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**European Communities (Quality and Safety of Human Tissues and Cells)
Regulations 2006**

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European Communities (Quality and Safety of Human Tissues and Cells)

Regulations 2006

Table of Contents

PART 1

PRELIMINARY

REGULATION	PAGE
1. Citation and Commencement.....	5
2. Interpretation.....	6
3. Application.....	11
4. Competent Authority.....	12

PART 2

PROVISIONS APPLICABLE FOR AUTHORISATION OF TISSUE ESTABLISHMENTS AND PROCUREMENT ORGANISATIONS

5. Requirements for authorisation.....	13
6. Authorisation of tissue establishment or procurement organisations.....	14
7. Suspension or revocation of authorisation.....	17
8. Responsible person for tissue establishment.....	20
9. Requirements for the procurement and supervision of procurement of human tissues and cells.....	22
10. Quality management and notification of serious adverse events and reactions	25

11.	Donor selection, evaluation and testing criteria.....	27
12.	Tissue and cell reception, processing, storage and distribution....	30
13.	Principles governing tissue and cell donation and voluntary unpaid donation.....	33
14.	Traceability and labelling of tissues and cells.....	34
15.	Import and export of human tissues and cells.....	35
16.	Relations between tissue establishments and third parties.....	36
17.	Objections to refusals of authorisation or suspension or revocation of authorisation.....	37
18.	Disclosure of information by tissue establishments and data protection.....	40
19.	Inspections.....	42
20.	Records to be kept by the Irish Medicines Board.....	44

PART 3

AUTHORISED OFFICERS AND TESTING, ETC. OF SAMPLES, ETC.

21.	Interpretation (Part 3)	45
22.	Authorised officers.....	47
23.	Taking of samples by authorised officers.....	52
24.	Certificate of result of test, etc. of sample, etc.....	54

PART 4

OFFENCES

25.	Offences	56
26.	Offence to import below standard tissues and cells into the State.....	59

27.	Offence by body corporate.....	60
28.	Defence of due diligence.....	61
29.	Proceedings may be brought by the IMB.....	62

PART 5

MISCELLANEOUS

30.	Reports by the IMB.....	63
31.	Specific epidemiological situations.....	64
32.	Fees.....	65

Schedule 1	Selection criteria for donors of tissues and/or cells (except donors of reproductive cells) as referred to in Regulation 11.2 (a) and 11 (7).....	66
Schedule 2	Laboratory tests required for donors (except donors of reproductive cells) as referred to in Regulation 11.1 (a) and (b).....	70
Schedule 3	Selection criteria and laboratory tests required for donors of reproductive cells as referred to in Regulation 11.(1) (c) and (d) and 11.(2)(b).....	73
Schedule 4	Cell and/or tissue donation and procurement procedures and reception at the tissue establishment as referred to in <i>Regulations 9 and 12 and 14</i>	77
Schedule 5	Certificate stating results of test, examination or analysis.....	86

I, Mary Harney, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Directive 2004/23/EC¹ of the European Parliament and of the Council of 31 March, 2004, setting standards of quality and safety for the donation, procurement, testing, preservation, processing, storage and distribution of human tissues and cells, and Commission Directive 2006/17/EC² of 8 February, 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, hereby make the following Regulations:

PART 1
PRELIMINARY

Citation and commencement

1. (1) These Regulations may be cited as the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006.

- (2) These Regulations, other than Regulations 9(2), 9 (4), 11(1), 11(2), 11 (7), 12(1), 12(2), 12(3), 12(4), 14(3), 14(4), and 14 (5) come into operation on 7 April, 2006.

- (3) Regulations 9(2), 9 (4), 11(1), 11(2), 11 (7), 12(1), 12(2), 12(3), 12(4), 14(3), 14(4), and 14 (5) come into operation on 1 November, 2006.

¹ OJ L102 of 7.4.2004, p. 48

² OJ I 38 of 9.2.2006, p.40

Interpretation.

2. (1) In these Regulations, unless the context otherwise requires -

“allogeneic use” means cells or tissues removed from one person and applied to another;

“appropriate fee” means the fee concerned charged pursuant to *Regulation 32(1)*;

“authorised officer” means a person appointed under *Regulation 22(1)*;

“autologous use” means cells or tissues removed from and applied in the same person;

“cells” means individual human cells or a collection of human cells when not bound by any form of connective tissue;

“Commission” means the European Commission;

“the Directive” means Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

“the Directives” means Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and Commission Directive 2006/17/EC of 8 February, 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;

“direct use” means any procedure where cells are donated and used without banking;

“distribution” means the transportation and delivery of tissues or cells intended for human applications;

“donation” means donating human tissues or cells intended for human applications;

“donor” means every human source, whether living or deceased, of human cells or tissues;

“functions” includes powers and duties, and references to the performance of functions include, with respect to powers and duties, references to the exercise of powers and the carrying out of the duties;

“human application” means the use of tissues or cells on or in a human recipient and extracorporeal applications;

“IMB” means the Irish Medicines Board established by section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended;

“inspection” means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these Regulations;

“Minister” means the Minister for Health and Children;

“organ” means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

“partner donation” means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

“preservation” means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

“prescribed activity” means any activity consisting of any aspect of -

- (a) the donation, procurement, testing, processing, preservation, storage or distribution of tissues or cells for human applications;

(b) the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells for use in manufactured products, where these products are not covered by other Directives;

(c) the donation, procurement and testing of tissues and cells for use in manufactured products, where those products are covered by other Directives;

“processing” means all operations involved in the preparation, manipulation, preservation, and packaging of tissues or cells intended for human applications;

“procurement” means a process by which tissue or cells are made available;

“procurement organisation” means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and may not be authorised as a tissue establishment”

“quality system” means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

“quarantine” means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

“reporting year” means the period of 12 months ending on 31 December;

“reproductive cells” means all tissues and cells intended to be used for the purpose of assisted reproduction;

“responsible person”, in relation to a tissue establishment, means the person who has been designated pursuant to *Regulation 8* as the responsible person for that tissue establishment;

“serious adverse event” means any untoward occurrence associated with the procurement testing, processing, storage or distribution of tissues and cells -

- (a) that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients, or
- (b) which might result in, or prolong, hospitalisation or morbidity;

“serious adverse reaction” means an unintended response, including a communicable disease, in the donor or in the recipient associated with procurement or human application of tissues and cells -

- (a) that is fatal, life-threatening, disabling or incapacitating, or
- (b) which results in, or prolongs, hospitalisation or morbidity;

“site”, means any premises at which any prescribed activity or activities are carried out;

“Standard Operating Procedures” (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

“storage” means maintaining the tissues and cells under appropriate controlled conditions until distribution;

“tissue” means all constituent parts of the human body formed by cells;

“tissue establishment” means a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage or distribution of human tissues and cells are undertaken;

“traceability” means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the

recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;

“validation” (or “qualification” in the case of equipment or environments) means the establishment of documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product, which meets its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;

(2) In these Regulations -

- (a) words and expressions which are also used in the Directive have the same meaning as in the Directive,
- (b) a reference to any other enactment, EC Directive or Regulation shall be construed as a reference to that enactment, EC Directive or Regulation as amended or extended by any other enactment, EC Directive or Regulation, including a Regulation of these Regulations,
- (c) a reference to a Regulation is a reference to a Regulation of these Regulations,
- (d) a reference to a paragraph, subparagraph, clause or subclause is a reference to a paragraph, subparagraph, clause or subclause of the provision in which the reference occurs, and
- (e) a reference to a Schedule is a reference to a Schedule of these Regulations.

Application.

