REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Regulation Gazette No. 9234 *Regulasiekoerant*

Vol. 536 Pretoria, 26 February / Februarie 2010 No. 32966

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IMPORTANT ANNOUNCEMENT

Closing times PRIOR TO PUBLIC HOLIDAYS for

GOVERNMENT NOTICES, GENERAL NOTICES, REGULATION NOTICES AND PROCLAMATIONS 2010

*The closing time is **15:00** sharp on the following days:*

- **18 March,** Thursday, for the issue of Friday **26 March 2010**
- **25 March,** Thursday, for the issue of Thursday **1 April 2010**
- **31 March,** Wednesday, for the issue of Friday **9 April 2010**
- **22 April,** Thursday, for the issue of Friday **30 April 2010**
- **10 June,** Thursday, for the issue of Friday **18 June 2010**
- **5 August,** Thursday, for the issue of Friday **13 August 2010**
- **16 September,** Thursday, for the issue of Thursday **23 September 2010**
- **23 September,** Thursday, for the issue of Friday **1 October 2010**
- **9 December,** Thursday, for the issue of Friday **17 December 2010**
- **15 December,** Wednesday, for the issue of Friday **24 December 2010**
- **21 December,** Tuesday, for the issue of Friday **31 December 2010**
- **30 December,** Thursday, for the issue of Friday **7 January 2011**

Late notices will be published in the subsequent issue, if under special circumstances, a late notice is accepted, a double tariff will be charged

The copy for a SEPARATE *Government Gazette* must be handed in not later than three calendar weeks before date of publication

BELANGRIKE AANKONDIGING

Sluitingstye VOOR VAKANSIEDAE vir

GOEWERMENTS-, ALGEMENE- & REGULASIE-KENNISGEWINGS ASOOK PROKLAMASIES 2010

*Die sluitingstyd is stiptelik **15:00** op die volgende dae:*

- **18 Maart,** Donderdag, vir die uitgawe van Vrydag **26 Maart 2010**
- **25 Maart,** Donderdag, vir die uitgawe van Donderdag **1 April 2010**
- **31 Maart,** Woensdag, vir die uitgawe van Vrydag **9 April 2010**
- **22 April,** Donderdag, vir die uitgawe van Vrydag **30 April 2010**
- **10 Junie,** Donderdag, vir die uitgawe van Vrydag **18 Junie 2010**
- **5 Augustus,** Donderdag, vir die uitgawe van Vrydag **13 Augustus 2010**
- **16 September,** Donderdag, vir die uitgawe van Donderdag **23 September 2010**
- **23 September,** Donderdag, vir die uitgawe van Vrydag **1 Oktober 2010**
- **9 Desember,** Donderdag, vir die uitgawe van Vrydag **17 Desember 2010**
- **15 Desember,** Woensdag, vir die uitgawe van Vrydag **24 Desember 2010**
- **21 Desember,** Dinsdag, vir die uitgawe van Vrydag **31 Desember 2010**
- **30 Desember,** Donderdag, vir die uitgawe van Vrydag **7 Januarie 2011**

Laat kennisgewings sal in die daaropvolgende uitgawe geplaas word. Indien 'n laat kennisgewing wel, onder spesiale omstandighede, aanvaar word, sal 'n dubbeltarief gehef word

Wanneer 'n APARTE *Staatskoerant* verlang word moet die kopie drie kalenderweke voor publikasie ingedien word

PROCLAMATION

by the

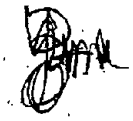
President of the Republic of South Africa

No. R. 3, 2010

GENETICALLY MODIFIED ORGANISMS AMENDMENT ACT, 2006 (ACT No. 23 OF 2006): COMMENCEMENT

Under section 17 of the Genetically Modified Organisms Amendment Act, 2006 (Act No. 23 of 2006), I hereby determine that all the provisions of the said Act shall come into operation on **26 February 2010.**

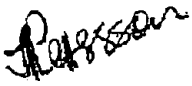
Given under my Hand and the Seal of the Republic of South Africa at Cape Town, this Fifteenth day of February Two Thousand and Ten.



J.G. ZUMA

President

By Order of the President-in-Cabinet:



TINA JOEMAT-PETTERSSON

Minister of the Cabinet

PROKLAMASIE

van die

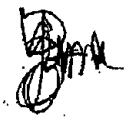
President van die Republiek van Suid-Afrika

No. R. 3, 2010

WYSIGINGSWET OP GENETIES GEMANIPULEERDE ORGANISMES, 2006 (WET No. 23 VAN 2006): INWERKINGTREDING

Kragtens artikel 17 van die Wysigingswet op Geneties Gemanipuleerde Organismes, 2006 (Wet No. 23 van 2006), bepaal ek hierby dat al die bepalings van genoemde Wet op **26 Februarie 2010** in werking tree.

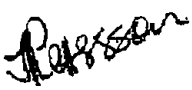
Gegee onder my Hand en die Seël van die Republiek van Suid-Afrika, te Kaapstad, op hierdie Vyftiende dag van Februarie Tweeduisend-en-Tien.



J.G. ZUMA

President

Op las van die President-in-Kabinet:



TINA JOEMAT-PETTERSSON

Minister van die Kabinet

GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

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 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 fumish 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 commences, 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.

No. R. 120 **26 Februarie 2010**

WET OP GENETIES GEMANIPULEERDE ORGANISMES, 1997 (WET No. 15 VAN 1997)

REGULASIES

Die Minister van Landbou, Bosbou en Visserye, handelende kragtens artikel 20 van die Wet op Geneties Gemanipuleerde Organismes, 1997 (Wet No. 15 van 1997), vaardig hierby die regulasies soos in die bylae uiteengesit uit en herroep die regulasies soos gepubliseer by Goewermentskennisgewing No. R. 1420 van 26 November 1999.

BYLAE

Woordomskrywing

1. In hierdie regulasies, tensy uit die samehang anders blyk, het 'n woord of uitdrukking waaraan die Wet 'n betekenis heg, daardie betekenis, en beteken—

"die riglyne" die Riglyne en Prosedures vir Geneties Gemanipuleerde Organismes goedgekeur deur die Raad kragtens artikel 5(2)*(f)* van die Wet;

"die Wet" die Wet op Geneties Gemanipuleerde Organismes, 1997 (Wet No. 15 van 1997);

"fasiliteit" 'n plek waar die beheerde gebruik van 'n geneties gemanipuleerde organisme plaasvind; en

"inperkingsvlak" die mate van fisiese inperking verskaf in 'n fasiliteit wat bepaal word deur, maar nie beperk is nie tot, die ontwerp van die fasiliteit, die geïnstalleerde toerusting en die prosedures wat gebruik word wat beantwoord aan die geïdentifiseerde risikovlak.

Magtiging om 'n bedrywigheid te verrig

2. (1) Behoudens subregulasie (2) mag geen aansoeker 'n bedrywigheid in die Republiek van Suid-Afrika verrig nie, behalwe kragtens 'n permit om sodanige bedrywigheid te verrig.

(2) Ondanks subregulasie (1) word 'n permit in daardie subregulasie bedoel, nie vereis nie vir organismes wat gebruik word in omstandighede van beheerde gebruik by inperkingsvlakke 1 of 2 wat ooreenkomstig regulasie 8 geregistreer is.

