No. R. 266 **1 April 2011**

NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

REGULATIONS RELATING THE IMPORT AND EXPORT OF HUMAN TISSUE, BLOOD, BLOOD PRODUCTS, CULTURED CELLS, STEM CELLS, EMBRYOS, ZYGOTES AND GAMETES

The Minister of Health intends, in terms of section 68 of the National Health Act, 2003 (Act No. 61 of 2003), after consultation with the National Health Council, to make the regulations in the Schedule.

Interested person are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 within three months from the date of publication of this notice.

SCHEDULE

Definitions

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

"Act" means the National Health Act, 2003 (Act No. 61 of 2003);

"annexure" means an annexure to these regulations;

"applicant" means any organisation, institution or person applying for an export or import permit;

"authorised organisation, institution or person" means any organisation, institution or person referred to in regulation 3(1), 4, 5(1), 6(1) or 7(1);

"biological standards" mean norms or guidelines used to ensure the preservation of biological substances of human origin for the purpose which these substances are intended to be used;

blastocyst" means a pre-implantation embryo consisting of an outer layer which forms the placenta and a 30 to 200 cell inner cell mass which develops into the foetus;

"blastomere" **means** an undifferentiated embryonic cell, also called a "blastocyte";

"blood" means human blood intended for transfusion purposes, including the components thereof, but excludes blood specimens intended for pathology testing;

"blood donor" means any living person who voluntarily and not for remuneration has blood withdrawn from him or her for the subsequent administering thereof to themselves or another person or for processing into blood products;

"category" means the classification of human substances in categories as set out in Annexure 1, 2 and 3;

"cDNA" means a single stranded segment of DNA that is complimentary to the mRNA (messenger RNA) of a coding DNA segment a whole exon or a whole gene or part of a gene;

"DNA" means Deoxyribose Nucleic Acid which is a nucleic acid composed of building blocks called nucleotides;

"diagnostic substance" means any product or device produced from a substance that may be used in the diagnosis of any disease or condition that may be transmitted by blood or a blood product;

"embryo" means a human offspring in the first eight weeks of conception;

"embryonic tissue" means tissue from an embryo;

"foetus" means a human offspring from eight weeks after conception until birth;

"foetal tissue" means tissue from a foetus;

"import" means import into the Republic in any manner;

"Medicines Control Council" means the organisation established in terms of section 2 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) or its successor in title;

"plasma" means –

(a) the fluid portion of blood obtained as a by-product of whole blood donation; or

(b) plasma collected directly from a person by a process of plasmapheresis;

"primary container" means the container into which plasma is directly placed;

"primary organisation or person" means an organisation or person which or who is, within the relevant laws of the particular country, an organisation or person similar to an authorised organisation, institution or person;

"Republic" means the Republic of South Africa;

"RNA" means Ribonucleic Acid, which is a linear sequence of ribonucleotides;

"Standards of Practice" means the standards of practice for blood transfusion in South Africa, determined by the Minister;

"stem cell" means any embryonic stem cell or circulating, bone marrow, umbilical cord or haemopoietic progenitor cell, or any cell that is capable of replicating or proliferating and giving rise to a differentiated cell;

"substance" means tissue, blood, blood product or gamete;

Import and Export Permits

2 (1) No person may import or export any tissue or any blood, blood product, , cultured cells, stem cells or embryo without a permit issued in terms of these regulations.

(2) Any person who wishes to import or export any tissue or any blood, blood product, cultured cells, stem cells, embryo, zygote or gamete, must apply in writing to the Director-General in the form set out in Annexure 4 or 5 of these regulations.

(3) The Director-General may on receipt of the application issue a permit to a person authorising such a person to import or export, subject to such conditions as the Director-General may determine and record on the permit, including an expiry date, any tissue or any blood, blood product, and cultured cells.

(4) The Director-General may issue a permit authorising the applicant to export or import any tissue, blood, blood product, and cultured cells. If he or she is satisfied that the information submitted in support of an application for a permit meets the requirements of these regulations.

3 (1) An applicant for an export permit must have proof in writing that the tissue or gametes for which an export permit is being applied for, was or were donated in terms of the Act, and that the tissue or gametes to be exported are to be used in terms of the Act, and such proof must accompany the application.