3. (1) Subject to *paragraph (2)*, these Regulations shall apply to all prescribed activities.

(2) These Regulations shall not apply to –

- (a) tissues and cells used as an autologous graft within the same surgical procedure;
- (b) blood and blood components as defined by the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations, 2005 (S. I. No 360 of 2005);
- (c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.

(3) These Regulations shall apply to tissues and cells that are applied to the human body in clinical trials.

(4) These Regulations shall apply without prejudice to the Data Protection Acts 1988 and 2003 in so far as those Acts transpose Directive 95/46/EC³ of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

³ OJ L 281 of 23.11.1995, p.31

Competent Authority.

4. (1) The IMB is designated as the competent authority in the State for the purposes of the Directives and these Regulations.

(2) The IMB may enter into a contractual arrangement with a person for the purposes of the person assisting the IMB to perform its functions under the Directives and these Regulations.

PART 2
PROVISIONS APPLICABLE FOR AUTHORISATION OF TISSUE ESTABLISHMENTS
AND PROCUREMENT ORGANISATIONS

Requirements for authorisation.

5. (1) No person may carry out any prescribed activity otherwise than in accordance with an authorisation granted under *Regulation 6* (including any conditions to which the authorisation is subject).

(2) Tissue establishments shall comply with the requirements of Article 28(a) of the Directive. Pending a decision on the requirements of 28(a), tissue establishments shall comply with the standards set by the IMB under Regulation 6(2).

Authorisation of tissue establishment or procurement organisations

6. (1) Subject to Regulation 6(2), the IMB may grant an authorisation to a tissue establishment to carry out any prescribed activity at a specified site or sites, having satisfied itself that the tissue establishment -

- (a) complies with the requirements referred to in Article 28(a) of the Directive, and
- (b) complies with other relevant requirements of the Directives and these Regulations.

(2) Pending decisions on the requirements pursuant to Article 28 (a), (c), (g) and (h) of the Directive, the IMB shall set appropriate standards of quality and safety in respect of the matters referred to in Article 28 (a), (c), (g) and (h) and the IMB will have regard to these standards in respect of the matters referred to in these paragraphs when granting authorisations until such decisions have been made.

(3) An application for authorisation under *paragraph (1)* shall be made to the IMB.

(4) All applications for authorisation must –

- (a) include all relevant information as determined by the IMB, and
- (b) be accompanied by the appropriate fee.

(5) The IMB may –

- (a) grant or refuse any authorisation applied for under *paragraph (3)*, and
- (b) grant such authorisation -
 - (i) in respect of particular sites or prescribed activities only, and

(ii) subject to conditions.

(6) Where the IMB grants an authorisation, it shall give notice in writing to the tissue establishment specifying, in the case of prescribed activities, the prescribed activities which the tissue establishment may undertake under these Regulations at each site in respect of which authorisation is granted, and if the grant is subject to conditions, the conditions which apply to the undertaking of those activities,

(7) Subject to the requirements of *paragraph (8)*, the IMB may at any time remove or vary any of the conditions referred to in *paragraph 5(b)(ii)*, or may impose additional conditions.

(8) Where the IMB removes or varies any condition or imposes any additional condition pursuant to *paragraph (7)*, it shall serve a notice on the tissue establishment concerned which shall -

- (a) give details of the conditions which it proposes to remove, or of the variation which it proposes to make to any existing conditions, or of any additional condition which it proposes to impose,
- (b) give the reasons for its decision, and
- (c) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition shall apply.

(9) A tissue establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the IMB.

(10) Any application by a tissue establishment for approval to make a substantial change in its activities must be -

- (a) made in writing to the IMB, and

(b) accompanied by the appropriate fee.

(11) For the purpose of this Regulation, a substantial change in a tissue establishment's activities is any change -

(a) to the site or sites from which the tissue establishment operates or to the prescribed activities to be carried out at each site, and which would result in a failure to comply with the requirements of the Directives and these Regulations,

or

(b) to the quality system, as set out in accordance with Article 28(c) of the Directive, which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the prescribed activities which the tissue establishment has been authorised to undertake pursuant to this Regulation.

(12) The IMB shall authorise the tissue and cell preparation processes, which the tissue establishment may carry out in accordance with the requirements set out in Article 28(g) of the Directive.

(13) The IMB may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation.

(14) The IMB shall authorise the procurement of tissues and cells in accordance with the requirements of the Directives and these Regulations in respect of procurement organisations.

(15) The IMB shall authorise the laboratories that carry out the tests required for donors in accordance with the Directives and these Regulations.

Suspension or revocation of authorisation.

7. (1) Subject to *paragraph (2)*, the IMB may suspend or revoke the authorisation of a tissue establishment in respect of a site or sites and/or prescribed activity on one or more of the following grounds -

- (a) that the tissue establishment or process has not complied with the requirements of the Directives and these Regulations,
- (b) that a prescribed activity has not been or cannot be carried out pursuant to the requirements of the Directives and these Regulations.
- (c) that any tissues or cells cannot be supplied to hospitals for human application in such a state that they could be safely used, or
- (d) that the information given by the tissue establishment pursuant to *Regulation 6(4)* and *19 (3)* was false or incomplete in any material respect.

(2) Subject to *paragraph (3)*, before suspending or revoking the authorisation of a tissue establishment, the IMB shall serve notice on the tissue establishment stating that it intends to suspend or revoke its authorisation with effect from the date specified in the notice which shall be not less than 7 days from the date on which the notice is served.

(3) Where the IMB considers that it is necessary in the interests of safety, it may, by a notice served on a tissue establishment, suspend or revoke its authorisation with immediate effect.

(4) Where -

- (a) the tissue establishment has failed, in any material respect, to comply with the requirements of these Regulations, or

- (b) the information given by the tissue establishment pursuant to *Regulation 6(4)* and *19(3)* was false or incomplete in any material respect,

and the IMB considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the tissue establishment in the first instance, it may serve a notice on the responsible person of the tissue establishment in accordance with *paragraph (5)*.

(5) A notice served under this paragraph shall -

- (a) identify the requirements of these Regulations in respect of which the tissue establishment has failed to comply with or, in the case of false or incomplete information, the further information which is required,
- (b) identify the action which the tissue establishment is required to take, and
- (c) give the timescale within which the tissue establishment shall take the action identified in *subparagraph (b)*.

(6) If the tissue establishment fails to comply with the requirements set out in the notice within the specified timescale, the IMB may, by a notice served on the tissue establishment, suspend or revoke the authorisation of the tissue establishment.

(7) A suspension or revocation pursuant to *paragraph (6)* shall take effect -

- (a) in a case where the IMB considers that it is necessary in the interests of safety, immediately, or
- (b) in all other cases, from a date specified in the notice.

(8) Any suspension pursuant to *paragraph (1)* or *(6)* shall be for such period as the IMB shall consider necessary having regard to the reasons for the suspension.

(9) The suspension or revocation of an authorisation under *paragraph (1) or (6)* may be total, or may be limited to a particular prescribed activity or to one or more prescribed activities carried out at a particular site or sites, or to a particular tissue or cell.

Responsible person for tissue establishment.

8. (1) Subject to *paragraph (2)*, a tissue establishment shall designate a person who is responsible for the following functions -

- (a) ensuring that all prescribed activities are carried out in accordance with the requirements of these Regulations,
- (b) providing information to the IMB as required under Regulation 6, and
- (c) the implementation in the tissue establishment of the requirements under Regulations 9, 10, 11, 12, 14, 15, 16, 18, 19 and 20.