(3) 'n Aansoeker moet, afgesien van voldoening aan hierdie regulasies, ook voldoen aan alle ander wetsvoorskrifte wat bedrywighede met geneties gemanipuleerde organismes reël.

Aansoeke en besluitneming

3. (1) 'n Aansoek, in papier- en elektroniese formaat, moet op die toepaslike aansoekvorm, wat by die kantoor van die registrateur verkrygbaar is, by die registrateur ingedien word.

(2) Tensy hierdie regulasies elders anders bepaal, moet 'n aansoek gelys in kolom 1 van Tabel 1 van die Aanhangsel verwerk word binne die tydperk genoem in kolom 2 van Tabel 1 van die Aanhangsel.

(3) 'n Aansoek bedoel in subregulasie (1) moet die volgende insluit-

(a) 'n wetenskaplik gegronde risikobeoordeling;

(b) beoogde risikobestuursmaatreëls;

(c) 'n afskrif en bewys van openbare kennis gegee soos vereis by regulasie 9; en

(d) indien die Raad dit vereis, 'n beoordeling ooreenkomstig die Wet op Nasionale Omgewingsbestuur, 1998 (Wet No. 107 van 1998), en enige ander toepaslike wetsvoorskrifte, van die invloed van die beoogde bedrywigheid op die omgewing en 'n bepaling van die sosio-ekonomiese oorwegings van die bedrywigheid.

(4) Indien 'n aansoeker openbare kennis moet gee, word dit gedoen ooreenkomstig regulasie 9 en die aansoek bedoel in subregulasie (1) word by die registrateur ingedien voor die datum waarop die kennisgewing gepubliseer word.

(5) Elke aansoek bedoel in subregulasie (1) moet vergesel gaan van die toepaslike aansoekgeld vermeld in Tabel 2 van die Aanhangsel.

(6) Die registrateur moet, ná ontvangs van 'n aansoek bedoel in subregulasie (1) -

(a) binne vyf werkdae ná sodanige ontvangs skriftelik ontvangs van die aansoek erken; en

(b) die aansoek ondersoek vir voldoening aan die vereistes van die Wet en hierdie regulasies, en -

(i) indien die aansoek in enige opsig nie voldoen aan die vereistes van die Wet en die regulasies nie, die aansoek na die aansoeker terugverwys met vermelding van die tekortkoming in die aansoek; of

(ii) indien die aansoek aan die vereistes van die Wet en die regulasies voldoen, die aansoek aan die Komitee en/of die Raad vir oorweging voorlê.

(7) Die Raad kan—

(a) 'n aansoek bedoel in subregulasie (6)(b)(ii) goedkeur en die registrateur skriftelik magtig om die toepaslike permit om die bedrywigheid te onderneem op sodanige bepalings en voorwaardes as wat die Raad nodig ag, aan die aansoeker uit te reik; of

(b) die aansoek weier; of

(c) bykomstige inligting aanvra van die aansoeker, die registrateur, die Komitee of enige ander persoon wat 'n kundige op 'n bepaalde wetenskaplike gebied is.

(8) Die Raad moet redes verskaf vir 'n besluit geneem kragtens subregulasie (7).

(9) 'n Aansoeker moet die registrateur onverwyld in kennis stel, sowel mondeling as skriftelik, van enige verandering in die inligting verstrek in 'n aansoek ingedien kragtens hierdie regulasie, ongeag of die aansoek kragtens subregulasie (7) oorweeg is, al dan nie.

(10) Ná ontvangs van enige verandering bedoel in subregulasie (8) moet die registrateur die besonderhede van die verandering voorlê aan die Komitee en/of die Raad, wat van die aansoeker kan vereis om 'n nuwe aansoek in te dien.

(11) Die Raad stel die bepalings en voorwaardes waarop die registrateur 'n verlengingspermit mag uitreik vir 'n bedrywigheid waarvoor 'n permit vantevore reeds uitgereik is.

Wetenskaplik gegronde risikobeoordeling

4. (1) Geen persoon mag 'n bedrywigheid onderneem nie, tensy 'n gepaste en toereikende beoordeling gedoen is van die potensiële nadelige uitwerking daarvan op die omgewing en op die gesondheid en veiligheid van mens en dier.

(2) 'n Risikobeoordeling moet op 'n wetenskaplik grondige wyse geskied met inagneming van erkende risikobeoordelingsmetodes en -tegnieke wat in daardie stadium op nasionale, regionale en internasionale vlak toegepas word.

(3) 'n Risikobeoordeling moet, soos gepas, die volgende stappe behels-

(a) die identifisering van enige potensiële nadelige uitwerking wat kan ontstaan uit die nuwe genotipiese en/of fenotipiese eienskappe van die geneties gemanipuleerde organisme;

(b) 'n evaluering van die waarskynlikheid dat sodanige nadelige uitwerking sal realiseer, met inagneming van die vlak van en soort blootstelling van die potensiële ontvangeromgewing van die geneties gemanipuleerde organisme;

(c) 'n evaluering van die gevolge indien daardie nadelige uitwerking realiseer;

(d) 'n beraming van die algehele risiko wat die geneties gemanipuleerde organisme inhou, gegrond op die evaluering van die waarskynlikheid en gevolge daarvan as die geïdentifiseerde nadelige uitwerking sou realiseer.

(4) 'n Risikobeoordeling word van geval tot geval gedoen en moet die oorweging en evaluering van al die beskikbare tersaaklike wetenskaplike inligting insluit, met inbegrip van deskundige advies verskaf en riglyne gestel deur toepaslike internasionale organisasies.

(5) Die aansoeker moet die data waarop die risikobeoordeling berus, saam met die aansoek aan die registrateur verskaf.

(6) 'n Gebrek aan wetenskaplike kennis of wetenskaplike konsensus word nie vertolk as 'n aanduiding van 'n bepaalde risikovlak, 'n aanvaarbare risiko of die afwesigheid van risiko nie.

Sosio-ekonomiese oorwegings

5. (1) 'n Bepaling van die sosio-ekonomiese invloed kan inligting oor die invloed van die bedrywigheid op die volgende insluit, maar is nie daartoe beperk nie –

(a) die voortbestaan en diversiteitsomvang van biologiese hulpbronne;

(b) die verlies van toegang tot genetiese en ander natuurlike hulpbronne wat voorheen beskikbaar was;

(c) kulturele tradisies, kennis en gebruike;

(d) inkomste, mededingendheid of ekonomiese markte; en

(e) voedselsekerheid.

Omgewingsimpakbeoordeling

6. (1) Daar kan van 'n aansoeker vereis word om 'n omgewingsimpakbeoordeling te doen ooreenkomstig artikel 78 van die Nasionale Omgewingsbestuur: Biodiversiteitswet, 2004 (Wet No. 10 van 2004).

(2) Die Raad kan ooreenkomstig subregulasie (1), van geval tot geval, by die Minister van Omgewingsake aanbeveel dat 'n omgewingsimpakbeoordeling vereis word.

Risikobestuur

7. (1) Met behoorlike inagneming van regulasie 4, en in die besonder die wetenskaplik gegronde risikobeoordeling, moet elke aansoek maatreëls insluit vir die bestuur van die potensiële risiko's wat vir 'n beoogde bedrywigheid geïdentifiseer is.

