DEPARTMENT OF AGRICULTURE

R. No. 1420… **26 November 1999**

GENETICALLY MODIFIED ORGANISMS ACT, 1997
(ACT No. 15 OF 1997)

REGULATIONS

The Minister of Agriculture, acting under section 20 of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), hereby –

(a) makes the regulations set out in the Schedule hereto; and

(b) determines that the said regulations shall come into operation on 1 December 1999.

SCHEDULE

Definitions

1. In these regulations, unless the context otherwise indicates, any word or expression to which a meaning has been assigned thereto in the Act, shall have that meaning and –

"**activity**" means work undertaken with regard to the development, production, use and application of genetically modified organisms;

"**facility**" means any place where organisms are being genetically modified under conditions of contained use;

"**the Act**" means the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997); and

"**the guidelines**" means the Guidelines and Procedures for Genetically Modified Organisms as approved by the Council in terms of section 5(l) of the Act.

Authority to import, export, develop, produce, use, release or distribute genetically modified organisms

2. (1) Subject to the provisions of subregulation (2), no applicant may import to or export from the Republic of South Africa, or develop, produce, use, release or distribute any genetically modified organism in the Republic of South Africa except in terms of a permit to undertake such an activity.

(2) Notwithstanding the provisions of subregulation (1), a permit referred to in the said subregulation shall not be required for organisms that are used under conditions of contained use in academic and research facilities, and for those organisms specified in Table 3 of the Annexure.

(3) An applicant shall, besides complying with the provisions of these regulations, also comply with the provisions of all other laws regulating the importation and exportation of genetically modified organisms.

Risk assessment of activities

3. (1) No person shall undertake any activity involving genetic modification unless a suitable and sufficient assessment of the risks created thereby to the environment and human health has been made.

(2) Lack of scientific knowledge or consensus on the safe use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk.

Registration of facility and maintenance of records

4. (1) Subject to the provisions of subregulation (4), all facilities shall be registered with the registrar.

(2) An application for the registration of a facility shall be submitted to the registrar on a form that is obtainable from the office of the registrar.

(3) A separate application shall be lodged with the registrar in respect of each facility and each such application shall be accompanied by a locality map that clearly indicates where the facility is situated.

(4) Applications for the registration of a facility that has already been active prior to the commencement of these regulations, shall be submitted to the registrar within one (1) year of the date of such commencement: Provided that, if the Minister deems it necessary, upon the advice of the Committee, that a facility should be registered prior to the expiration of the one-year period, the Minister may by way of a written notice to the user, require that a particular facility be registered within a period specified in that notice.

(5) Upon registration of a facility, the registrar shall furnish, within three (3) months of receipt of an application, the applicant with a certificate of registration and a copy of the guidelines.

(6) The user of a registered facility shall, *inter alia* in hard copy format, keep and maintain the certificate of registration referred to in subregulation (5) and all records pertaining to risk assessments.

(7) The certificate and records referred to in subregulation (6) shall, upon request, be made available to the registrar or an inspector.

(8) The user shall notify the registrar of any change to the information provided in terms of this regulation and shall not dispose of any list, register and record maintained in terms of this regulation.

Applications for and issue of permits

5. (1) Unless the contrary is stated elsewhere in these regulations, a person intending to conduct any activity specified in column 1 of Table 1 of the Annexure, shall conduct such activity under the authority of a permit issued by the registrar.

(2) An application for a permit referred to in subregulation (1), shall be submitted to the registrar on a form that is obtainable from the office of the registrar.

(3) An application referred to in subregulation (2), shall be made not less than the number of days specified in column 2 of Table 1 of the Annexure, prior to the proposed commencement of the corresponding activity.

(4) The Council and Committee shall attend to applications within reasonable time frames as may be determined

by the registrar from time to time in order to enable the registrar to issue permits within the number of days specified in column 2 of Table 1 of the Annexure opposite the corresponding activity.

(5) Where an applicant is unable to provide any information that is requested in an application form, such applicant shall, when submitting the application form to the registrar, furnish the registrar with written reasons for such inability.

(6) The applicable application fees specified in Table 2 of the Annexure shall accompany each application referred to in subregulation (2).

(7) The registrar shall, after receipt of an application referred to in subregulation (2) -

(a) acknowledge, in writing, receipt of such application within two (2) working days of such receipt; and

(b) examine the conformity of the application to the requirements of the Act; and -

(i) if the application does not conform to the requirements of the Act in any respect, immediately refer the application back to the applicant and request the applicant to rectify the application; or

(ii) if the application conforms to the requirements of the Act, submit the application to the Council for consideration.