(2) A tissue establishment shall not designate a person under *paragraph (1)* unless that person has -

- (a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of -
 - (i) a university course of study, or
 - (ii) a course recognised as an equivalent course by the IMB, and
 - (b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under these Regulations for at least 2 years, in an establishment (or more than one establishment) in any Member State lawfully undertaking activities related to the collection or testing (or both) of tissues and cells, or to their procurement, storage and distribution.
- (3) The IMB shall from time to time publish details of courses recognised by it for the purpose of *paragraph (2)(a)(ii)*.
- (4) Tissue establishments shall inform the IMB of the name of the responsible person referred to in *paragraph (1)*.

(5) The responsible person may delegate any of the functions specified in *paragraph (1)* to other persons who shall be qualified by training and experience to perform them.

(6) Tissue establishments shall notify the IMB of the name of any persons to whom functions have been delegated by the responsible person under *paragraph (5)*, and the specific functions which have been delegated to such persons.

(7) Where the responsible person or a person to whom functions have been delegated under *paragraph (5)* is permanently or temporarily replaced, the tissue establishment shall without delay provide the IMB with the name of the replacement, details of his or her qualifications and the date on which the replacement began his or her duties.

(8) If the IMB considers that the responsible person does not meet the requirements of *paragraph (2)*, it may serve a notice to that effect on the tissue establishment.

(9) If, within 14 days of receiving a notice in accordance with *paragraph (8)*, a tissue establishment is not able to demonstrate to the reasonable satisfaction of the IMB that the responsible person does meet the requirements of *paragraph (2)*, it shall, without delay -

- (a) relieve him or her of the duties of responsible person in respect of the tissue establishment,
- (b) appoint a new responsible person in his or her place, and
- (c) notify the IMB that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Requirements for the procurement and supervision of procurement of human tissues and cells.

9. (1) Tissue establishments shall ensure that:-
- (a) tissue and cell procurement and testing:-
 - (i) take place in conditions authorised for that purpose,
 - (ii) are carried out by persons with appropriate training and expertise,
 - (b) the tests required for donors shall be carried out by a qualified laboratory authorised by the IMB.
- (2) The IMB shall ensure that the tissue and cell donation and procurement procedures comply with the requirements set out in Schedule 4.
- (3) A tissue establishment shall ensure that appropriate control measures are in place for the procurement of tissues and cells.
- (4) The IMB shall only authorise the procurement of human tissues and cells, with the exception of partner donation of reproductive cells for direct use, when the requirements in (a) to (k) are met:-
- a) procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured, or a tissue establishment authorised for procurement,
 - b) the tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Schedule 1,

- c) the tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue/cell procurement, unless they are employed by the same establishment or organisation, specifying the type(s) of tissues and /or cells and/or test samples to be procured and the protocols to be followed,
- d) there shall be Standard Operating Procedures (SOPs) for the verification of :
 - (i) donor identity;
 - (ii) the details of donor or donor family consent or authorisation;
 - (iii) the assessment of the selection criteria for donors as detailed in *Regulation 11*;
 - (iv) the assessment of the laboratory tests required for donors as detailed in *Regulation 11*.

There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application, or in the case of tissue/cell samples, to the laboratory for testing, in accordance with Schedule 4,

- e) procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Schedule 4,
- f) procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in point 1.3 of Schedule 4 and with due regard to relevant national and international regulations, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement,
- g) procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy,

- h) where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively,
- i) the procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in Schedule 4,
- j) a unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose,
- k) donor documentation shall be maintained in accordance with point 1.4 of Schedule 4.

Quality Management and notification of serious adverse events and reactions.

10. (1) A tissue establishment shall -
- (a) establish and maintain a quality system based on the principles of good practice and in accordance with the requirements set out under Article 28(c) of the Directive,
 - (b) ensure that all testing and processes are validated,
 - (c) take all necessary measures to ensure that the quality system includes at least documentation on the following: –
 - (i) SOPs,
 - (ii) guidelines,
 - (iii) training and reference manuals,
 - (iv) reporting forms,
 - (v) donor records, and
 - (vi) information on the final destination of tissues and cells, and that this documentation is readily available for inspection by the IMB.
- (2) Tissue establishments shall ensure that the data necessary to ensure traceability are in accordance with *Regulation 14*.
- (3) Tissue establishments, through the responsible person, shall notify the IMB of and provide the IMB with a report analysing the cause of and ensuing outcome of -
- (a) any serious adverse events and reactions, which may influence the quality and safety of tissues and cells, and
 - (b) any serious adverse reactions observed during or after clinical applications, which may be linked to the quality and safety of tissues and cells.
- (4) A tissue establishments, through the responsible person, shall -

- (a) ensure that an accurate, rapid and verifiable procedure is in place, which will enable it to recall from distribution any product which may be related to any notification referred to in *paragraph (3)*, and
- (b) keep a record of its activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with Schedule 4.
- (c) submit an annual report on its activities, which will be publicly accessible, to the IMB.

(5) All persons using human tissues and cells regulated by the Directives and these Regulations shall report any relevant information to establishments engaged in the donation, procurement, testing processing, storage or distribution of human tissue and cells in order to facilitate traceability and ensure quality and safety control.

Donor Selection, Evaluation and Testing Criteria.

11. (1) The IMB and tissue establishments shall ensure that-
- (a) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Schedule 2,
 - (b) the tests referred to in sub paragraph (a) are carried out in compliance with the general requirements set out in point 2 of Schedule 2,
 - (c) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Schedule 3,
 - (d) the tests referred to in sub paragraph (c) are carried out in compliance with the general requirements set out in point 4 of Schedule 3.
- (2) The IMB and tissue establishments shall ensure that donors comply with the selection criteria set out in -
- (a) Schedule 1 for donors of tissues and cells, except donors of reproductive cells,
 - (b) Schedule 3 for donors of reproductive cells.
- (3) Tissues and cells shall not be procured unless the information at *paragraph (4)* has been provided by the tissue establishment or procurement organisation to the donor (in the case of a living adult donor) or the next of kin (in the case of a deceased donor or a person who is unable to give consent) and informed consent has been given for such procurement.
- (4) The person in charge of the donation process in a tissue establishment or procurement organisation, prior to the procurement of such tissues and/or cells, in relation to living donors, shall ensure that –
- (a) the donor, or the donor's next of kin, (in the case of a person who is unable to give consent) has been properly informed of at least those

aspects relating to the donation and procurement process outlined in (c),

- (b) the information is given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor,
- (c) the information covers -
 - (i) the purpose and nature of the procurement, its consequences and risks,
 - (ii) analytical tests, if they are performed,
 - (iii) recording and protection of donor data,
 - (iv) medical confidentiality,
 - (v) therapeutic purpose and potential benefits,
 - (vi) the applicable safeguards intended to protect the donor,
- (d) the donor is informed that he or she has the right to receive the confirmed results of the analytical tests, clearly explained,
- (e) information is given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue and/or cell procurement can be carried out.

(5) The person in charge of the donation and procurement processes in a tissue establishment or procurement organisation, prior to the procurement of such tissues and/or cells, in relation to deceased donors, shall ensure that –

- (a) all information is given and all necessary consents and authorisations are obtained in accordance with these Regulations,
- (b) the confirmed results of the donor's evaluation are communicated and clearly explained to the relevant persons in accordance with these Regulations.

(6) The tissue establishment or procurement organisation shall, in relation to the donation and procurement of tissues and cells:-

- (a) put and keep in place procedures for the evaluation of donors,
- (b) apply selection and evaluation criteria for all donors of tissues and/or cells in accordance with *Regulation 11*,
- (c) maintain records of the results of donor evaluations and tests and report to donors any relevant abnormal findings from the evaluations, and tests.