(2) Die Raad moet, wanneer hy besluit om 'n aansoek goed te keur, die gepastheid vasstel van die meganismes, maatreëls en strategieë wat deur die aansoeker beoog word om geïdentifiseerde risiko's gedurende die bedrywigheid te bestuur of te beheer en, waar toepaslik, verdere meganismes voorskryf.

(3) Risikobestuursmeganismes, -maatreëls en -strategieë bedoel in subregulasie (2) kan die volgende insluit, maar is nie daartoe beperk nie –

(a) die inperking of insluiting van geneties gemanipuleerde organismes;

(b) die verskuiwing van geneties gemanipuleerde organismes;

(c) die berging en inventarisering van geneties gemanipuleerde organismes;

(d) die wegdoening van residuele of oortollige geneties gemanipuleerde organismes;

(e) die oes en/of beskikking oor geneties gemanipuleerde organismes ná afhandeling van die bedrywigheid;

(f) die skoonmaak van toerusting wat tydens die bedrywigheid gebruik word;

(g) die monitering van nakoming van permitvoorwaardes;

(h) die beperking van onregmatige toegang tot geneties gemanipuleerde organismes; en

(i) die hou en bestuur van rekords en verslae.

(4) Alle inligting wat verband hou met subregulasie (3) en enige ander verbandhoudende inligting moet binne die tydperk soos bepaal deur die registrateur, aan die Raad, die registrateur of 'n inspekteur beskikbaar gestel word.

Registrasie van 'n fasiliteit

8. (1) Alle fasiliteite wat bedrywighede uitvoer, moet by die registrateur geregistreer wees.

(2) 'n Aansoek om die registrasie van 'n fasiliteit moet by die registrateur ingedien word op 'n vorm wat by die kantoor van die registrateur verkrygbaar is.

(3) 'n Afsonderlike aansoek moet ten opsigte van elke fasiliteit by die registrateur ingedien word en elke sodanige aansoek moet die volgende insluit, maar is nie daartoe beperk nie –

(a) die naam van die persoon wat verantwoordelikheid dra vir die fasiliteit;

(b) 'n plan van die fasiliteit wat die verskillende eenhede in die fasiliteit aandui;

(c) 'n liggingskaart wat duidelik aandui waar die fasiliteit geleë is, met inbegrip van die geografiese koördinate daarvan;

(d) 'n wetenskaplik gegronde risikobeoordeling van die bedrywigheid of bedrywighede wat in die fasiliteit uitgevoer word;

(e) die beoogde risikobestuursmeganismes, -maatreëls en strategieë; en

(f) die voorgeskrewe registrasiegeld.

(4) Die registrateur moet die Komitee nader vir oorweging van die aansoek en 'n aanbeveling.

(5) Ná registrasie van 'n fasiliteit moet die registrateur bewyse van regsitrasie en inligting oor toepaslike riglyne aan die aansoeker verskaf.

(6) Die registrasie van 'n fasiliteit is vir 'n tydperk van drie jaar geldig, waarna die persoon bedoel in subregulasie (3)*(a)* aansoek om die hernuwing van die registrasie moet doen.

(7) Die persoon verantwoordelik vir die fasiliteit moet, in onder meer papierformaat, die registrasiesertifikaat bedoel in subregulasie (6) en alle rekords met betrekking tot risikobeoordeling en -bestuur bewaar en in stand hou.

(8) Die sertifikaat en rekords bedoel in subregulasie (7) moet, binne die tydperk wat die registrateur bepaal en op versoek, aan die registrateur of 'n inspekteur beskikbaar gestel word.

(9) Die persoon verantwoordelik vir die fasiliteit moet die registrateur in kennis stel van enige verandering in die inligting wat ingevolge hierdie regulasie verskaf is.

(10) Ná ontvangs van 'n kennisgewing van 'n verandering bedoel in subregulasie (9) kan die registrateur van die persoon verantwoordelik vir die fasiliteit vereis om 'n nuwe aansoek in te dien.

Openbare kennisgewing van beoogde vrystelling of kommoditeitsklaring van geneties gemanipuleerde organismes

9. (1) Openbare kennisgewing moet geskied in die vorm van 'n kennisgewing, gepubliseer in die gedrukte media, waarin die publiek van die aansoek in kennis gestel word.

(2) Die aansoeker moet, indien dit 'n beoogde algemene of kommoditeitsvrystelling is, die kennisgewing publiseer in minstens drie nuusblaaie wat nasionaal versprei word en, indien dit 'n beoogde proefvrystelling is, dit publiseer in minstens twee (2) nuusblaaie wat in die onmiddellike omgewing en een nuusblad wat nasionaal versprei word.

(3) Indien geen nuusblaaie versprei word in die onmiddellike omgewing waarin die beoogde toetsvrystelling gaan plaasvind nie, moet die aansoeker die publiek op ander doeltreffende kommuniksiewyses in kennis stel. Wanneer bekendmaking op ander doeltreffende kommunikasiewyses geskied, moet dokumente van sodanige bekendmaking as bewys aan die registrateur verskaf word.

(4) Die aansoeker moet een papierafskrif en een elektroniese kopie van die kennisgewing bedoel in subregulasie (2) by die registrateur indien binne sewe (7) dae ná die datum waarop die kennisgewing gepubliseer is.

(5) Die kennisgewing bedoel in subregulasie (2) moet minstens die volgende besonderhede bevat –

(a) die volle naam en adres van die aansoeker;

(b) die doel van die kennisgewing;

(c) 'n algemene beskrywing van die geneties gemanipuleerde organismes, met inbegrip van die naam van die skenkerorganisme, die ontvangerorganisme (indien dit verskil) en die ingevoegde gene bv.die nuwe eienskap en die merkergene (indien teenwoordig);

(d) waar toepaslik, 'n beskrywing van die vrystellingsplek, met inbegrip van die naam van die stad of dorp, die grootte van die vrystelling en inligting met betrekking tot die omliggende omgewing;

(e) inligting oor hoe om toegang tot 'n afskrif van die aansoek te kry;

(f) 'n versoek dat belanghebbende partye kommentaar of besware in verband met die aansoek indien binne 'n tydperk vermeld in die kennisgewing: Met dien verstande dat sodanige tydperk minstens dertig (30) dae ná die datum waarop die laaste kennisgewing in die media verskyn, moet wees; en

(g) die adres van die registrateur by wie kommentaar of besware ingedien kan word.

(6) Die registrateur moet enige kommentaar of besware wat binne die tydperk bedoel in subregulasie (5)*(f)* ontvang word, na die Raad verwys.

(7) Die registrateur kan enige ander maatreël tref om belanghebbende partye in kennis te stel van aansoeke wat kragtens hierdie regulasie ingedien is en hulle versoek om kommentaar of besware in te dien.

