GOVERNMENT NOTICES

DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES

No. R. 120 **26 February 2010**

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

REGULATIONS

The Minister of Agriculture, Forestry and Fisheries acting under section 20 of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), hereby make the regulations set out in the schedule hereto and repeal the regulations published by Government Notice No. R. 1420 of 26 November 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 –

"**containment level**" means the degree of physical containment provided within a facility, as determined by but not limited to the design of the facility, the equipment installed, and the procedures used that correspond to the level of risk identified;

"**facility**" means any place where contained use of a genetically modified organism takes place;

"**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(2)(f) of the Act.

Authority to conduct an activity

2. (1) Subject to the provisions of sub-regulation (2), no applicant may conduct any activity in the Republic of South Africa except in terms of a permit to undertake such an activity.

(2) Notwithstanding the provisions of sub-regulation (1), a permit referred to in the said sub-regulation shall not be required for organisms that are used under conditions of contained use, at containment level 1or 2 that have been registered in accordance with Regulation 8.

(3) An applicant shall, apart from complying with the provisions of these regulations, also comply with the provisions of all other laws regulating activities with genetically modified organisms.

Applications and decision-making

3. (1) An application shall be submitted, in hard copy and electronic format, to the registrar on the relevant application form, that is obtainable from the office of the registrar.

(2) Unless the contrary is stated elsewhere in these regulations, any application listed in column 1 of Table 1 of the Annexure shall be processed within the time period specified in column 2 of Table 1 of the said Annexure.

(3) An application referred to in sub-regulation (1) shall include the following –

(a) a scientifically-based risk assessment,

(b) proposed risk management measures,

(c) copy of public notice as required in terms of Regulation 9, and

(d) if so determined by the Council, an assessment, in accordance with the provisions of the National Environmental Management Act, 1998 (Act No. 107 of 1998) and any other applicable laws, of the impact of the proposed activity on the environment and an assessment of the socio-economic considerations of the activity.

(4) Where an applicant is required to conduct a public notification it shall be done in accordance with Regulation 9 and the application referred to in sub-regulation 3(1) shall be submitted to the Registrar prior to the notice being published.

(5) The applicable application fee specified in Table 2 of the Annexure shall accompany each application referred to in sub-regulation (1).

(6) The registrar shall, after receipt of an application referred to in sub-regulation (1) -

(a) acknowledge, in writing, receipt of such application within five (5) working days of such receipt; and

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

(i) if the application does not conform to the requirements of the Act and the regulations in any respect, refer the application back to the applicant, indicating the deficiency in the application; or

(ii) if the application conforms to the requirements of the Act and the regulations, submit the application to the Committee and/or Council for consideration.

(7) The Council may -

(a) approve an application referred to in sub-regulation (6)(b)(ii) and authorise the registrar in writing to furnish the applicant with the applicable permit to undertake the activity concerned on such terms and conditions as the Council considers necessary;

(b) refuse such application; or

(c) request additional information from the applicant, the registrar, the Committee or any person knowledgeable in a specific field of science.

(8) The Council shall provide reasons for any decision taken in terms of sub-regulation 7.

(9) An applicant shall immediately notify the registrar, both verbally and in writing, of any change in information provided in an application submitted in terms of this regulation, regardless of whether the such application has been considered under sub-regulation (7) or not.

(10) Upon receipt of any change referred to in sub-regulation (8) above, the registrar shall refer the details of such change to the Committee and/or Council which may require the applicant to submit a new application.

(11) The Council shall determine the terms and conditions under which the Registrar may issue an extension permit for an activity for which a permit has been issued previously.

Scientifically based risk assessment

4. (1) No person shall undertake an activity unless a suitable and sufficient assessment of the potential adverse effects to the environment, human and animal health and safety has been made.

(2) Any risk assessment shall be conducted in a scientifically sound manner, taking into consideration recognised risk assessment methods and techniques that are currently applied at national, regional and international level.

(3) Any risk assessment shall entail, as appropriate, the following steps –

(a) Identification of any potential adverse effect resulting from the novel genotypic and/or phenotypic characteristics of the genetically modified organism.

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the potential receiving environment to the genetically modified organism.

(c) An evaluation of the consequences should these adverse effects be realized.

(d) An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.

(4) A risk assessment shall be conducted on a case-by-case approach and shall include the consideration and evaluation of all available relevant scientific information, including expert advice of, and guidelines developed by, relevant international organizations.

(5) The applicant shall provide data on which the risk assessment was based together with the application, to the registrar.

(6) Lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk.