(7) In the case of autologous donation, the suitability criteria of the donor shall be established in accordance with the requirements in point 2.1 of Schedule 1.

Tissue and cell reception, processing, storage and distribution.

12. (1) Tissue establishments shall ensure that human tissue and cells and associated documentation comply with the requirements set out in Schedule 4.

(2) The IMB shall ensure that the reception of tissues and cells at the tissue establishment complies with the requirements set out in Schedule 4.

(3) A tissue establishment shall verify and record the fact that the packaging of tissues and cells received complies with the requirements of point 1.5 of Schedule 4,

(4) Tissues and cells that do not comply with point 1.5 of Schedule 4, shall be discarded.

(5) Tissue establishments shall document the acceptance or rejection of received tissues or cells.

(6) Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with *Regulation 14*.

(7) Tissue establishments shall hold tissue and cells in quarantine until such time as the requirements relating to donation, testing and information have been met in accordance with *Regulation 11*.

(8) Tissue establishments shall:

(a) include in their SOPs all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions,

(b) ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements in Article 28(h) of the Directive,

- (c) ensure that any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in the Directive and in this paragraph,
- (d) include in their SOPs special provisions for the handling of tissue and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel,
- (e) ensure that all procedures associated with the storage of tissues and cells are documented in the SOPs and that the storage conditions comply with the requirements under Article 28(h) of the Directive,
- (f) ensure that all storage processes are carried out under controlled conditions,
- (g) establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells,
- (h) not distribute processed tissues or cells until the requirements laid down in these Regulations are met.

(9) Tissue establishments shall have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments authorised in accordance with *Regulation 6* without prejudice to any domestic law concerning the disposal of donated tissues or cells, according to the consent pertaining to them.

(10) Tissue establishments shall ensure that personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28 (c) of the Directive.

(11) Tissue establishments shall ensure –

(a) the quality and safety of tissues and cells during distribution,

(b) distribution conditions comply with the requirements referred to in Article 28(h) of the Directive.

Principles governing tissue and cell donation and voluntary unpaid donation.

13. (1) The Minister shall draw up national guidelines, to include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells, with a view to offering or seeking financial gain or comparable advantage, for promotion and publicity activities in support of the donation of human tissues and cells.

(2) The national guidelines, referred to in *paragraph (1)* shall endeavour to ensure that the procurement of tissues and cells is carried out on a non-profit basis.

(3) Tissue establishments shall:

(a) comply with national guidelines laid down for the promotion and publicity activities in support of the donation of human tissues and cells,

(b) make every effort to ensure voluntary and unpaid donations of tissues and cells.

(4) Without prejudice to *paragraph (3)* tissue establishments may make good the expenses and inconveniences related to the donation, in accordance with national guidelines.

Traceability and labelling of tissues and cells.

14. (1) A tissue establishment shall ensure that all tissues and cells, which it procures, processes, stores or distributes, can be fully identified and traced from donor to end user, or disposal, and vice versa. This traceability will also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

(2) A tissue establishment shall implement a donor identification system which assigns a unique code to each tissue or cell donation and to each of the products associated with it.

(3) A tissue establishment must use a labelling system that contains the information or references allowing a link to the information referred to in Schedule 4 and Article 28(h) of the Directive.

(4) A tissue establishment shall keep such records of the information referred to in Schedule 4 and such additional records as are necessary -

- (a) for the identification and traceability of each single tissue or cell donation and each single tissue or cell unit and its components (including tissues and cells which are imported into the European Community), and products coming into contact with these tissues and cells,
- (b) to ensure full traceability from donation and procurement, processing or storage to the point of delivery to a hospital or site, and at all stages,

for a period of not less than 30 years after clinical use. Data storage may also be in electronic form.

(5) A tissue establishment shall ensure that the labelling, documentation and packaging on each tissue or cell supplied by it, shall conform with the requirements in Schedule 4.

Import and export of human tissues and cells

15. (1) The IMB shall ensure that –
 - (a) all imports of tissues and cells from third countries, and
 - (b) all exports of tissues and cells to third countries,are undertaken by authorised tissue establishments.

- (2) Tissue establishments shall ensure that imported tissues and cells -
 - (a) can be traced from donor to the recipient and vice versa in accordance with the requirements in Regulation 14,

 - (b) meet standards of quality and safety equivalent to those laid down in the Directives and these Regulations.

- (3) Tissue establishments shall ensure that all exports to third countries comply with the requirements of these Regulations.

- (4) The IMB may directly authorise the import or export of –
 - (a) tissues and cells referred to in *Regulation 6(13)*,
 - (b) certain tissues and cells, in case of emergency.

- (5) The IMB shall take all necessary measures to ensure that imports and exports of tissues and cells at *paragraph (4)* meet quality and safety standards equivalent to those laid down in the Directives and these Regulations.

Relations between tissue establishments and third parties.

16. (1) Tissue establishments shall establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances-

- (a) where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party,
- (b) where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution,
- (c) where a tissue establishment provides services to a tissue establishment which is not authorised,
- (d) where a tissue establishment distributes tissue or cells processed by third parties.

(2) Agreements between tissue establishments and third parties must be examined by the IMB, within the authorisation framework of *Regulation 6*.

(3) Tissue establishments shall evaluate and select third parties on the basis of their ability to meet the standards laid down in the Directives and these Regulations.

(4) Tissue establishments shall keep a complete list of the agreements referred to in *paragraph (1)* that they have established with third parties.

(5) Agreements between tissue establishments and third parties shall specify the responsibilities of third parties and detailed procedures.

(6) Tissue establishments shall provide copies of agreements with third parties at the request of the IMB.

Objections to refusals of authorisation or suspension or revocation of authorisation

17. (1) A tissue establishment which objects to -
- (a) the refusal of authorisation, or the imposition of any condition pursuant to *Regulation 6(5)*, or
 - (b) any suspension or revocation of authorisation, or any notice served, pursuant to *Regulation 6(8) or 7*,

may notify the IMB of its desire to make written representations to, or to appear before and be heard by, a person appointed by the IMB for that purpose.

(2) Any notification of an objection pursuant to *paragraph (1)* shall be made within 14 days of service on the tissue establishment of the notice to which the notification pursuant to *paragraph (1)* relates.

(3) Where the IMB receives a notification pursuant to *paragraph (1)*, it shall appoint a person to consider the matter.

(4) The person appointed pursuant to *paragraph (3)* shall determine the procedure to be followed with respect to the consideration of any objection.

(5) The person appointed pursuant to *paragraph (3)* shall consider any written or oral objections made by the tissue establishment in support of its objection, and shall make a recommendation to the IMB.

(6) A recommendation made pursuant to *paragraph (5)* shall be made in writing to the IMB, and a copy of it shall be sent to the tissue establishment concerned, or to its nominated representative.

(7) The IMB shall take into account any recommendation made pursuant to *paragraph (5)*.

(8) Within 14 days of receipt of any recommendation made pursuant to *paragraph(5)*, the IMB shall inform the tissue establishment whether it accepts the recommendation and, if it does not accept it, of the reasons for its decision.

(9) Subject to *paragraph (11)*, where the IMB is notified of an objection pursuant to *paragraph (1)(b)* before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation or notice in respect of which the objection is made shall not take effect until –

- (a) the person appointed pursuant to *paragraph (3)* has considered the matter in accordance with the provisions of this Regulation and made a recommendation, and
- (b) the IMB has informed the tissue establishment concerned of its decision with regard to the recommendation pursuant to *paragraph (8)*.