Bekendmaking van 'n ongeluk

10. (1) In die geval van 'n ongeluk waarby geneties gemanipuleerde organismes betrokke is, is dit die verantwoordelikheid van die betrokke gebruiker om toe te sien dat die registrateur onmiddellik sowel mondeling as skriftelik van daardie ongeluk in kennis gestel word en terselfdertyd, of so gou moontlik daarna, voorsien word van –

(a) beskikbare toepaslike inligting oor die beraamde hoeveelhede, die identiteit en die toepaslike eienskappe en/of kenmerke van die geneties gemanipuleerde organisme;

(b) inligting oor die omstandighede en geraamde datum van die vrystelling;

(c) inligting oor die gebruik van die geneties gemanipuleerde organisme in die land van oorsprong;

(d) enige beskikbare inligting oor die moontlike nadelige gevolge vir die omgewing en die gesondheid en veiligheid van mens en dier;

(e) inligting oor die noodmaatreëls wat tot op datum getref is en alternatiewe korttermyn-, mediumtermyn- en langtermyn-risikobestuursmaatreëls wat getref kan word, ooreenkomstig met maar nie beperk tot regulasie 7(3), om nadelige gevolge vir die omgewing en die gesondheid en veiligheid van mens en dier te voorkom of te verminder;

(f) 'n kontakpunt vir nadere inligting; en

(g) enige ander toepaslike inligting.

(2) Die Raad kan, met inagneming van die inligting wat ingevolge hierdie regulasie voorsien is, die registrateur opdrag gee om 'n paneel aan te stel om ondersoek in te stel na die oorsake van die ongeluk en daaroor verslag te doen.

(3) (a) Die paneel beoog in subregulasie (2) moet bestaan uit 'n persoon of persone wat na die mening van die registrateur oor deskundige kennis beskik, wat andersins geskik is om na die ongeluk ondersoek in te stel en daaroor verslag te doen, en wat geen belang by die aangeleentheid het nie.

(b) Indien die paneel uit meer as een persoon bestaan, moet die registrateur een van die lede as voorsitter van die paneel aanwys.

(4) Die Raad moet die registrateur skriftelik opdrag gee om enige geaffekteerde of potensieel geaffekteerde staat, die Bioveiligheidsklaringshuis en, waar van toepassing, enige betrokke internasionale organisasie in kennis te stel van 'n onopsetlike oorgrensbeweging wat waarskynlik 'n nadelige uitwerking sal hê op die bewaring en volhoubare gebruik van biologiese diversiteit of die gesondheid en veiligheid van mens en dier in sodanige geaffekteerde staat of potensieel geaffekteerde staat, en hom te voorsien van die inligting bedoel in subregulasie (1).

Bepalings met betrekking tot appèl

11. (1) 'n Appèl kragtens artikel 19 van die Wet moet –

(a) skriftelik by die Minister aangeteken word binne dertig (30) dae vanaf die datum waarop die appellant skriftelik van die betrokke beslissing of stappe in kennis gestel is;

(b) die verwysingsnommer en datum van die dokument waardeur die appellant van daardie beslissing of stappe in kennis gestel is, vermeld;

(c) die gronde waarop die appèl berus, vermeld; en

(d) vergesel gaan van die gelde vermeld in Tabel 2 van die Aanhangsel.

(2) Die appellant moet 'n afskrif van die appèl wat kragtens subregulasie (1) aangeteken is, by die registrateur indien.

(3) Die appèlraad kan die appellant en enige ander party versoek om voor die appèlraad te verskyn om 'n geskilpunt van die appèl op te klaar.

(4) Die appellant en enige party bedoel in subregulasie (3) moet, minstens sewe (7) dae voor die tyd, skriftelik deur die voorsitter van die appèlraad in kennis gestel word van die datum en tyd waarop en die plek waar hy of sy voor die appèlraad moet verskyn.

(5) Die voorsitter kan, vir doeleindes van 'n appèlsitting waarvoor subregulasie (3) voorsiening maak, versoek dat nuwe wetenskaplike of tegniese getuienis of enige ander inligting wat na die mening van die appèlraad regstreeks op die appèl van toepassing is, binne sodanige tydperk as wat die voorsitter bepaal, skriftelik by die voorsitter ingedien word.

(6) Die appellant moet die besonderhede van elke grond waarop die appèl berus, uiteensit en 'n afskrif beteken aan die registrateur en sodanige ander party as wat die voorsitter gelas, en moet daarna bewys van sodanige betekening aan die voorsitter en die registrateur lewer.

(7) By 'n appèlsitting waarvoor subregulasie (3) voorsiening maak –

(a) kan die voorsitter -

(i) enige persoon wat wesenlike inligting kan gee rakende die onderwerp van die appèl of wat in sy of haar besit of onder sy of haar beheer enige dokument het wat betrekking op die onderwerp van die appèl het, oproep om voor die appèlraad te verskyn ten einde ondervra te word of daardie dokument voor te lê, en die registrateur mag enige dokument aldus voorgelê, vir ondersoek terughou;

(ii) 'n eed afneem of 'n bevestiging aanvaar van enige persoon wat as getuie by die appèlsitting geroep word; en

(iii) enige persoon wat kragtens paragraaf *(a)*(i) opgeroep is, as 'n getuie roep en hom of haar ondervra of van hom of haar vereis om enige dokument in sy of haar besit of onder sy of haar beheer voor te lê;

(b) word enige persoon bedoel in subregulasie (3) toegelaat -

(i) om gedurende die appèlsitting getuies te roep en ander getuies te kruis-ondervra; en

(ii) sy of haar getuie in kennis te stel van die datum, tyd en plek van die appèlsitting en om sodanige getuie se teenwoordigheid by die sitting te verseker;

(c) word die appellant toegelaat om sy of haar saak eerste te stel en getuies te roep; en

(d) word enige persoon bedoel in subregulasie (3) daarna toegelaat om sy of haar saak te stel en getuies te roep.

(8) Die appellant en enige ander party bedoel in subregulasie (3) is geregtig op regsverteenwoordiging by enige verskyning voor die appèlraad.

(9) Indien 'n persoon wat in die appèlraad aangestel is -

(a) tydens 'n ondersoek van die appèl of so kort voor die aanvang van die ondersoek te sterwe kom dat die vakature nie betyds gevul kan word nie;

(b) nie in staat is om as sodanig op te tree nie en 'n ander persoon nie betyds aangestel kan word nie; of

(c) nadat die ondersoek 'n aanvang geneem het, nie in staat is om daarmee voort te gaan nie,

kan die partye ooreenkom dat die ondersoek voortgesit word deur die oorblywende lede, en indien die persoon wat gesterf het of onbekwaam geword het, die voorsitter van die appèlraad was of is, stel die Minister een van die oorblywende lede aan om as voorsitter waar te neem.

(10) (a) Indien die partye nie kragtens subregulasie (9) ooreenkom nie, word die ondersoek verdaag ten einde die Minister in staat te stel om 'n lid ooreenkomstig artikel 19(2)*(a)* van die Wet aan te stel in die plek van die lid wat gesterf het of onbekwaam geword het.

(b) Wanneer 'n aanstelling kragtens paragraaf *(a)* gedoen is, gaan die ondersoek, indien die partye aldus ooreenkom, voort vanaf die punt waar dit deur die afsterwe of onbekwaamwording van 'n lid onderbreek is, of, indien die partye nie aldus ooreenkom nie, word dit van nuuts af begin.

(11) 'n Appèlraad moet, binne negentig (90) dae vanaf die datum waarop die appèlraad die toepaslike dokumentasie rakende die appèl ontvang het, die Minister en die registrateur van 'n beslissing rakende 'n appèl, en die redes vir daardie beslissing, voorsien.

