

(f) by the substitution of paragraphs (k) to (n) of the following paragraphs respectively:

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

[(l)] (n) with the consent of the Minister approve and **[publish] make available** guidelines for all uses of genetically modified organisms;

[(m)] (o) advise the Minister on-

- (i) prohibitions;
- (ii) the authorization and exercise of the necessary control of imports and exports;
- (iii) all activities relating to **[the development, production, use, application, release and distribution of]** genetically modified organisms;
- (iv) the authorization or notification of contained uses;
- (v) the authorization 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)] (p) make recommendations to the Minister on the appointment of members to the Committee.

Amendment of section 9 of Act 15 of 1997

6. Section 9 of the principal Act is hereby amended –

- (a) by the substitution for section 9 of the following section:
 “ (1) The registrar shall, subject to the instructions of and the conditions laid down by the Council-
- (a) issue a permit, including an extension permit, as required or prescribed under this Act;
- (b) where he or she has ascertained or suspects on reasonable grounds that any activities relating to genetically modified organisms are being conducted [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 activities relating to genetically modified organisms are being conducted [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.
- (b) by the insertion after paragraph (f) of subsection (1) of the following paragraph:
(g) attend to any other matter with regard to biosafety of genetically modified organisms.
- (c) by the insertion after paragraph (g) of subsection (1) of the following section:
“(2) Notwithstanding the provisions of subsection (1)(a) to (g), the registrar may issue an extension permit for importation and exportation of genetically modified organisms, and for extending the time period to complete activities relating to genetically modified organisms, for which a permit had previously been issued.”

Amendment of section 10 of Act 15 of 1997

7. Section 10 of the principal Act is hereby amended –

- (a) by the substitution of subsection (1) for paragraph (b) of the following paragraph:
 “(b) two persons shall be from the public sector and shall have knowledge of ecological matters and have a non-prejudicial position, with regard to genetically modified organisms.”

Amendment of section 11 of Act 15 of 1997

8. Section 11 of the principal Act is hereby amended –

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

"(b) advise, on request or of its own accord, the Minister, the Council, the Registrar, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them."

Amendment of section 17 of Act 15 of 1997

9. Section 17 of the principal Act is hereby amended –

(a) by the substitution of subsection (2) of the following subsection:

"(2) The liability for damage caused by activities relating to [the use or release of a] genetically modified organism shall, unless otherwise indicated through a process identified in terms of Article 27 of the Protocol, 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] person concerned at the time of such [use or release] activity shall not be held liable for any damage unless such [user] person 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."

Amendment of section 18 of Act 15 of 1997

10. Section 18 of the principal Act is hereby amended –

(a) by the substitution of subsection (2) for paragraphs (a) and (c) of the following paragraphs respectively:

"(a) the general description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use;

(c) [the evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.] a summary of the risk assessment of the impact on the environment and human health."

Amendment of section 19 of Act 15 of 1997

11. Section 19 of the principal Act is hereby amended –

(a) by the substitution of subsection (2) for paragraphs (a) and (b) of the following paragraphs respectively:

"(2)(a) An appeal board shall be appointed within 60 days from the date of receipt of the appeal by the registrar, provided that the Minister may, if deemed necessary, extend the period by 30 days and shall consist of the [person or] persons who, in the opinion of the Minister, [has or] have expert knowledge of the matter on appeal and who [is or] are otherwise suitable to make a decision on [decide on the issues of] the appeal concerned.

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

(b) by the substitution of subsection (4) for paragraph (c) of the following paragraph:

"(c) make such other order as it may deem fit in order to minimize a significant negative impact on the environment or human health."

(c) by the substitution of subsection (6) of the following subsection:

"(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, and copies thereof to the registrar."

Amendment of section 20 of Act 15 of 1997

12. Section 20 of the principal Act is hereby amended –

(a) by the substitution of paragraph (a) of subregulation (1) of the following paragraph:

"(a) regarding the applications for and [the issue of permits] the period within which the permit, including extension permit, shall be issued in terms of this Act;"

Short title

This Act shall be called the Genetically Modified Organisms Amendment Act, 2004, and shall come into operation on a date fixed by the President by proclamation in the *Gazette*.

(8 October 2004)