(10) Subject to *paragraph (11)*, where the IMB is notified of an objection pursuant to *paragraph (1)(b)*, within the period specified in *paragraph (2)*, to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made shall cease to have effect until -

- (a) the person appointed pursuant to *paragraph (3)* has considered the matter in accordance with the provisions of this Regulation and made a recommendation, and

- (b) the IMB has informed the tissue establishment concerned of its decision with regard to the recommendation pursuant to *paragraph (8)*.

(11) *Paragraphs (9) and (10)* shall not apply -

- (a) in relation to a suspension or revocation, which takes immediate effect in accordance with *Regulation 7(3)*, or
- (b) in any other case, where the IMB determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the tissue establishment concerned.

Disclosure of information by tissue establishments and data protection

18. (1) A tissue establishment shall ensure that all information, including genetic information which is collected for the purposes of these Regulations is held securely so that it is -

- (a) available for the purpose of tracing donations,
- (b) not disclosed except -
 - (i) in accordance with one or more of the requirements of *paragraph (2)*, or
 - (ii) where it has been rendered anonymous so that donors and recipients are no longer identifiable, and
- (c) subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records and transfer of information.

(2) The requirements of this paragraph are -

- (a) the disclosure is made in accordance with an order of a court or is otherwise required by law,
- (b) the disclosure is to an authorised officer, or
- (c) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(3) Where a disclosure is made to an authorised officer pursuant to *paragraph (2)(b)*, the authorised officer shall not further disclose the information received unless -

- (a) the disclosure is made in accordance with an order of a court or is otherwise required by law,
- (b) the disclosure is to another authorised officer or an officer of the IMB where this is necessary for the proper performance of any function of any such officer, or
- (c) the information has been rendered anonymous so that the donors are no longer identifiable.

(4) Where a disclosure is made pursuant to *paragraph (3)*, the person to whom the disclosure is made shall not further disclose the information he or she receives other than in accordance with the requirements of that paragraph.

(5) The responsible person shall ensure that he or she puts in place procedures to resolve data discrepancies.

(6) The responsible person shall ensure that the identity of the recipient is not disclosed to the donor or his family and vice versa, without prejudice to any national law which may come into force on the conditions for disclosure, notably in the case of gametes donation.

Inspections

19. (1) The IMB shall conduct a regular inspection of each site of a tissue establishment, not less than once every 2 years, for the purpose of ensuring that -
 - (a) the procedures and activities carried out by tissue establishments comply with the requirements of these Regulations,
 - (b) documents or other records relating to the requirements of the these Regulations are examined,
 - (c) problems relating to compliance with those requirements are identified,
 - (d) the site complies with the requirements of the Directives and these Regulations.
- (2) The IMB may conduct such additional inspections of tissue establishment sites or facilities of third parties, as it considers necessary for the purpose of ensuring compliance with the requirements of these Regulations.
- (3) The IMB may also serve a notice on a tissue establishment requiring that it furnish the IMB with such information concerning its compliance with these Regulations and as shall be specified in the notice within such period as shall be specified in the notice.
- (4) Any tissue establishment which receives a request for information in accordance with *paragraph (3)* shall provide the information requested within the period specified in the notice.
- (5) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the IMB shall request such information, conduct such inspections, or carry out control measures, in accordance with this Regulation as it shall consider appropriate.
- (6) Any reference to an inspection of a site which the IMB is required or empowered to conduct by virtue of this Regulation, shall be construed so as to include an inspection of premises within the State at which any of the prescribed activities are carried

out by any person on behalf of, and pursuant to a contractual arrangement with, a tissue establishment.

(7) For the avoidance of doubt, it is hereby declared that the IMB's functions under this Regulation in relation to a tissue establishment are also applicable in the case of a tissue establishment seeking authorisation under *Regulation 6*.

(8) The IMB, on receipt of a duly justified request from the competent authority in another Member State shall organise such inspection or carry out control measures.

(9) The IMB shall, upon the request of another Member State, or the Commission, provide information on the results of inspections and control measures carried out, in relation to the requirements of the Directives.

Records to be kept by the Irish Medicines Board

20. (1) The IMB shall keep such records of information which it receives from, or relating to, tissue establishments as it considers appropriate in accordance with *Regulation 12* and shall, in particular, keep records relating to -

- (a) authorisations under *Regulation 6*,
- (b) the designation of responsible persons under *Regulation 8*,
- (c) notification of serious adverse events and serious adverse reactions by tissue establishments pursuant to *Regulation 10(3)*, and
- (d) inspections or requests for information under *Regulation 19*.

(2) The IMB shall maintain a publicly accessible register of tissue establishments, specifying the activities for which they have been authorised.

(3) The IMB shall assist the Commission to establish a network linking the national tissue establishment registers.

PART 3

AUTHORISED OFFICERS AND TESTING, ETC. OF SAMPLES, ETC.

Interpretation (Part 3)

21. In this Part -

“inspect” includes search;

“premises” means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport relevant things;

“record” includes, in addition to a record in writing -

- (a) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid or some other instrument) of being reproduced in legible or audible form,
- (b) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid or some other instrument) of being reproduced in visual form, and
- (c) a photograph,

and any reference to a copy of a record includes -

- (d) in the case of a record to which *paragraph (a)* of this definition applies, a transcript of the sounds or signals embodied therein,
- (e) in the case of a record to which *paragraph (b)* of this definition applies, a still reproduction of the images embodied therein, and

- (f) in the case of a record to which *paragraphs (a) and (b)* of this definition apply, such a transcript together with such a still reproduction;

“relevant thing” means -

- (a) any tissue or cells,
- (b) any article or substance used in the donation, procurement, processing preservation or storage of any tissue or cells or products manufactured from tissues and cells.

Authorised officers.

22. (1) The IMB -

- (a) may appoint such and so many persons as the IMB thinks fit to be authorised officers for the purposes of these Regulations, and
- (b) shall furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(2) An authorised officer shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with these Regulations or conducting inspections pursuant to *Regulation 19*, an authorised officer may -

- (a) subject to *paragraph (5)*, enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds to believe that it is necessary to visit, including -
 - (i) any premises owned or managed by a tissue establishment, or at which the tissue establishment carries out any prescribed activities,
 - (ii) any premises of any person who carries out any prescribed activities on behalf of, and pursuant to a contractual arrangement with a tissue establishment,
 - (iii) where any facilities for donor evaluation and testing are in the premises of any person other than a tissue establishment, those facilities in that person's premises, and

- (iv) any premises at which books, records or other documents (including documents stored in non-legible form) relating to any prescribed activities are stored or kept,
- (b) at such premises inspect and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,
- (c) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,
- (d) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of -
 - (i) the premises,
 - (ii) any relevant thing at the premises, or
 - (iii) any equipment, machinery or plant at the premises,as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,
- (e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under these Regulations,

- (f) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis,
- (g) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes does not comply with the requirements of these Regulations not be sold or distributed or moved from the premises, without his or her consent,
- (h) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,
- (i) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,
- (j) without payment, take samples of any relevant thing, detained pursuant to *subparagraph (i)*, for the purposes of any test, examination, or analysis, or
- (k) where the taking of samples of any relevant thing pursuant to *subparagraph (f)* or *(j)* is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant under *paragraph (6)*, be accompanied by such number of -

- (a) other authorised officers,

- (b) members of the Garda Síochána, or
- (c) persons with expertise relating to any relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than -

- (a) with the consent of the occupier, or
- (b) in accordance with a warrant issued under *paragraph (6)*.