(2) In the case of gametes, zygotes and embryos a permit will only be issued if-

(a) An application for an export permit is accompanied by the donor information required in terms of *Regulations Relating to Artificial Fertilisation of Persons and Related Matters but* excluding the identification of the donor or

(b) An application for an import permit is accompanied by the information required in terms of regulation 3(3)(a) above, and the gametes are to be used in an identified and confirmed recipient.

Whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate

4 (1) The Director-General may at her or his discretion issue an export permit which is contrary to the provisions of regulation 4(10)(a) and 4(12)(a) and subject to the provisions of regulation 4(12)(b) –

(a) For rare blood or whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate, on humanitarian grounds;

(b) In a case of emergency; or

(c) For the blood or whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate to be administered to a citizen or permanent resident of the Republic who is in a country other than the Republic.

(2) No import or export permit shall be issued for placenta tissue, embryonic or foetal tissue, or embryonic, foetal and umbilical stem cells, except with the written consent of the Minister and subject to any condition as the Minister may determine.

(3) In the case of tissue for therapeutic use, an import permit shall only be issued if the application is accompanied by information in respect of the health status of the donor, particularly regarding transmissible diseases and the results of tests performed in that regard.

(4) Tissue with a mass less than 50g and which is intended for diagnostic and research purposes, is excluded from the provisions of regulation 4(3).

(5) (a) The Director-General may refuse to issue an import or export permit under regulation 4(1) if the information required in terms of these regulations has not been provided.

(b) In the event of the Director-General not issuing a permit in terms of regulation 4(5)(a), the reasons for not issuing a permit must be provided in writing to the applicant.

(6) A permit issued in terms of regulation 4(1) must not be used for any commercial or advertising purposes.

(7) An applicant to whom a permit has been issued, must ensure that the transportation of the substance for which a permit has been issued, is in accordance with biological standards applicable to such substance...

(8) (a) An applicant to whom a permit has been issued in terms of regulation 4(1), must keep a record of such export or import in accordance with the form in Annexure 6 or 7;

(b) The record in paragraph (a) must be submitted to the Director-General before the end of February each year, for the preceding calendar year; and

(c) The provisions of paragraphs (a) and (b) are not applicable to the exportation or importation of blood, plasma and serum in category 3 of Annexure 3, and tissue in regulation 7(6).

(9) (a) Prior to the issuing of an export permit for biological substances of human origin the Director-General must be satisfied that the supply requirements of the Republic for the substance for which an export permit is being applied for, have been met;

(b) The supply requirements under paragraph (a) shall be determined by a minimum level of national stock, for a period determined by the Director-General based on the average, supply or availability, as the case may be; and

(c) In compliance with paragraph (b), the applicant must provide the Director-General with written information of stock levels, with the export permit request.

(10) (a) The issuing of an export permit for biological substances may only be to a Southern African Development Community (SADC) member state, provided that the requirements of the Republic's market have been met;

(b) Each consignment of biological substances of human origin imported into the Republic shall be accompanied by a certificate from the supplier, stating that the substance has been exported in terms of the applicable laws and regulations of the country from which such substance originates;

(c) Each consignment of biological substances of human origin exported from the Republic shall be imported in terms of the applicable laws and regulations of the country for which such substance is procured.

(11) Each consignment of blood or blood products to be exported or imported shall be accompanied by –

(a) A certificate from the national blood transfusion service stating that the blood or blood product has been tested in accordance with the *Regulations Regarding Blood and Blood Products;*

(b) The results of such tests; and

(c) Substantive motivation addressed to the Director-General in writing in a case of any deviation from the provisions of paragraphs (a) or (b).

(12) (a) Notwithstanding the provisions of this paragraph, each consignment of blood or substance to be used for the supply of a blood product which is imported and which is intended for therapeutic purposes, must be tested by the national transfusion service in accordance with the requirements of the *Regulations Regarding Blood and Blood Products.*

(b) The Director-General may, after consultation with the national blood transfusion service determine the tests that must be carried out on imported substances.

(13) The Minister may, subject to the provisions of section 58 of the Act, based on substantive motivation, exempt any organisation, institution or person from any provision of these regulations subject to conditions the Minister may determine.

Blood, plasma and serum, cultured cells, stem cells, embryo, zygote or gamete for reagent, research or diagnostic purposes

5 (1) An applicant for a category 1 blood product in Annexure 3 must be an organisation or person conducting *bona fide* research in the human health field, or be involved in the testing of human substances for diagnostic purposes.

(2) (a) Plasma may only be exported for the manufacture of reagents, controls or diagnostic substances for blood transfusion services.

