

GOVERNMENT NOTICES GOEWERMENSKENNISGEWINGS

DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES DEPARTEMENT VAN LANDBOU, BOSBOU EN VISSERYE

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 1 or 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.

Notification of an accident

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

- (a) available relevant information on the estimated quantities, identity and relevant characteristics and/or traits of the genetically modified organism,
- (b) Information on the circumstances and the estimated date of the release,
- (c) Information on the use of the genetically modified organism within the originating Country,
- (d) Any available information about the possible adverse effects on the environment, human and animal health and safety,
- (e) Information on emergency measures taken to date and alternative short-term, medium-term and long-term risk management measures in accordance with but not limited to regulation 7(3) that could be taken to avoid or mitigate adverse effects on the environment, human and animal health and safety,
- (f) A point of contact for further information,
- (g) Any other relevant information

(2) The Council may, taking into consideration the information provided in terms of this regulation, instruct the registrar to appoint a panel to enquire into and report on the causes of such accident.

- (3) (a) The panel referred to in sub-regulation (2) shall consist of a person or persons who, in the opinion of the registrar, has or have expert knowledge and who is or are otherwise suitable to investigate and report on the accident and does not have any interest in the matter, and
- (b) If the panel consists of more than one person, the registrar shall designate one of the members as a chairperson of the panel.

(4) The Council shall instruct the registrar in writing to notify and provide any 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 the conservation and the sustainable use of biological diversity or human and animal health and safety in such an affected or potentially affected State, with the information listed in sub-regulation (1).

Provisions with regard to appeal

11. (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 Table 2 of the Annexure.

(2) The appellant shall submit a copy of the appeal lodged in terms of sub-regulation (1) above to the registrar.

(3) The appeal board may request the appellant and any other party to appear before the appeal board to clarify any issue on appeal.

(4) The appellant, and any party referred to in sub-regulation (3), shall be notified in writing by the chairperson of 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 chairperson may, for the purpose of a hearing provided for in sub-regulation (3), request that new scientific or technical evidence or any other information that is, in the opinion of the appeal board, directly applicable to the appeal be lodged with the chairperson in writing within such period as the chairperson may determine.

(6) The appellant shall set out the particulars of each ground upon which the appeal is based and serve a copy on the registrar and such other party as the chairperson may direct and thereafter furnish the chairperson and the registrar with proof of such service.

(7) At a hearing provided for in sub-regulation (3) –

(a) the chairperson may –

- (i) summon any person who may give material information concerning the subject matter of the appeal or who has in his or her possession or custody or under his or her control any document which has any bearing upon the subject matter of the appeal, to appear before the appeal board to be interrogated or produce that document, and the registrar may retain for examination any document so produced;
- (ii) administer an oath to or accept an affirmation from any person called as a witness at the hearing; and
- (iii) call as a witness, any person summoned in terms of paragraph (a) (i) and interrogate him or her and require him or her to produce any document in his or her possession or custody or under his or her control.

(b) any person referred to in sub-regulation (3) shall be allowed to:

- (i) call witnesses during the hearing and to cross-examine other witnesses; and
- (ii) notify his or her witness of the date, time and place of the hearing and to ensure their presence at the hearing.

(c) the appellant shall be allowed to present his or her case first and to call witnesses; and

(d) any other person referred to in sub - regulation (3) shall then be allowed to present his or her case and call witnesses.

(8) The appellant and any other party referred to in sub - regulation (3) shall be entitled to legal representation during any appearance before the appeal board.

(9) If a person appointed on the appeal board –

- (a) dies during the investigation of the appeal or so soon before the commencement of the investigation that the vacancy cannot be filled in time;
- (b) is unable to act and another person cannot be appointed in time; or
- (c) is, after the investigation has commenced, unable to continue therewith,

the parties may agree that the investigation be continued by the remaining members, and where the member who has died or has become incapacitated was or is the chairperson of the board, the Minister shall designate one of the remaining members to act as the chairperson.

- (10) (a) If the parties do not agree under sub-regulation (9), the investigation shall be adjourned to enable the Minister to appoint a member, in accordance with section 19 (2) (a), in the place of the member who has died or has become incapacitated.
- (b) Where an appointment has been made under sub-regulation 10 (a), the investigation shall, if the parties so agree, be continued as from the stage at which the investigation was interrupted by the death or incapacitation of a member, or shall, if the parties do not so agree, be commenced *de novo*.

(11) An appeal board shall provide the Minister and the registrar with a decision and reasons for the decision, of the appeal within ninety (90) days from the date that the appeal board has received the relevant documentation pertaining to the appeal.

(12) After the Minister has made a final decision, the registrar shall make the decision, together with the reasons therefore, available to all parties directly involved in the appeal and the public within thirty (30) days.

Matters concerning the Biosafety Clearing House

12. The Registrar shall communicate the following information to the Biosafety Clearing House:

- (a) The Act and accompanied Regulations,
- (b) Any guidelines developed in accordance with section 5(2)(f) of the Act,
- (c) Any agreement or arrangement entered into under section 5(1)(k) of the Act,
- (d) Summary of the science-based risk assessment according to the format determined by the registrar.
- (e) Final decisions regarding the -
- (i) importation and trial release of a genetically modified organism,
- (ii) transit of a specific genetically modified organism,
- (iii) use of a genetically modified organism as food, feed or for processing
- (iv) conditional general release or general release of a genetically modified organism
- (f) The reconsideration of any decision in accordance with section 5(2)(g) of the Act
- (g) Simplified procedures regarding the intentional transboundary movement of a genetically modified organism, as approved by the Council.
- (h) Notice of an unintentional transboundary movement, as provided for in regulation 10(4).
- (i) Notice of an illegal transboundary movement

Offences and penalties

13. Any person who contravenes or fails to comply with these Regulations, any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act 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

14. (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: Biosafety
30 Hamilton Street
PRETORIA
0001

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

ANNEXURE**TABLE 1****APPLICATIONS AND THE PERIOD REQUIRED FOR PROCESSING AND DECISIONS**

| Application | No. of days |
|--|--------------------|
| 1 | 2 |
| 1. Importation and exportation of genetically modified organisms with general release / commodity clearance approval | 30 |
| 2. Contained use of genetically modified organisms and/or import or export permit * | 120 |
| 3. Trial release of genetically modified organisms and/or import or export permit * | 120 |
| 4. General release of genetically modified organisms | 270 |
| 5. Extension permit | 90 |
| 6. Use of genetically modified organisms with commodity clearance approval | 30 |
| 7. Registration of facilities | 60 |
| 8. Commodity clearance of genetically modified organisms | 270 |

*import /export of genetically modified organisms that do not have general release or commodity clearance approval

TABLE 2
FEES PAYABLE

| Application | Fees* |
|--|--|
| 1. Importation/exportation of genetically modified organisms with general release status | R 300,00 each |
| 2. Contained use of genetically modified organisms | R 910,00 each (Excluding import or export costs) |
| 3. Trial release of genetically modified organisms | R 2 550, 00 each (Excluding import or export costs) |
| 4. General release / commodity clearance of genetically modified organisms | R 15 600,00 each |
| 5. Appeal | R 3 700,00 each |
| 6. Extension permit | R 2050,00 each |
| 7. Registration of facility | R 3 70,00 each |
| 8. Commodity use permit | R 210,00 each |

*As annually published in the tariff book.