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that -

- (a) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,
- (b) books, records or other documents (including documents stored in non-legible form) referred to in *paragraph (3)(a)(iv)* are being stored or kept in any dwelling, or
- (c) a dwelling is occupied in whole or in part by an undertaking carrying out any prescribed activity,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under *paragraph (3)(b) to (k)*.

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.

(8) A statement or admission made by a person pursuant to a requirement under *paragraph (3)(e)* shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under *Regulation 25(6)*).

(9) Nothing in this Regulation shall be taken to compel the production by any person of a document of which he or she would be exempt from production in proceedings in a court on the ground of legal professional privilege.

Taking of samples by authorised officers.

23. (1) Subject to *paragraph (3)*, where an authorised officer takes a sample of a relevant thing, he or she shall -

- (a) divide the sample into 3 approximately equal parts,
- (b) place each part into separate containers, and
- (c) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with *paragraph (1)*, he or she shall -

- (a) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,
- (b) retain one of the sealed containers, and
- (c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in *Regulation 24(1)(a),(b) or (c)*.

(3) Where a relevant thing is contained in a container and its division into parts pursuant to *paragraph (1)* is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of such relevant things for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of *paragraph (1)*, and the provisions of *paragraphs (1) and (2)* shall apply thereto accordingly.

(4) Where an authorised officer takes a relevant thing pursuant to *Regulation 22(3)(k)*, he or she shall -

- (a) place the relevant thing in a container,

- (b) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that section, and
- (c) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by a person mentioned in *Regulation 24(1)(a), (b) or (c)*.

Certificate of result of test, etc. of sample, etc.

24. (1) In any proceedings for an offence under these Regulations, a certificate in the form specified in Schedule 5 of these Regulations signed by -

(a) either -

(i) the State Chemist, or

(ii) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(b) either -

(i) a public analyst appointed under section 10 of the Sale of Food and Drugs Act 1875 to 1936, or

(ii) another analyst authorised by such a public analyst to sign the certificate, or

(c) a chemist or analyst appointed by the IMB,

stating the result of any test, examination or analysis of a sample of any relevant thing, or of a relevant thing, as the case may be, forwarded under *Regulation 23(2)(c)* or *(4)(c)* shall, with regard to that sample of the relevant thing, or the relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is

proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this section “trademark” has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

PART 4
OFFENCES

Offences.

25. (1) A person who contravenes any of the provisions of *Regulation 5(1), 6(9), 8 (except Regulation 8(3), 9, 10, 11, 12, 14, or 19 (4))* shall be guilty of an offence and liable on summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding 6 months, or to both.

(2) Any person who fails to comply with a notice of suspension or revocation of the person's authorisation served pursuant to *Regulation 7*, except where the operation of that notice has been suspended pursuant to *Regulation 17*, or has been withdrawn or revoked by the IMB, shall be guilty of an offence and liable on summary conviction to a fine not exceeding €2,000, or to a term of imprisonment not exceeding 6 months, or to both.

(3) Any person who knowingly supplies tissue or cells which are not labelled in accordance with the requirements of *Regulation 14* shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to a term of imprisonment not exceeding 3 months, or to both.

(4) Any person who -

- (a) contravenes *Regulation 18*, or
- (b) discloses any information referred to in *Regulation 18(1)* to which he or she has access by virtue of these Regulations, otherwise than in accordance with the provision of *Regulation 18(2)* and (3),

shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to a term of imprisonment not exceeding 3 months, or to both.

(5) Any person who -

- (a) obstructs or interferes with an authorised officer, a member of the Garda Síochána, or a person with expertise relating to any relevant

thing (within the meaning of *Regulation 21*), in the course of performing a function conferred on him or her by these Regulations or a warrant under *Regulation 22(6)*, or

- (b) impedes the performance by the officer, member, or person with expertise, as the case may be, of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to *Regulation 22*, or
- (c) in purported compliance with such request or requirement or in answer to such question gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to imprisonment for a term not exceeding 3 months, or to both.

(6) A person who falsely represents himself or herself to be an authorised officer shall be guilty of an offence and liable on summary conviction to a fine not exceeding €1,000, or to imprisonment for a term not exceeding 3 months, or to both.

(7) Nothing in *paragraph (5)(b)* shall be construed as requiring any person to answer any question or to give any information if to do so might incriminate him or her or, in the case of a person who is married, his or her spouse.

(8) On conviction for an offence under these Regulations (including an offence under *Regulation 26*), the court may, in addition to any other penalty -

- (a) order any relevant thing (within the meaning of *Regulation 21*) to which the offence relates to be forfeited to the IMB for destruction or other disposal as the IMB thinks fit,

- (b) upon application made to it by or on behalf of the IMB, order the person convicted of the offence to pay to the relevant person all or part of the costs of such destruction or other disposal subject to such conditions, if any, as are specified in the order.

Offence to import below standard tissues and cells into the State.

26. Any person who imports into the State any tissues or cells (including tissues or cells intended for use as a starting material or raw material in manufactured products) from a country or territory outside the European Community which do not meet standards of quality and safety equivalent to those laid down in the Directives and these *Regulations* is guilty of an offence and liable on summary conviction to a fine not exceeding €2,000, or to imprisonment for a term not exceeding 6 months, or to both.

Offence by body corporate.

27. (1) Where an offence under these Regulations which is committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any person who, when the offence was committed, was a director, manager, secretary or other officer of the body or a person who was purporting to act in any such capacity, that person, as well as the body corporate, shall also be guilty of an offence and shall also be liable to be proceeded against and punished as if guilty of the offence committed by the body corporate.

(2) Where the affairs of a body corporate are managed by its members, *paragraph (1)* applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

Defence of due diligence.

28. (1) In any proceedings for an offence under *Regulation 25* or *26*, or *Regulation 25* or *26* as read with *Regulation 27*, it shall be a defence for the person charged to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to a defence under *paragraph (1)*, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not.

Proceedings may be brought by the IMB.

29. (1) Summary proceedings for an offence under these Regulations may be brought and prosecuted by the IMB.

PART 5
MISCELLANEOUS

Reports by the IMB

30. The IMB shall, before the 7 April, 2009 and every three years thereafter, send to the Commission a report on the activities undertaken in relation to the provisions of the Directive, including an account of the measures taken in relation to inspection and control.

Specific epidemiological situations.

31. Where the IMB is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of tissue and cell donations -

- (a) it may notify tissue establishments of additional deferral criteria for the donation of tissues and cells that must be adopted by them, and
- (b) it shall notify the Commission of -
 - (i) the epidemiological situation, and
 - (ii) the additional criteria, if any, which tissue establishments are required to adopt in relation to it pursuant to *subparagraph (a)*.

Fees.

32. (1) The IMB may charge fees which shall be equal to the respective amounts which the IMB estimates it will incur in, or in connection with, performing the functions referred to in these Regulations to which the fees respectively relate.

(2) Where the costs incurred -

- (a) are greater than the appropriate fee, then the difference between those costs and that fee shall be payable by the tissue establishment concerned or its authorised representative, to the IMB, and
- (b) are less than the appropriate fee, the difference between those costs and that fee shall be repayable by the IMB to the tissue establishment concerned or its authorised representative.