(8) The Council may -

(a) approve an application referred to in subregulation (7)(b)(ii) and authorise the registrar to furnish the applicant with the applicable permit to undertake the activity concerned; or

(b) refuse such application and furnish written reasons therefor.

(9) The Council may in performing its function in terms of subregulation (8), consider the socio-economic impact that the introduction of a genetically modified organism may have on a community living in the vicinity of such introduction.

(10) An applicant shall immediately notify the registrar of any change in information provided in an application submitted in terms of this regulation if such application has not yet been considered under subregulation (8).

(11) Upon receipt of any change referred to in subregulation (10), the registrar shall refer the details of such change to the Council who may require the applicant to submit a fresh application.

(12) The registrar may, at his or her discretion, fast track any application for an activity involving genetically modified organisms for which a permit had previously been issued.

(13) When submitting documents in terms of these regulations to the Council, the registrar shall also submit such documents to the Committee when applicable.

Public notification of proposed trial release and general release of genetically modified organisms

6. (1) The applicant shall notify the public of any proposed release of genetically modified organisms prior to the

application for a permit for such release.

(2) Public notification shall be in the form of a standard notice published in the printed media informing the public of the intended release.

(3) The notice referred to in subregulation (2), shall be obtainable from the office of the registrar and shall, *inter alia*, require the applicant to fill in the following details:

(a) full name and address of the applicant;

(b) a full description of the genetically modified organisms that the applicant proposes to release;

(c) a description of the proposed trial release, including the area and environment in which the release is to take place;

(d) a request that interested parties submit comments or objections in connection with the intended release to the registrar within a period specified in the notice: Provided that such period shall not be less than thirty (30) days after the date on which the notice appears in the media; and

(e) the address, of the registrar, to which comments or objections may be submitted.

(4) The applicant shall publish the completed notice in at least three newspapers circulating in the area in which the proposed release is to take place.

(5) A copy of the notice and proof of publication thereof shall accompany the application for the release.

(6) The registrar shall refer any comments or objections received from interested parties to the Council.

(7) The Council shall, when considering an application for a release, consider all the comments and objections referred to the Council in connection with the said application.

Accidents

7. In the event of an accident involving genetically modified organisms, it shall be the responsibility of the user concerned to ensure that –

(a) the registrar is notified immediately both verbally and in writing of such accident and the registrar is at the same time, or as soon as possible thereafter, supplied with information regarding -

(i) the circumstances of the accident;

(ii) the identity and quantity of the genetically modified organisms released;

(iii) any information that is necessary to assess the impact of the accident on the environment and human health; and

(iv) the emergency measures taken to avoid or mitigate any adverse impact of such accident on the environment and human health; and

(b) all appropriate short-term, medium-term and long-term measures are taken to avoid or mitigate any adverse impact of such accident on the environment and human health.

Requirements for effective management of waste

8. (1) Any person who possesses or controls waste shall manage and dispose of such waste so that the waste does not have any negative impact on the environment and human health.

(2) The person mentioned in subregulation (1), shall comply with all relevant national, provincial and local authority legislation in his or her management and the disposal of the waste in his or her possession or under his or her control.

Provisions with regard to appeal

9. (1) An appeal in terms of section 19 of the Act shall –

(a) be lodged with the Minister in writing within thirty (30) days from the date on which the appellant was notified in writing of the decision or action concerned;

(b) state the reference number and the date of the document by means of which such appellant was notified of that decision or action;

(c) state the grounds on which the appeal is based; and

(d) be accompanied by the fee specified in item 5 of Table 2 of the Annexure.

(2) The appellant shall lodged an appeal with the office of the Minister and submit a copy thereof to the registrar.

(3) The appeal board may request the appellant to appear before the appeal board in order to clarify any issue on appeal.

(4) The appellant shall be notified in writing by the appeal board not less than seven (7) days in advance of the date, time and place at which he or she is to appear before the appeal board.

(5) The appellant shall be entitled to legal representation during any appearance before the appeal board.

(6) An appeal board shall provide the Minister with a decision on the appeal within thirty (30) working days after an appeal has been lodged with the appeal board.

Offences and penalties

10. Any person who contravenes or fails to comply with any provision or requirement of these regulations shall be guilty of an offence and shall be liable to the penalties as provided for in the Act.

Address for the submission of documents

11. (1) Any application, notice, appeal or other document that is to be submitted to the registrar in terms of these regulations shall –

(a) when forwarded by post, be addressed to –

The Registrar: Genetically Modified Organisms
Private Bag X973
PRETORIA
0001

(b) when delivered by hand, be addressed to or delivered to -

The Registrar: Genetically Modified Organisms
Directorate: Genetic Resources
Dirk Uys Building – Room 263
30 Hamilton Street
PRETORIA

(2) Application forms may also be requested at the above-mentioned addresses.