(12) Nadat die Minister die finale beslissing gemaak het, moet die registrateur daardie beslissing, asook die redes daarvoor, binne dertig (30) dae aan al die partye wat regstreeks by die appèl betrokke is en aan die publiek beskikbaar stel.

Aangeleenthede rakende die Bioveiligheidsklaringshuis

12. Die registrateur moet die volgende inligting aan die Bioveiligheidsklaringshuis oordra –

(a) Die Wet en die regulasies daarkragtens;

(b) enige riglyne ontwikkel kragtens artikel 5(2)(f) van die Wet;

(c) enige ooreenkoms of reëling aangegaan soos bedoel in artikel 5(1)(k) van die Wet;

(d) 'n samevatting van die wetenskaplik gegronde risikobeoordeling in die formaat bepaal deur die registrateur;

(e) finale besluite oor –

(i) die invoer en proefvrystelling van 'n geneties gemanipuleerde organisme;

(ii) die vervoer van 'n geneties gemanipuleerde organisme;

(iii) die gebruik van 'n geneties gemanipuleerde organisme as voedsel of voer of vir prosessering; en

(iv) die voorwaardelike algemene vrystelling of algemene vrystelling van 'n geneties gemanipuleerde organisme;

(f) die heroorweging van enige besluit kragtens artikel 5(2)(g) van die Wet;

(g) vereenvoudigde prosedures rakende die oorgrensbeweging van 'n geneties gemanipuleerde organisme, soos goedgekeur deur die Raad;

(h) die bekendmaking van 'n onopsetlike oorgrensbeweging soos bepaal in regulasie 10(4);

(i) kennisgewing van 'n onwettige oorgrensbeweging.

Misdrywe en strawwe

13. Enige persoon wat hierdie regulasies of 'n voorwaarde, beperking, verbod, voorbehoud of lasgewing ingevolge die Wet opgelê of uitgereik, oortree of versuim om daaraan te voldoen, is aan 'n misdryf skuldig en is strafbaar met die strawwe waarvoor die Wet voorsiening maak.

Adres vir die indiening van dokumente

14. (1) 'n Aansoek, kennisgewing, appèl of ander dokument wat ingevolge hierdie regulasies by die registrateur ingedien moet word, moet –

(a) indien dit per pos ingedien word, gerig word aan -

Die Registrateur: Geneties Gemanipuleerde Organismes
Privaat Sak X973
PRETORIA
0001

(b) indien dit per hand ingedien word, gerig word aan en afgelewer word by -

Die Registrateur: Geneties Gemanipuleerde Organismes
Direktoraat Bioveiligheid
Hamiltonstraat 30
PRETORIA
0001

(2) Aansoekvorms kan ook by bostaande adresse aangevra word.

AANHANGSEL

TABEL 1

AANSOEKE EN TYDPERK BENODIG VIR VERWERKING EN BESLUITNEMING

Aansoek	Aantal dae
1	2
1. Invoer of uitvoer van geneties gemanipuleerde organismes met algemene vrystellings- of kommoditeitsklaringsgoedkeuring	30
2. Beheerde gebruik van geneties gemanipuleerde organismes, en/of invoer- of uitvoerpermit daarvoor*	120
3. Proefvrystelling van geneties gemanipuleerde organismes, en/of invoer- of uitvoerpermit daarvoor*	120
4. Algemene vrystelling van geneties gemanipuleerde organismes	270
5. Verlengingspermit	90
6. Gebruik van genetiese gemanipuleerde organismes met kommoditeitsklaringsgoedkeuring	30
7. Registrasie van fasiliteite	60
8. Kommoditeitsklaring van geneties gemanipuleerde organismes	270

*invoer/uitvoer van geneties gemanipuleerde organismes waarvoor nie algemene vrystellings- of kommoditeitsklaringsgoedkeuring verleen is nie

TABEL 2

GELDE BETAALBAAR

Aansoek	Gelde*
1. Invoer of uitvoer van geneties gemanipuleerde organismes met algemene vrystellingstatus	R 300,00 elk
2. Beheerde gebruik van geneties gemanipuleerde organismes	R 910,00 elk Uitsluitende invoer of uitvoer koste
3. Proefvrystelling van geneties gemanipuleerde organismes	R 2 550,00 elk Uitsluitende invoer of uitvoer koste
4. Algemene vrystelling of kommoditeitsklaring van geneties gemanipuleerde organismes	R 15 600,00 elk
5. Appèl	R 3 700,00 elk
6. Verlengingspermit	R 2050,00 elk
7. Registrasie van fasiliteit	R 370,00 elk
8. Kommoditeitsgebruikspermit	R 210,00 elk

* Soos jaarliks in die tariefboek gepubliseer.

DEPARTMENT OF ENVIRONMENTAL AFFAIRS
DEPARTEMENT VAN OMGEWINGSAKE

No. R. 142 **26 February 2010**

MARINE LIVING RESOURCES ACT, 1998 (ACT NO. 18 OF 1998)

AMENDMENT OF REGULATIONS PUBLISHED IN GOVERNMENT NOTICE R. 1111 OF 2 SEPTEMBER 1998, AS AMENDED

The Minister of Water and Environmental Affairs has under Section 77 of the Marine Living Resources Act, 1998 (Act No. 18 of 1998), made the regulations in the Schedule hereto.

SCHEDULE

Definitions

1. In this schedule "the Regulations" means the regulations published under Government Notice No. R. 1111 of 2 September 1998, as amended by Government Notice R.27 of 14 January 2000, Government Notice R. 1129 of 17 November 2000, Government Notice R. 1344 of 8 December 2000; Government Notice R. 1428 of 29 December 2000, Government Notice R.375 of 4 May 2001, Government Notice R.1000 of 12 October 2001, Government Notice R.765 of 6 June 2003, Government Notice R.1376 of 3 October 2003, Government Notice R.1455 of 8 October 2003, Government Notice R.1669 of 12 November 2003, Government Notice R.1829 of 15 December 2003, Government Notice R.469 of 2 April 2004, Government Notice 329 of 6 April 2005, Government Notice 426 of 3 May 2005, Government Notice R. 8818 of 4 January 2008, Government Notice R. 8826 of 1 February 2008, Government Notice R. 343 of 8 March 2008 , Government Notice R. 1223 of 14 November 2008,Government Notice R. 343 of 28 March 2008 , Government Notice R 724 of 4 July 2008, Government Notice R 725 of 4 July 2008, Government Notice R 1223 of 14 November 2008 and Government Notice R 249 of 6 March 2009.

Amendment of Annexure 2 of the Regulations

2. Annexure 2 is hereby amended by the substitution for item 4 of Part A of the following item:

"(4) Chokka squid (*Loligo vulgaris reynaudii*) - from 12h00 noon on 11 August to 12h00 noon on 22 September and from 12h00 noon on 19 October to 12h00 noon on 23 November in any year".