SCHEDULE 1

Selection criteria for donors of tissues and/or cells (except donors of reproductive cells) as referred to in *Regulation 11.2 (a) and 11 (7)*

Selection criteria for donors are based on an analysis of risks related to the application of the specific cells/tissues. Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in Regulation 8, donors must be excluded from donation if any of the following criteria applies:

1. Deceased Donors

1.1 General criteria for exclusion

- 1.1.1 Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies.
- 1.1.2 History of a disease of unknown aetiology.
- 1.1.3 Presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma in situ of the uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to scientific evidence. Donors with malignant diseases can be evaluated and considered for cornea donation, except for those with retinoblastoma, haematological neoplasm, and malignant tumours of the anterior segment of the eye.
- 1.1.4 Risk of transmission of diseases caused by prions. This risk applies, for example, to:
 - (a) people diagnosed with Creutzfeldt-Jakob Disease, or variant Creutzfeldt-Jakob Disease, or having a family history of non-iatrogenic Creutzfeldt-Jakob disease.
 - (b) People with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;
 - (c) Recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

For variant Creutzfeldt-Jakob Disease, further precautionary measures may be recommended.

- 1.1.5. Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissue and cells to be donated. Donors with bacterial septicaemia may be evaluated and considered for eye donation, but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue.
- 1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status) hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.
- 1.1.7. History of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the tissue to be retrieved.
- 1.1.8. Indications that test results of donor blood samples will be invalid due to:
 - (a) the occurrence of haemodilution, according to the specifications in section 2 of Schedule 2, where a pre-transfusion sample is not available; or
 - (b) treatment with immunosuppressive agents.
- 1.1.9 Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.
- 1.1.10 Presence on the donor's body of physical signs implying a risk of transmissible disease(s) as described in point 1.2.3 of Schedule 4.
- 1.1.11 Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.
- 1.1.12 Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist.
- 1.1.13 Transplantation with xenografts.

1.2 Additional exclusion criteria for deceased child donors.

1.2.1 Any children born from mothers with HIV infection or that meet any of the exclusion criteria described in section 1.1 must be excluded as donors until the risk of transmission of infection can be definitely ruled out.

- (a) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection or at risk of such infection, and who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests;
- (b) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors.

2. Living Donors

2.1 Autologous Living Donor

2.1.1. If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of contamination with adventitious agents and/or mix-ups.

2.2 Allogeneic Living Donor

2.2.1 Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening our persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.

- 2.2.2 Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient) based on the specific tissue or cells to be donated, together with the donor's physical status and medical history and the results of behavioural and clinical investigations and laboratory tests establishing the donor's state of health.
- 2.2.3 The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1 Depending on the tissue or cell to be donated, other specific exclusion criteria may need to be added, such as:
- (a) pregnancy (except for donors of umbilical cord blood cells and amniotic membrane and sibling donors of haematopoietic progenitors);
 - (b) breastfeeding;
 - (c) in the case of haematopoietic progenitor cells, the potential for transmission of inherited conditions.

SCHEDULE 2

Laboratory tests required for donors (except donors of reproductive cells) as referred to in Regulation 11.1 (a) and (b).

1. Biological tests required for donors

1.1 The following biological tests must be performed for all donors as a minimum requirement;

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HbsAg Anti HBc
Hepatitis C	Anti- HCV- Ab
Syphilis	See 1.4 (below)

1.2 HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

1.3 When anti-HBc is positive and HbsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use.

1.4 A validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. A donor whose specimen tests reactive on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use.

1.5 In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, *Trypanosoma cruzi*).

1.6 For autologous donors, point 2.1.1. in Schedule 1 applies.

2. General requirements to be met for determining biological markers

2.1 The tests must be carried out by a qualified laboratory, authorised as a testing centre by the IMB, using CE marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.

2.2 The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.

2.3 When potential donors have lost blood and have recently received donated blood, blood components, colloids or crystalloids, blood testing may not be valid due to haemodilution of the sample. An algorithm must be applied to assess the degree of haemodilution in the following circumstances:

(a) ante-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding blood sampling or if crystalloids were infused in the hour preceding blood sampling;

(b) post-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding death or if crystalloids were infused in the hour preceding death.

Tissue establishments may accept tissues and cells from donors with plasma dilution of more than 50% only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

2.4 In the case of a deceased donor, blood samples must have been obtained just prior to death, or if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death.

2.5 (a) In the case of living donors (except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors, for practical reasons), blood samples must be

obtained at the time of donation or if not possible, within 7 days post donation (this is the 'donation sample').

(b)Where tissues and cells of allogeneic living donors can be stored for long periods, repeat sampling and testing is required after an interval of 180 days. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days post donation.

(c)Where tissues and cells of allergenic living donors cannot be stored for long periods and repeat sampling is therefore not possible, paragraph 2.5(a) above applies.

2.6 If, in a living donor (except bone marrow stem-cell and peripheral blood stem-cell donors) the 'donation sample' as defined in paragraph 2.5(a) above, is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

2.7 In the case of bone marrow and peripheral blood stem-cell collection, blood samples must be taken for testing within 30 days prior to donation.

2.8 In the case of neonatal donors, the biological tests may be carried out on the donor's mother to avoid medically unnecessary procedures upon the infant.

SCHEDULE 3

Selection criteria and laboratory tests required for donors of reproductive cells as referred to in Regulation 11 (1) (c) and (d) and 11 (2), (b)

1. Partner donation for direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

2.1 The clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result.

2.2 The following biological tests must be carried out to assess the risk of cross contamination:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg
	Anti-HBc
Hepatitis C	Anti-HCV-Ab

In case of sperm processed for intrauterine insemination, not to be stored and if the tissue establishment can demonstrate that the risk of cross contamination

and staff exposure has been addressed through the use of validated processes, the biological testing may not be required.

- 2.3 Where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised.
- 2.4 HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.
- 2.5 In certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, *T. cruzi*).
- 2.6 Positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

- 3.1 Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g; superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor).
- 3.2 The donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with point 1.1 of Schedule 2 and

sperm donors must additionally be negative for Chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT).

- 3.3 HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.
- 3.4 In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CamV, *T.cruzi*).
- 3.5 For autologous donors, point 2.1.1 in Schedule 1 applies.
- 3.6 Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in these Regulations. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

- 4.1 The tests must be carried out in accordance with points 2.1 and 2.2 of Schedule 2.
- 4.2 Blood samples must be obtained at the time of donation.
- 4.3 Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required.

Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

SCHEDULE 4

Cell and/or tissue donation and procurement procedures and reception at the tissue establishment as referred to in Regulations 9 and 12 and 14

1. Donation and procurement procedures

1.1 *Consent and donor identification*

1.1.1. Before the procurement of tissues and cells proceeds, an authorised person must confirm and record:

- (a) that consent for the procurement has been obtained in accordance with *Regulation 11*; and
- (b) how and by whom the donor has been reliably identified.

1.1.2. In the case of living donors, the health professional responsible for obtaining the health history must ensure that the donor has:

- (a) understood the information provide,
- (b) had an opportunity to ask questions and been provided with satisfactory responses;
- (c) confirmed that all the information provided is true to the best of his/her knowledge.

1.2 *Donor evaluation (this section does not apply to partner donation of reproductive cells or to autologous donors)*

1.2.1. An authorised person must collect and record the donor's relevant medical and behavioural information according to the requirements described in point 1.4

1.2.2. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the donor, for living donors, and the following when appropriate:

- (a) the medical records of the donor;
- (b) an interview with a person who knew the donor well, for deceased donors;
- (c) an interview with the treating physician;
- (d) an interview with the general practitioner;
- (e) the autopsy report.

1.2.3. In addition, in the case of a deceased donor, and in the case of a living donor when justified, a physical examination of the body must be performed to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

1.2.4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

1.3. Procurement procedures for tissues and cells

1.3.1. The procurement procedures must be appropriate for the type of donor and the type of tissue/cells donated. There must be procedures in place to protect the safety of the living donor.

1.3.2. The procurement procedures must protect those properties of the tissues/cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.