(b) Plasma referred to in paragraph (a) may only be exported to a primary organisation or person, or an organisation which or person that is a manufacturer or supplier of diagnostic substances for blood transfusion services.

(3) The organisation or person referred to in subregulation (2)(a), must state in writing the purpose for which the plasma exported from the Republic will be used, and such statement must accompany the application for an export permit.

(4) Each primary container with plasma must be conspicuously marked with the following words: "HUMAN PLASMA FOR DIAGNOSTIC OR RESEARCH PURPOSES: NOT FOR THERAPEUTIC USE", with each character of such wording being at least 5mm in size.

(5) The total volume of plasma exported per shipment for purposes referred to in subregulation (2)(a), shall not exceed 5000 ml.

(6) Every application for an export permit for plasma referred to subregulation (2)(a), is restricted to a single organisation or person mentioned in that application and for a single shipment from a single authorised organisation, institution or person.

(7) An applicant for an export permit for category 1 blood production Annexure 3 must have consent in writing from the donor that if the donation is not suitable for transfusion purposes, then that donation may be used for the advancement of medicine, and such consent must be confirmed by the applicant in writing when applying for a permit.

Disposal of tissue, blood, blood products , cultured cells, stem cells, embryo, or gametes imported without permit or contrary to permit conditions

6 (1) Where any tissue or blood, blood product, , cultured cells, stem cells, embryo or gamete has been imported in contravention of these regulations or conditions of a permit, the Director-General may–

(a) Order the importer concerned in writing to destroy or to remove from the Republic the tissue, blood, blood product, , cultured cells, stem cells, embryo or gamete so imported within the period determined by the Director-General and at the expense of that importer; and

(b) Order that, if the importer concerned does not so destroy or remove the tissue, blood, blood product, , cultured cells, stem cells, embryo or gamete concerned, it shall be forfeited to the State.

(2) If the importer contemplated in sub-regulation (1), after receipt of a written order under that regulation, fails to comply with such order, the Director-General may seize the tissue, blood, blood product or gamete and so dispose thereof in such manner as she or he may deem fit, at the expense of the importer.

(3) Any person who considers herself or himself aggrieved by a decision of the Director-General in connection with her or his application for the issue of a permit in terms of regulation 2(2) or with an order under regulation 6(1), may within 60 days after the date of such decision or order appeal in writing to the Minister, who may confirm, alter or set aside that decision or order.

Register

7 (1) A register must be kept by an authorised institution that has imported or exported any biological substance in terms of these regulations.

(2) The following particulars must be recorded in the register contemplated in sub-regulation (1), in respect of -

(a) Import of a biological substance, in which case the form in Annexure 6 must be completed:

(i) The name, address, telephone number, facsimile number and e-mail address of the authorised institution that has imported the substance;

(ii) The name, address, telephone number, fax number and e-mail address of the organisation or person who has imported the substance on behalf of an authorised institution;

(iii) The period for which the record of imports are applicable;

(iv) The name of the substance, date of import, quantity of the substance and the name of the primary organisation or person which or who has exported or supplied the substance to the Republic for each import of each substance within the period referred to in sub-paragraph (iii) above;

(v) The name of the substance, date of import, quantity of the substance and the name of the organisation or person which or who has exported or supplied the substance to the Republic, on behalf of a primary organisation

or person, for each import of each substance within the period referred to in subparagraph (iii);

(vi) In respect of the person entering information in the register of imports –

(aa) the name of the person;

(bb) position or rank of the person within the authorised institution; and

(cc) the signature of that person; and

(vii) The date on which the information has been entered in the import register by the person referred to in subparagraph (vi) above;

(b) Export of a human substance, in which case the form in Annexure 7 must be completed:

(i) The name, address, telephone number, fax number and e-mail address of the authorised institution that has exported the substance;

(ii) The name, address, telephone number, fax number and e-mail address of the organisation or person who has exported the substance on behalf of an authorised organisation, institution or person;

(iii) The period for which the record of exports are applicable;

(iv) The name of the substance, date of export, quantity of the substance and the name of the primary organisation or person which or who has procured the substance from the Republic, for each export of each substance within the period referred to in sub-paragraph (iii) above;

(v) The name of the substance, date of export, quantity of the substance and the name of the organisation or person which or who has procured the substance from Republic on behalf of the primary organisation or person, for each export of each substance within the time period referred to in sub-paragraph (iii) above;

(vi) In respect of the person entering information in the register of exports –

(aa) the name of the person;

(bb) position or rank of the person within the authorised organisation or institution, or organisation or institution; and

(cc) the signature of that person; and

(vii) The date on which the information has been entered in the export register by the person referred to in sub-paragraph (vi) above.