DEPARTMENT OF LABOUR
DEPARTEMENT VAN ARBEID

No. R. 121 **26 February 2010**

LABOUR RELATIONS ACT, 1995

BARGAINING COUNCIL FOR THE LAUNDRY, CLEANING AND DYEING INDUSTRY (CAPE): EXTENSION OF AMENDMENT OF SICK BENEFIT FUND COLLECTIVE AGREEMENT TO NON-PARTIES

I, **MEMBATHISI MPHUMZI SHEPHERD MDLADLANA**, Minister of Labour, hereby in terms of section 32(2) of the Labour Relations Act, 1995, declare that the Collective Agreement which appears in the Schedule hereto, which was concluded in the **Bargaining Council for the Laundry, Cleaning and Dyeing Industry (Cape)** and is binding in terms of section 31 of the Labour Relations Act, 1995, on the parties which concluded the Collective Agreement, shall be binding on the other employers and employees in that Industry, with effect from **8 March 2010** and for the period ending 31 December 2010.

MMS MDLADLANA
MINSTER OF LABOUR

No. R. 121 26 Februarie 2010

WET OP ARBEIDSVERHOUDINGE, 1995

BEDINGINGSRAAD VIR DIE WAS- SKOONMAAK- EN KLEURNYWERHEID (KAAP): UITBREIDING VAN WYSIGING VAN SIEKTE BYSTANDFONDS KOLLEKTIEWE OOREENKOMS NA NIE-PARTYE

Ek, **MEMBATHISI MPHUMZI SHEPHERD MDLADLANA,** Minister van Arbeid, verklaar hierby, kragtens artikel 32(2) van die Wet op Arbeidsverhoudinge, 1995, dat die Kollektiewe Ooreenkoms wat in die Engelse Bylae hiervan verskyn, en wat in die **Bedingingsraad vir die Was- Skoonmaak- en Kleurnywerheid (Kaap)** aangegaan is en kragtens artikel 31 van die Wet op Arbeidsverhoudinge, 1995, bindend is op die partye wat die Kollektiewe Ooreenkoms aangegaan het, bindend is vir die ander werkgewers en werknemers in daardie Nywerheid, met ingang van **8 Maart 2010** en vir die tydperk wat op 31 Desember 2010 eindig.

MMS MDLADLANA
MINISTER VAN ARBEID

SCHEDULE

BARGAINING COUNCIL FOR THE LAUNDRY, CLEANING AND DYEING INDUSTRY (CAPE)

SICK BENEFIT FUND COLLECTIVE AGREEMENT

in accordance with the provisions of the Labour Relations Act, 1995, made and entered into by and between the

Laundry and Allied Workers' Union of South Africa

(hereinafter referred to as the "union" or "employee body", whose domicilium details are in Clause 1 of the Appendix) of the one part and the

Cape Town and District Laundry, Cleaners and Dyers' Association

(hereinafter referred to as the "employer" or the "employer body", whose domicilium details are in Clause 2 of the Appendix) of the other part, both being the parties to the Bargaining Council for the Laundry, Cleaning and Dyeing Industry (Cape), to amend the Agreement published under Government Notice No. R. 1237 of 21 November 2008.

1. SCOPE OF APPLICATION OF AGREEMENT

1.1 The terms of this Agreement shall be observed in the Laundry, Cleaning and Dyeing Industry (Cape) by

(a) All employers who are members of the employers' organisation and by all employees who are members of the trade union and who are engaged or employed in the Industry;

(b) In the Magisterial Districts of the Cape, Wynberg, Bellville, Goodwood, Simonstown, Paarl, Somerset West, Strand, Stellenbosch, Kuils River and Wellington.

1.2 Notwithstanding the provisions of sub-clause (1), the terms of this Agreement shall also apply to all employers and employees who are engaged or employed in the industry.

2. PERIOD OF OPERATION

This Agreement shall come into operation on such date as may be fixed by the Minister of Labour in terms of section 32(2) of the Act and shall remain in force until 31 December 2010.

3. CLAUSE 8: BENEFITS

(1) Delete sub-clauses 8.6, 8.7 and 8.8.

4. THE APPENDIX

(1) Re-publish "**THE APPENDIX**" in its entirety.

SIGNED ON THIS ..19.. DAY OF **September** TWO THOUSAND AND NINE

M ROBARTS
Chairperson

Y BESTER
Vice-Chairperson

D BUISE
Secretary of the Bargaining Council for the Laundry, Cleaning and Dyeing Industry (Cape)

"THE APPENDIX		
1.	**THE EMPLOYEE PARTY** **DOMICILIUM CITANDI ET EXECUTANDI**	Laundry and Allied Workers' Union of South Africa P.O. Box 12946 Mowbray 7705 Suite 601, 6th Floor Premier Centre 451 Main Road Observatory 7946 Tel: 021-448 5055 Fax 021-448 6017 Email: lcd@mweb.co.za
2.	**THE EMPLOYER PARTY AND SICKFUND DOMICILIUM CITANDI ET EXECUTANDI**	Cape Town and District Laundry Cleaners' and Dyers' Association P.O. Box 109, Cape Town 8000 c/o Suite 107, 1st Floor Premier Centre 451 Main Road Observatory 7946 Tel: 021-448 8000 Fax 021-448 8001 **Email: council@laundrybc.co.za**
3.	**MEMBERS' CONTRIBUTIONS**	**R70.30 per member per month of which** • **R27.00 shall be paid by the employer** • **R43.30 shall be paid by the employee**
4.	**BENEFITS**	**TO MEMBERS:** **General Medical Benefit: R1 210p.a.**
5.	**COMPULSORY CONTRIBUTORY WAITING PERIOD PRIOR TO RECEIVING BENEFITS**	5 (FIVE) CALENDAR MONTHS
6.	**SICKFUND BANK ACCOUNT**	**BANK: First National Bank (FNB)** **BRANCH Mowbray** **BSB 250-655** **ACCOUNT 6219 858 0279** **TYPE CHEQUE A/C** "

No. R. 122 **26 February 2010**

LABOUR RELATIONS ACT, 1995

BARGAINING COUNCIL FOR THE LAUNDRY, CLEANING AND DYEING INDUSTRY (CAPE): EXTENSION OF PERIOD OF OPERATION OF SICK BENEFIT FUND COLLECTIVE AGREEMENT

I, **MEMBATHISI MPHUMZI SHEPHERD MDLADLANA**, Minister of Labour, hereby, in terms of section 32(6)(a)(i) of the Labour Relations Act, 1995, extend the period fixed in Government Notice No. R.1238 of 21 November 2008, by a further period ending 31 December 2010.

MMS MDLADLANA
MINISTER OF LABOUR

No. R. 122 **26 Februarie 2010**

WET OP ARBEIDSVERHOUDINGE, 1995

BEDINGINGSRAAD VIR DIE WAS- SKOONMAAK- EN KLEURNYWERHEID (KAAP): VERLENGING VAN TYDPERK VAN SIEKTE BYSTANDFONDS KOLLEKTIEWE OOREENKOMS

Ek, **MEMBATHISI MPHUMZI SHEPHERD MDLADLANA**, Minister van Arbeid, verleng hierby, kragtens artikel 32(6)(a)(i) van die Wet op Arbeidsverhoudinge, 1995, die tydperk vasgestel in Goewermentskennisgewing No. R.1238 van 21 November 2008, met 'n verdere tydperk wat op 31 Desember 2010 eindig.