Socio-economic considerations

5. (1) An assessment of socio-economic impact may include but is not limited to information on the impact of the activity on the following –

(a) the continued existence and range of diversity of the biological resources,

(b) access to genetic and other natural resources previously available,

(c) cultural traditions, knowledge, and practices,

(d) income, competitiveness or economic markets, and

(e) food security.

Environmental impact assessment

6. (1) An applicant may be required to conduct an environmental impact assessment in accordance with Section 78 of the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004).

(2) In accordance with sub-regulation 6(1) the Council may on a case-by-case approach make a recommendation to the Minister of Environmental Affairs on whether an environmental impact assessment will be required.

Risk management

7. (1) With due consideration of Regulation 4 and specifically the science-based risk assessment, every application shall include measures to manage the potential risks identified for a proposed activity.

(2) The Council shall, when taking a decision to approve an application, determine the appropriateness of the mechanisms, measures and strategies proposed by the applicant to manage or control identified risks during the activity and impose further mechanisms where appropriate.

(3) Risk management mechanisms, measures and strategies referred to in sub-regulation (2) may include, but is not limited, to the following –

(a) containment and confinement of genetically modified organisms,

(b) movement of genetically modified organisms,

(c) storage and inventory of genetically modified organisms,

(d) disposal of residual or excess genetically modified organisms,

(e) harvest and/or disposal of genetically modified organisms after completion of the activity,

(f) cleaning of any equipment used during the activity;

(g) monitoring for compliance to permit conditions,

(h) restriction of unlawful access to genetically modified organisms, and

(i) management and maintenance of records and reports.

(4) All information relating to sub-regulation (3) or any other related information shall be made available to the Council, Registrar, or an inspector within the period specified by the Registrar.

Registration of a facility

8. (1) All facilities conducting activities 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 include, but is not limited to –

(a) the name of the person taking responsibility for the facility,

(b) a map of the facility that indicates the different units within the facility,

(c) a locality map that clearly indicates where the facility is situated, including its geographic coordinates,

(d) a science-based risk assessment of the activity(ies) within the facility,

(e) proposed risk management mechanisms, measures and strategies; and

(f) the prescribed fee.

(4) The registrar shall approach the Advisory Committee for consideration of the application and a recommendation.

(5) Upon registration of a facility, the registrar shall furnish the applicant, with proof of registration and information on relevant guidelines.

(6) Registration of a facility shall be valid for a period of three (3) years, upon which the person referred to in paragraph (a) of sub-regulation (3) must apply for renewal of the registration.

(7) The person responsible for the facility shall, *inter alia* in hard copy format, keep and maintain the certificate of registration referred to in sub-regulation (6) and all records pertaining to risk assessment and risk management.

(8) The certificate and records referred to in sub-regulation (7) shall, upon request, be made available to the registrar or an inspector within the period specified by the registrar.

(9) The person responsible for the facility must notify the registrar of any change to the information provided in terms of this regulation.

(10) Upon receipt of any change referred to in sub-regulation (9), the registrar may require the person responsible for the facility to submit a new application.

Public notification of proposed release or commodity clearance of genetically modified organisms

9. (1) Public notification shall be in the form of a notice published in the printed media informing the public of the application.

(2) For a proposed general or commodity release the applicant shall publish the notice in at least three national newspapers and for a proposed trial release in at least two (2) newspapers circulating in the immediate area and one (1) newspapers circulating nationally.

(3) Where no newspapers circulate in the immediate area in which the proposed trial release will take place, the applicant shall inform the public through other means of effective communication. Where notification via other means of effective communication was undertaken, record of such proceedings must be provided to the Registrar as proof.

(4) The applicant shall submit one hard copy and one electronic copy of the notice referred to in sub-regulation (2) to the registrar within seven (7) days from the date that the notice was published.

(5) The notice referred to in sub-regulation (2) shall contain at least the following details:

(a) full name and address of the applicant;

(b) objective of the application;

(c) a general description of the genetically modified organisms, including the name of the donor organism, recipient organism (if different) and inserted genes e.g. novel trait and marker genes (if present);

(d) where appropriate a description of the place of release, including the name of the town, the size of the release and information pertaining to the surrounding environment;

(e) information on how to access a copy of the application;

(f) a request that interested parties submit comments or objections in connection with the application 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 last notice appears in the media; and

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

(6) The registrar shall refer any comments received within the time period referred to in sub-regulation (5)(f) from interested parties to the Council.

(7) The registrar may take any other measure to notify interested parties of applications made in terms of this regulation and invite written comments from such parties.