(3) (a) A copy of the register referred to in sub-regulation (1) must be provided to the Director-General at intervals not exceeding six months by the authorised institution.;

(b) The register referred to in paragraph (a) must be retained for a minimum period of five years after the last entry in such register.

Delegation of powers

8 (a) The Director-General may, subject to such conditions she or he may determine, in writing delegate to any officer in the Department any power conferred upon her or him by or under these regulations.
(b) The Director-General shall not be divested of a power delegated by her or him under paragraph (a), and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

Offences and penalties

9. Any person who contravenes or fails to comply with any provision of these regulations shall be guilty of an offence, and liable on conviction to a fine or to imprisonment for e period not exceeding 10 years or to both fine and such imprisonment.

DR A MOTSOALEDI
MINISTER OF HEALTH

Annexure 1

BLOOD, PLASMA, CULTURED CELLS, STEM CELLS, EMBRYO, ZYGOTE, GAMETES AND SERUM FOR REAGENT, DIAGNOSTIC, THERAPEUTIC, REPRODUCTIVE OR RESEARCH PURPOSES

Diagnostic, Therapeutic, Reproductive or Research Material (< 50 ml) **Category 1**	**Bulk Unprocessed Laboratory Plasma (50 ml - 5000 ml) Category 2**	
Blood Plasma Serum Cultured cells Chorionvillus sample Stem cells Embryos Zygotes Gametes Foetal tissue	Bulk diseased-state plasma Plasma	

Annexure 2

DEPARTMENT OF HEALTH
APPLICATION FOR AN IMPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

PART A

APPLICANT					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
MAIN BUSINESS1[1]					
TELEPHONE NO.		FAX NO.		E-MAIL	

SUBSTANCE(S) FOR WHICH AN IMPORT PERMIT IS REQUIRED	
SUBSTANCE2[2]	***QUANTITY 3[3]***
Period during which import(s) will take place	

ORGANISATION OR PERSON EXPORTING THE SUBSTANCE (S) TO SOUTH AFRICA4[4]	
NAME OF PERSON	
Rank/Position	
NAME OF ORGANISATION	
Address of organisation or person	

1[1] The main business of the organisation or person must be provided, e.g. fractionation unit, exporting agent or broker, researcher, etc.

3[3] The quantity must be expressed in mass, volume or units, whichever is most appropriate.

4[4] If the exporting organisation or person is not a primary organisation or person in terms of the *Regulations* and intends to export the substance(s) on behalf of such primary organisation or person, the applicant must obtain the information required in Section 2 of Part B in respect of such primary organisation or person.

COUNTRY					
MAIN BUSINESS[2]					
TELEPHONE NO.		FAX NO.		E-MAIL	

PURPOSE (S) FOR WHICH SUBSTANCE (S) IS (ARE) TO BE USED5[5]

Annexure 2

DEPARTMENT OF HEALTH

APPLICATION FOR AN IMPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

PART B

Section 1

AUTHORISED ORGANISATION, INSTITUTION OR PERSON IMPORTING THE SUBSTANCE (S)					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		FAX NO.		E-MAIL	

Section 2

PRIMARY ORGANISATION OR PERSON EXPORTING THE SUBSTANCE(S) TO SOUTH AFRICA	
NAME OF PERSON	
Rank/Position	
NAME OF	

5[5] The synopsis and not the substance of the detail must be furnished. .

ORGANISATION					
Address of organisation or person					
COUNTRY					
MAIN BUSINESS[2]					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

NAME OF ENQUIRIES CONTACT PERSON	**TELEPHONE NUMBER**	
	( )	
NAME OF PERSON SUBMITTING APPLICATION	**SIGNATURE**	**DATE**

Annexure 3

DEPARTMENT OF HEALTH

APPLICATION FOR AN EXPORT LICENCE FOR BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

PART A

APPLICANT1					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
MAIN BUSINESS2					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

1 If the applicant is not an authorised institution in terms of the s 54 Notice and intends to export the substance(s) on behalf of such authorised institution , then the applicant must obtain the information required in Section 1 of Part B in respect of such authorised institution.

2 The main business of the organisation or person must be provided, e.g. fractionation unit, exporting agent or broker, researcher, etc.