MMS MDLADLANA
MINISTER VAN ARBEID

No. R. 123 **26 February 2010**

LABOUR RELATIONS ACT, 1995

LABOUR RELATIONS ACT, 1995: BARGAINING COUNCIL FOR THE CANVAS GOODS INDUSTRY: (WITWATERSRAND AND PRETORIA) RENEWAL OF PERIOD OF MAIN COLLECTIVE AGREEMENT

I, IAN MACUN, Executive Manager: Collective Bargaining, duly authorised thereto by the Minister of Labour, hereby, in terms of section 32(6)(a)(ii) of the Labour Relations Act, 1995, declare the provisions of Government Notices Nos. R. 586 of 14 May 2004. R. 1167 of 15 October 2004, R. 157 and R. 158 of 24 February 2006, R. 992 of 13 October 2006, and R. 1042 of 20 October 2006, to be effective from the date of publication of this notice and for the period ending 30 June 2012.

I MACUN

EXECUTIVE MANAGER: COLLECTIVE BARGAINING

No. R. 123 **26 Februarie 2010**

WET OP ARBEIDSVERHOUDINGE, 1995

BEDINGINGSRAAD VIR DIE SELDOEKWARENYWERHEID (WITWATERSRAND EN PRETORIA) HERNUWING VAN TYDPERK VAN HOOF KOLLEKTIEWE OOREENKOMS

Ek, IAN MACUN, Uitvoerende Bestuurder: Kollektiewe Bedinging, behoorlik daartoe gemagtig deur die Minister van Arbeid, verklaar hierby, kragtens artikel 32(6)(a)(ii) van die Wet op Arbeidsverhoudinge, 1995, dat die bepalings van Goewermentskennisgewings Nos R. 586 van 14 Mei 2004, R. 1167 van 15 Oktober 2004, R. 157 en R. 158 van 24 Februarie 2006, R. 992 of 13 Oktober 2006, en R. 1042 van 20 Oktober 2006, van krag is vanaf die datum van publikasie van hierdie kennisgewing en vir die tydperk wat op 30 Junie 2012 eindig.

I MACUN

UITVOERENDE BESTUURDER: KOLLEKTIEWE BEDINGING

SOUTH AFRICAN REVENUE SERVICE
SUID-AFRIKAANSE INKOMSTEDIENS

No. R. 126

26 February 2010

CUSTOMS AND EXCISE ACT, 1964.
AMENDMENT OF SCHEDULE NO. 1 (NO. 1/1/1401)

In terms of section 48 of the Customs and Excise Act, 1964, Part 1 of Schedule No. 1 to the said Act is hereby amended to the extent set out in the Schedule hereto.

N NENE
DEPUTY MINISTER OF FINANCE

SCHEDULE

By the substitution of the following subheading:

Heading	Subheading	CD	Article Description	Statistical Unit	Rate of Duty			
					General	EU	EFTA	SADC
40.09	4009.21		- - Without fittings:					

By the insertion after subheading 4009.21 of the following subheadings:

Heading	Subheading	CD	Article Description	Statistical Unit	Rate of Duty			
					General	EU	EFTA	SADC
40.09	4009.21.10	9	- - - With an inside diameter of 100 mm or less	kg	free	free	free	free
40.09	4009.21.90	7	- - - Other	kg	15%	3,75%	9,5%	free

DOEANE- EN AKSYNSWET, 1964.
WYSIGING VAN BYLAE NO. 1 (NO. 1/1/1401)

Kragtens artikel 48 van die Doeane- en Aksynswet, 1964, word Deel 1 van Bylae No. 1 by bogenoemde Wet hiermee gewysig, in die mate in die Bylae hierby aangetoon.

N NENE
ADJUNKMINISTER VAN FINANSIES

BYLAE

Deur die vervanging van die volgende subpos:

Pos	Subpos	T S	Artikel Beskrywing	Statistiese Eenheid	Skaal van Reg			
					Algemeen	EU	EFTA	SAOG
40.09	4009.21		- - Sonder toebehore:					

Deur na subpos 4009.21 die volgende subposte in te voeg:

Pos	Subpos	T S	Artikel Beskrywing	Statistiese Eenheid	Skaal van Reg			
					Algemeen	EU	EFTA	SAOG
40.09	4009.21.10	9	- - - Met 'n binnedeursnee van 100 mm of minder	kg	vry	vry	vry	vry
40.09	4009.21.90	7	- - - Ander	kg	15%	3,75%	9,5%	vry

SPORT AND RECREATION SOUTH AFRICA
SPORT EN REKREASIE SUID-AFRIKA

No. R. 124 **26 February 2010**

Draft 2010 HEALTH REGULATIONS:

INVITATION TO SUBMIT YOUR INPUTS ON THE DRAFT REGULATIONS RELATING TO THE ACCREDITATION OF FOREIGN MEDICAL CONTINGENTS AND APPROVAL OF MEDICINES, SCHEDULED SUBSTANCES AND MEDICAL DEVICES (hereinafter referred to as **"the draft Regulations");**

The Minister of Sport and Recreation intends to promulgate the draft Regulations during May 2010 and has published the Regulations as well as a notice inviting role players for their inputs in the Government Gazette.

Section 6 of the SECOND 2010 FIFA WORLD CUP SOUTH AFRICA SPECIAL MEASURES ACT (hereinafter referred to as **"the Act")** stipulates as follows:

"6. Regulations

(1) The Minister may, in consultation with the Minister of Trade and Industry or **the Minister of Health**, as the case may be, make regulations regarding-

(a) .....;

(b) **the suspension of the prohibition on the possession, compounding and dispensing of permitted medicines and Scheduled substances and permitted medical devices and the registration of and the performance of community service by health care providers, in order to give effect to the Organising Association Agreement;** and

(c) .....".

A copy of the Regulations can be obtained from:

1. Sport and Recreation South Africa by addressing an e-mail to Gideon Boshoff at gideon@srsa.gov.za or
2. the website of Sport and Recreation South Africa at www.srsa.gov.za

Role players as well as the public at large are hereby invited to submit its inputs on the draft Regulations **not later than 27 March 2010 to-**

- Gideon Boshoff at **gideon@srsa.gov.za** or **legalservices@srsa.gov.za**
- SRSA, Private Bag X896, PRETORIA, 0001 (marked for the attention of Legal Services); or
- The following fax no: 012 323 2135 (Attention: Legal Services)

No. R. 125 26 February 2010

SECOND 2010 FIFA WORLD CUP SOUTH AFRICA SPECIAL MEASURES ACT, 2006 (ACT NO. 12 OF 2006)

REGULATIONS RELATING TO THE ACCREDITATION OF FOREIGN MEDICAL CONTINGENTS AND APPROVAL OF MEDICINES, SCHEDULED SUBSTANCES AND MEDICAL DEVICES

The Minister of Sport and Recreation South Africa has, in consultation with the Minister of Health in terms of section 6 of the Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006), made the regulations in the Schedule.

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act, shall bear such meaning, and unless the context otherwise indicates—

"the Act" means the Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006).

Application for accreditation of foreign medical contingent

2. An application for the accreditation of a foreign medical contingent referred to in section 3(1)*(a)* of the Act must be submitted in a form similar to **Annexure "A"** and must be accompanied by -

(a) a certified copy of the bio-information page of the passport of every member of the foreign medical contingent;

(b) a passport sized colour photograph of every member of the foreign medical contingent attached to the corresponding copy of the said bio-information page of the passport; and

(c) proof of registration as a health care professional in the country of origin in respect of every member of the foreign medical contingent.