1.3.3. For deceased donation, the area of access must be restricted. A local sterile field using sterile drapes must be used. Staff conducting procurement must be clothed appropriately for the type of procurement. Usually, this will extend to being

scrubbed, gowned in sterile clothing and wearing sterile gloves, face shields and protective masks.

- 1.3.4. In the case of a deceased donor, the place of procurement must be recorded and the time interval from death to procurement must be specified so as to ensure that the required biological and/or physical properties of the tissues/cells are retained.
- 1.3.5. Once the tissues and cells have been retrieved from a deceased donor body, it must be reconstructed so that it is as similar as possible to its original anatomical appearance.
- 1.3.6. Any adverse event occurring during procurement that has or may have resulted in harm to a living donor and the outcome of any investigation to determine the cause must be recorded and reviewed.
- 1.3.7. Policies and procedures must be in place to minimise the risk of tissue or cell contamination by staff who might be infected with transmissible diseases.
- 1.3.8. Sterile instruments and devices must be used for tissue and cell procurement. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.
- 1.3.9. When reusable instruments must be used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.
- 1.3.10. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training on the use of such devices.

1.4. Donor documentation

1.4.1. For each donor, there must be a record containing:

- (a) the donor identification (first name, family name and date of birth – if a mother and child are involved in the donation, both the name and date of birth of the mother and the name, if known, and date of birth of the child);
- (b) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required);
- (c) outcome of body examination, where applicable;
- (d) haemodilution formula, where applicable;
- (e) the consent/authorisation form, where applicable;
- (f) clinical data, laboratory test results, and the results of other tests carried out;
- (g) if an autopsy was performed, the results must be included in the record (for tissues and cells that cannot be stored for extended periods, a preliminary verbal report of the autopsy must be recorded);
- (h) for haematopoietic progenitor cell donors, the donor's suitability for the chosen recipient must be documented. For unrelated donations, when the organisation responsible for procurement has limited access to recipient data, the transplanting organisation must be provided with donor data relevant for confirming suitability.

1.4.2. The organisation performing the procurement must produce a procurement report, which is passed on to the tissue establishment. This report must contain at least:

- (a) the identification, name and address of the tissue establishment to receive the cells/tissues;
- (b) donor identification data (including how and by whom the donor was identified);
- (c) description and identification of procured tissues and cells (including samples for testing);
- (d) identification of the person who is responsible for the procurement session, including signing;
- (e) date, time(where relevant, start and end) and location of procurement and procedure (SOP) used, including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where procurement took place);
- (f) for deceased donors, conditions under which the cadaver is kept: refrigerated (or not), time of start and end of refrigeration;
- (g) ID/batch numbers of reagents and transport solutions used.

The report must also contain the date and time of death where possible.

Where sperm is procured at home, the procurement report must state this and must contain only:

- (a) the name and address of the tissue establishment to receive the cells/tissues;
- (b) the donor identification.

The date and time of procurement may be included, where possible.

1.4.3. All the records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

1.4.4. Donor records, required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive acceptable to the competent authority.

1.5. *Packaging*

1.5.1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperature that preserve the required characteristics and biological function of the cells/tissues. The packaging must also prevent contamination of those responsible for packaging and transportation of the tissues or cells.

1.5.2. The packaged cells/tissues must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissue or cells.

1.5.3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.

1.6. *Labelling of the procured tissues/cells*

At the time of procurement, every package containing tissues and cells must be labelled. The primary tissue/cell container must indicate the donation identification or code and the type of tissues and cells. Where the size of the package permits, the following information must also be provided:

- (a) date (and time where possible) of donation;
- (b) hazard warnings;
- (c) nature of any additives (if used);
- (d) in the case of autologous donations, the label must state 'for autologous use only';
- (e) in the case of directed donations, the label must identify the intended recipient.

If any of the information under points (a) to (e) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

1.7. *Labelling of the shipping container*

When tissues/cells are shipped by an intermediary, every shipping container must be labelled at least with:

- (a) TISSUES AND CELLS and HANDLE WITH CARE;
- (b) The identification of the establishment from which the package is being transported (address and phone number) and the contact person in the event of problems;
- (c) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the container;
- (d) the date and time of the start of transportation;
- (e) specifications concerning conditions of transport relevant to the quality and safety of the tissues and cells;

- (f) in the case of all cellular products, the following indication: DO NOT IRRADIATE;
- (g) when a product is known to be positive for relevant infectious disease marker, the following indication: BIOLOGICAL HAZARD;
- (h) in the case of autologous donors, the following indication: 'FOR AUTOLOGOUS USE ONLY'.
- (i) specifications concerning storage conditions (such as DO NOT FREEZE).

2. Receipt of the tissue/cells at the tissue establishment

- 2.1. When the retrieved tissues/cells arrive at the tissue establishment, there must be documented verification that the consignment, including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Schedule and the specifications of the receiving establishment.
- 2.2. Each establishment must ensure that the tissue and cells received are quarantined until they, along with the associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.
- 2.3 Each tissue establishment must have a documented policy and specifications against which each consignment of tissues and cells, including samples, are verified. These must include the technical requirements and other criteria considered by the tissue establishment to be essential for the maintenance of acceptable quality. The tissue establishment must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other tissues and cells being processed, preserved or stored.
- 2.4 The data that must be registered at the tissue establishment (except for donors of reproductive cells intended for partner donation) include:

- (a) consent/authorisation; including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;
- (b) all required records relating to the procurement and the taking of the donor history, as described in the donor documentation section;
- (c) results of physical examination, of laboratory tests and of other tests (such as the autopsy report, if used in accordance with section 1.2.2.);
- (d) for allogeneic donors, a properly documented review of the complete donor evaluation against the selection criteria by an authorised and trained person;
- (e) in the case of cell cultures intended for autologous use, documentation of the possibility of medicinal allergies (such as to antibiotics) of the recipient.

2.5. In the case of reproductive cells intended for partner donation, the data to be registered at the tissue establishment include:

- (a) consent; including the purpose(s) for which the tissues and cells may be used (such as reproductive only and/or for research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;
- (b) donor identification and characteristics: type of donor, age, sex, presence of risk factors and, in the case of a deceased donor, the cause of death;
- (c) partner identification;
- (d) place of procurement;
- (e) tissues and cells obtained and relevant characteristics.

SCHEDULE 5

Regulation 24

**EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN TISSUES
AND CELLS) REGULATIONS 2006**

CERTIFICATE STATING RESULTS OF TEST, EXAMINATION OR ANALYSIS

This certificate is issued by me, the undersigned, for the purpose of *Regulation 24* of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006, being -

¹ _____ .

I hereby certify that I received, on the ___ day of _____, from

² _____ of _____ a sample of the relevant thing/the relevant thing*, being ³ _____ for test, examination or analysis: which was undamaged, duly sealed and marked ⁴ _____ .

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows-

⁵

Signature _____

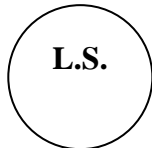
Date _____

Address _____

1. Here insert official title of person signing the certificate.
 2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.
 3. Here insert the name or description of the relevant thing.
 4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.
 5. Here insert the relevant results as appropriate.
- * Delete whichever is inapplicable.

GIVEN under my Official Seal,

7, April, 2006



Mary Harney,
Minister for Health and Children.

EXPLANATORY NOTE

These Regulations give effect to Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and Commission Directive 2006/17/EC of 8 February, 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

The Regulations may be cited as the European Communities (Quality and Safety of Human Tissues and Cells) Regulations, 2006.

The Regulations lay down standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health. They apply to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications and of manufactured products derived from human tissues and cells intended for human applications.