SUBSTANCE(S) FOR WHICH AN EXPORT PERMIT IS REQUIRED	
SUBSTANCE3	***QUANTITY 4***
Period during which import(s) will take place	

ORGANISATION OR PERSON IMPORTING THE SUBSTANCE (S) FROM SOUTH AFRICA5					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
COUNTRY					
MAIN BUSINESS[2]					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

PURPOSE(S) FOR WHICH SUBSTANCE(S) IS(ARE) TO BE USED6

Annexure 3

DEPARTMENT OF HEALTH

APPLICATION FOR AN EXPORT LICENCE FOR SUBSTANCES OF HUMAN ORIGIN

PART B

Section 1

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4 The quantity must be expressed in mass, volume or units, whichever is most appropriate.

5 If the importing organisation or person is not a primary organisation or person in terms of the *Regulations* and intends to import the substance(s) on behalf of such primary organisation or person, the applicant must obtain the information required in Section 2 of Part B in respect of such primary organisation or person.

6 Although detail is not required, the specific purpose(s) for which the substance(s) is(are) to be used must be clearly stated.

AUTHORISED ORGANISATION, INSTITUTION OR PERSON EXPORTING THE SUBSTANCE (S)					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

Section 2

PRIMARY ORGANISATION OR PERSON IMPORTING THE SUBSTANCE (S) FROM SOUTH AFRICA					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
COUNTRY					
MAIN BUSINESS[2]					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

NAME OF ENQUIRIES CONTACT PERSON	**TELEPHONE NUMBER**
	( )

NAME OF PERSON SUBMITTING APPLICATION	**SIGNATURE**	**DATE**

Annexure 4

REGISTER OF IMPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 1

AUTHORISED ORGANISATION, INSTITUTION OR PERSON IMPORTING THE SUBSTANCE(S)1					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

Section 2

ORGANISATION OR PERSON IMPORTING THE SUBSTANCE(S)					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

Section 3

ACTUAL IMPORTS FOR PERIOD:			
DATE	**SUBSTANCE**	**QUANTITY**	**NAME OF PRIMARY ORGANISATION OR PERSON**

1 If the imports have been done on behalf of the authorised institution by another organisation or person, section 2 must also be completed.

			EXPORTING/SUPPLYING THE SUBSTANCE TO SOUTH AFRICA2

Annexure 5

REGISTER OF IMPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 4

ACTUAL IMPORTS FOR PERIOD:			
DATE	SUBSTANCE	QUANTITY	NAME OF ORGANISATION OR PERSON EXPORTING/SUPPLYING THE SUBSTANCE TO SOUTH AFRICA

2 If the exports to South Africa have been done on behalf of a primary organisation or person, section 4 must also be completed.

Section 53

NAME OF PERSON PROVIDING INFORMATION	POSITION IN ORGANISATION	SIGNATURE	DATE

3 Section 5 must be completed in all instances.

Annexure 6

REGISTER OF EXPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 1

AUTHORISED ORGANISATION, INSTITUTION OR PERSON EXPORTING THE SUBSTANCE(S)1					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

Section 2

ORGANISATION OR PERSON EXPORTING THE SUBSTANCE(S)					
NAME OF PERSON					
Rank/Position					
NAME OF ORGANISATION					
Address of organisation or person					
TELEPHONE NO.		**FAX NO.**		**E-MAIL**	

Section 3

1 If the exports have been done on behalf of the authorised institution by another organisation or person, section 2 must also be completed.

ACTUAL EXPORTS FOR PERIOD:			
DATE	**SUBSTANCE**	**QUANTITY**	**NAME OF PRIMARY ORGANISATION OR PERSON IMPORTING/PROCURING THE SUBSTANCE FROM SOUTH AFRICA2**

Annexure 6

REGISTER OF EXPORTED BIOLOGICAL SUBSTANCES OF HUMAN ORIGIN

Section 4

ACTUAL EXPORTS FOR PERIOD:			
DATE	**SUBSTANCE**	**QUANTITY**	**NAME OF ORGANISATION OR PERSON IMPORTING/PROCURING THE SUBSTANCE FROM SOUTH AFRICA**

2 If the imports from South Africa have been done on behalf of a primary organisation or person, section 4 must also be completed.

Section 53

NAME OF PERSON PROVIDING INFORMATION	POSITION IN ORGANISATION	SIGNATURE	DATE

3 Section 5 must be completed in all instances.