Accreditation of foreign medical contingent

3. The accreditation of a foreign medical contingent granted by the Minister of Health in terms of section 3(1) of the Act, must be in a form similar to **Annexure "B".**

Request for approval of medicines, Scheduled substances and medical devices

4. A request for approval of medicines, Scheduled substances and medical devices that may be used by an accredited foreign medical contingent referred to in section 3(3)*(a)* of the Act, must be submitted in a form similar to **Annexure "C".**

Suspension of prohibition on possession, compounding and dispensing of permitted medicines, Scheduled substances and permitted medical devices

5. An accredited member of a foreign medical contingent is exempted from all prohibitions imposed by the laws listed in section 5(1)*(c)* of the Act, regarding possession, compounding and dispensing of medicines, Scheduled substances and medical devices for which an approval has been granted under regulation 4.

Suspension of prohibition on registration of and performance of community service

6. An accredited member of a foreign medical contingent is exempted from all prohibitions imposed by the laws listed in section 5(2)*(b)* of the Act, regarding the registration of and the performance of community services by health care providers.

Short title

7. These Regulations shall be called the Regulations relating to the Accreditation of Foreign Medical Contingents and Approval of Medicines, Scheduled Substances and Medical Devices, 2010.

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

ANNEXURE A

APPLICATION FOR AN ACREDITATION OF FOREIGN MEDICAL CONTINGENT

Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006)

Regulation 2

To be completed in full and submitted to the The Minister of Health. The form to be completed in black ink with BLOCK LETTERS. Applications that are not legible shall not be accepted. Where space provided is inadequate, attach additional information.

Note: Please attach the following documents:
(a) a certified copy of the bio-information page of the passport of every member of the foreign medical contingent;
(b)a passport sized colour photograph of every member of the foreign medical contingent (attach to relevent passport copy)
(c)proof of registration as a health care professional in the country of origin in respect of every member of the foreign medical contingent.

PARTICULARS OF MEMBERS OF FOREIGN MEDICAL CONTINGENT

FULL NAMES AND SURNAME	PASSPORT NUMBER	COUNTRY OF ORIGIN OF THE TEAM	REGISTERED PROFESSION

PERIOD DURING THE 2010 WORLD CUP FOR WHICH ACCREDITATION IS REQUIRED

From Y Y Y Y M M D D To Y Y Y Y M M D D

NAME OF EACH MEMBER OF THE TEAM TO WHOM THE MEMBERS OF THE FOREIGN MEDICAL CONTINGENT MAY RENDER HEALTH SERVICES

FULL NAMES AND SURNAME	FULL NAMES AND SURNAME

PARTICULARS OF A FIFA REPRESENTANTITIVE MAKING AN APPLICATION

ID number (Passport No. if foreigner) Gender

Date of birth Y Y Y Y M M D D Citizenship

Surname

Previous/Maiden surname

First names in full

Place of birth: City/Town Country of birth

Residential address: Street

Town/Village Province Postal code

I hereby in my capacity as .....(state the representative capacity in FIFA) in terms of section 3(1) of the Second 2010 FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006), apply to the Minister of Health for accreditation of persons mentioned above. I declare that the information supplied herein is to the best of my knowledge true and accurate.

Place..... Date..... Signature.....

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

ANNEXURE B

CERTIFICATE OF ACCREDITATION

Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006)

Regulation 3

I.....Minister of Health, hereby, in terms of section 3(1) of the Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006), grant accreditation to the undermentioned person, subject to the conditions specified hereunder.

PARTICULARS OF MEMBER OF FOREIGN MEDICAL CONTINGENT

Place Photograph

REGISTRATION NO.... .(Country of Origin)

FULL NAMES AND SURNAME	PASSPORT NUMBER	COUNTRY OF ORIGIN OF THE TEAM	REGISTERED PROFESSION

VALIDITY PERIOD

From Y Y Y Y M M D D To Y Y Y Y M M D D

CONDITIONS:

Place..... Date..... Signature.....

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

ANNEXURE C
PART 1

REQUEST FOR APPROVAL OF MEDICINES, SCHEDULED SUBSTANCES AND MEDICAL DEVICES TO BE USED BY AN ACCREDITED FOREIGN MEDICAL CONTINGENT

Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006)

Regulation 4

To be completed in full and submitted to the The Minister of Health. The form to be completed in black ink with BLOCK LETTERS. Request that are not legible shall not be accepted.

*Delete whichever is not applicable

MEDICINES

NAME OF MEDICINE	NAME OF MANUFACTURER	QUANTITY OF MEDICINE	FOREIGN REGISTRATION NUMBER

SCHEDULED SUBSTANCES

NAME OF SCHEDULED SUBSTANCE	NAME OF MANUFACTURER	QUANTITY OF SCHEDULED SUBSTANCE	FOREIGN REGISTRATION NUMBER

MEDICAL DEVICES

NAME OF MEDICAL DEVICE	NAME OF MANUFACTURER	QUANTITY OF MEDICAL DEVICE	FOREIGN REGISTRATION NUMBER

PARTICULARS OF A FIFA REPRESENTANTITIVE MAKING A REQUEST FOR APPROVAL

ID number (Passport No. if foreigner) Gender

Date of birth Y Y Y Y M M D D Citizenship

Surname

Previous/Maiden surname

First names in full

Place of birth: City/Town Country of birth

Residential address: Street

Town/Village Province Postal code

I hereby in my capacity as ....(state the representative capacity in FIFA) in terms of section 3(3) of the Second 2010 FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006), request the Minister of Health to approve the mentioned abovementioned medicines, scheduled substances and medical devices* to be used by ....(mention the team) foreign medical contingent. I declare that the information supplied herein is to the best of my knowledge true and accurate.

Place . .. ... Date ... . Signature... ... .

REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF HEALTH

ANNEXURE C
PART 2

APPROVAL OF MEDICINES, SCHEDULED SUBSTANCES AND MEDICAL DEVICES TO BE USED BY AN ACCREDITED FOREIGN MEDICAL CONTINGENT

Second FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006)

Regulation 4

*Delete whichever is not applicable

MEDICINES

NAME OF MEDICINE	NAME OF MANUFACTURER	QUANTITY OF MEDICINE	FOREIGN REGISTRATION NUMBER

SCHEDULED SUBSTANCES

NAME OF SCHEDULED SUBSTANCE	NAME OF MANUFACTURER	QUANTITY OF SCHEDULED SUBSTANCE	FOREIGN REGISTRATION NUMBER

MEDICAL DEVICES

NAME OF MEDICAL DEVICE	NAME OF MANUFACTURER	QUANTITY OF MEDICAL DEVICE	FOREIGN REGISTRATION NUMBER

CONDITIONS

I, ...Minister of Health, hereby, in terms of section 3(3) of the Second 2010 FIFA World Cup South Africa Special Measures Act, 2006 (Act No. 12 of 2006), approve the abovementioned medicines, scheduled substances and medical devices* to be used by..... ....(Name of the team) foreign medical contingent, subject to the conditions specified above.

Place. .... Date.. .... Signature . ...