ANNEXURE/AANHANGSEL

TABLE 1/TABEL 1

ACTIVITIES REQUIRING PERMITS AND TIME FRAMES FOR THE ISSUING THEREOF/AKTIWITEITE WAT PERMITTE VEREIS EN TYDRAME VIR DIE UITREIK DAARVAN

[Reg.5]

Activity/Aktiwiteit	No. of days/Getal dae
1	**2**
1. Importation and exportation of genetically modified organisms/ Invoer en uitvoer van geneties gemanipuleerde organismes	30
2. Contained use of genetically modified organisms/ Beheerde gebruik van geneties gemanipuleerde organismes	30
3. Trial release of genetically modified organisms/ Proefvrystelling van geneties gemanipuleerde organismes	90
4. General release and marketing of genetically modified organisms/ Algemene vrystelling en bemarking van geneties gemanipuleerde organismes	180

TABLE 2/TABEL 2

FEES PAYABLE/GELDE BETAALBAAR

Application/ Aansoek	Fees/Gelde
1. Importation/exportation of genetically modified organisms/ Invoer/uitvoer van geneties gemanipuleerde organismes	R 236,00 per application/ per aansoek
2. Contained use of genetically modified organisms/ Beheerde gebruik van geneties gemanipuleerde organismes	R 685,00 per application/ per aansoek
3. Trial release/ Proefvrystelling	R 1 694,00 per application/ per aansoek
4. General release and marketing/ Algemene vrystelling en bemarking	Actual cost + 15% handling fee /Fisiese koste + 15% hanteringsfooi
5. Appeal/ Appèl	R 3 600,00 each/ elk
6. Fast tracking/ Bespoediging	R 1590,00 each/ elk
7. GMO status certificates/ GGO status sertifikaat	R 105,00 each/ elk
8. Registration of facility/ Registrasie van fasiliteit	R 230,00 each/ elk
9. Use as food or feed or processing / Gebruik as voedsel, voer of vir verwerking	R156,00 each/elk

[Table 2 as substituted by R828 of 21 June 2002; R576 of 2 May 2003; R495 of 23 April 2004; R478 of 27 May 2005; R130 of 17 February 2006; R41 of 26 January 2007]

TABLE 3/ TABEL 3

GENETICALLY MODIFIED ORGANISMS THAT HAVE BEEN CLEARED FOR COMMERCIAL RELEASE AND/OR FOR FOOD AND ANIMAL FEED ONLY/ GENETIES GEMANIPULEERDE ORGANISMES WAT VERKLAAR IS VIR KOMMERSIËLE VRYSTELLING EN/OF SLEGS VIR VOEDSEL EN VEEVOER

Organism/ Organisme	Gene/ Geen	Marker/ Merker	Trait/ Eienskap	Variety strain/ Variëteit lyn	Permits already issued/Permitte alreeds uitgereik	Country of origin/ Land van oorsprong	Additional requirements/ Addisionele vereistes
1	2	3	4	5	6	7	8
Cotton/ Katoen	cry 1A (c)	Nptll	Insect^{R} / Insek^{W}	Line 531	Conditional general release/ Voorwaardelike algemene vrystelling	RSA/RSA	*IRMS/ *GPWBS
Maize/ Mielie	cry 1A (c)	Nptll	Insect^{R} / Insek^{W}	Mon 810	Conditional general release/ Voorwaardelike algemene vrystelling	RSA/RSA	*IRMS/ *GPWBS
Maize/ Mielie	pat	bla	Herbicide^{T} *(Glufosinate Ammonium)/*Onkruiddoder^{T}*(Glufosinate Ammonium)*	T25 T14	Commodity clearance/ Produk klaring	Argentina/ Argentinië	Compliance with prescribed protocol with regard to handling and packaging/In ooreenstemming met die voor-geskrewe protokol met betrekking tot hantering en verpakking
Soyabeans/ Sojaboon	EPSPS (RR)	Nptll	Herbicide^{T} *(Glufosinate)/* Onkruiddoder^{T} *(Glufosinate)*	Line 40-3-2	Commodity clearance/ Produk klaring	USA/VSA	Compliance with prescribed protocol with regard to handling and packaging/In ooreen-stemming met die voor-geskrewe protokol met betrekking tot hantering en verpakking

^{R} – Resistance/ ^{W} - Weerstand
^{T} – Tolerance/ ^{T} -Toleransie
*IPRM – Integrated Pest Resistance Management Strategy/
*GPWBS – GeÏntegreerde Plaagweerstandsbeheerstrategie