Draft Regulations laid before Parliament under paragraph 2(2) of Schedule 2 to the European Communities Act 1972, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2007 No.

HUMAN TISSUE

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

Made - - - -	*2007*
Coming into force	
for the purposes of regulation 1(3)	*2007*
for all other purposes	*5th July 2007*

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) in relation to health protection measures regulating the use of material of human origin(**2**);

A draft of this instrument was laid before Parliament in accordance with paragraph 2(2) of Schedule 2 to that Act and approved by a resolution of each House of Parliament;

Accordingly the Secretary of State, in exercise of the powers conferred by section 2(2) of that Act, makes the following Regulations:—

PART 1

CITATION, COMMENCEMENT, EXTENT AND INTERPRETATION

Citation and commencement

1.—(1) These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

(2) Except as provided by paragraph (3), these Regulations shall come into force on 5 July 2007.

(**1**) 1972 c.68.
(**2**) SI 2004/3037. In relation to measures in these Regulations relating to health protection measures regulating the use of material of human origin, the power of the Secretary of State under section 2(2) of the European Communities Act 1972 is exercisable in relation to Scotland by virtue of section 57(1) of the Scotland Act 1998 (c.46).

(3) These Regulations shall come into force on the day after the day on which they are made so far as necessary to enable anything (including the fixing of fees) to be done for the purposes of granting, varying, suspending or revoking licences in respect of activities required by virtue of these Regulations to be authorised by a licence on the commencement date.

Extent and application

2.—(1) These Regulations extend to England and Wales and Northern Ireland.

(2) Parts 1 to 5 and 7 of, and the Schedules to, these Regulations also extend to Scotland.

(3) These Regulations shall not apply in relation to the processing, preservation, storage, distribution, import and export of tissue or cells for use in manufactured products, including medical devices, to the extent that such activities are regulated by—

(a) the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994(**3**),

(b) the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**4**),

(c) the Medical Devices Regulations 2002(**5**), or

(d) the Medicines for Human Use (Clinical Trials) Regulations 2004(**6**).

(4) Paragraph (3) does not limit the application of the amendments made by Part 6 of these Regulations.

Designation of the competent authority

3. The Human Tissue Authority (in these Regulations referred to as "the Authority") is designated the competent authority for the purposes of the first, second and third Directives so far as they relate to tissue and cells.

References to Directives

4. In these Regulations—

"the first Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells(**7**),

"the second Directive" means Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells(**8**), and

"the third Directive" means Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 24 October 2006 as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells(**9**).

(**3**) SI 1994/105, as amended by SI 1994/899, SI 1995/541, SI 1996/482, SI 1998/574, SI 1999/566, SI 2001/795, SI 2002/236 and 542, SI 2003/623 and 2321, SI 2004/666 and SI 2005/2753.
(**4**) SI 1994/3144, as amended by SI 1998/3105, SI 2000/292, SI 2001/795, SI 2002/236, SI 2003/2321, SI 2004/3224, SI 2005/50, 768 and 2759 and SI 2006/1952.
(**5**) SI 2002/618, as amended by SI 2003/1697, SI 2005/2759 and 2909.
(**6**) SI 2004/1031, as amended by 2005/2754 and 2759 and SI 2006/1928 and 2984.
(**7**) OJ L102, 7.4.2004, p.48.
(**8**) OJ L38, 9.2.2006, p.40.
(**9**) OJ L294, 25.10.2006, p.32.

Interpretation of other terms

5.—(1) In these Regulations—

"the 2004 Act" means the Human Tissue Act 2004(**10**);

"autologous graft" means tissue or cells removed from and applied in the same person within the same surgical procedure;

"blood" means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods, but does not include lymphocytes intended for use for the purpose of haematopoietic stem cell transplantation;

"the commencement date" means 5 July 2007;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue, including cell lines grown outside the human body but not including —

(a) gametes,

(b) embryos outside the human body, or

(c) blood and blood components;

"designated individual", in relation to a licence under Schedule 1, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

"export" means export from the United Kingdom to a place outside the United Kingdom;

"human application", in relation to tissue or cells, means use on or in a human recipient, including use in extracorporeal applications but not including use for autologous graft;

"import" means import into the United Kingdom from a place outside the United Kingdom;

"licence holder" means a person who holds a licence under Schedule 1;

"licensed activity", in relation to a licence, means an activity which the licence authorises under Schedule 1;

"relevant third party premises" has the meaning given by regulation 6(2);

"serious adverse event" means any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells—

(a) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

(b) might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"storage" means maintaining tissue or cells, whether by preservation or in any other way, for more than 48 hours, and "store" is to be interpreted accordingly;

"tissue" means all constituent parts of the human body formed by cells, but does not include—

(**10**) 2004 c.30.

(a) gametes,

(b) embryos outside the human body, or

(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;

"third party" has the meaning given by regulation 6(2); and

"third party agreement" has the meaning given by regulation 6(1).

(2) Subject to paragraph (1) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in Article 3 of the first Directive, Article 1 of the second Directive and Article 2 of the third Directive (definitions).

(3) Subject to paragraphs (1) and (2) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in the 2004 Act as amended by these Regulations.

(4) For the purposes of these Regulations—

(a) a person who, from any premises, controls the provision of services for transporting tissue or cells is to be taken to distribute tissue or cells on those premises; and

(b) any reference to a requirement of any provision of the first, second or third Directive is a reference to a requirement which the provision requires be imposed in relation to the procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application.

References to third party agreements etc

6.—(1) For the purposes of these Regulations a "third party agreement" is an agreement in writing between a licence holder (or the designated individual on behalf of the licence holder) and another person, which is made in accordance with any directions given by the Authority under section 23(1) of the 2004 Act for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties), and under which the other person—

(a) carries on a licensed activity (other than storage), on behalf of the licence holder, or

(b) supplies to the licence holder any goods or services which may affect the quality or safety of tissue or cells.

(2) In these Regulations—

"relevant third party premises", in relation to a licence under Schedule 1, means any premises (other than premises to which the licence relates)—

(a) on which a third party procures, tests, processes or distributes, or to which a third party imports or from which a third party exports, tissue or cells on behalf of any person authorised by a licence to carry on that activity, or

(b) from which a third party provides any goods or services which may affect the quality or safety of tissue or cells to any person in connection with licensed activities carried on by that person; and

"third party" means a person with whom a licence holder has a third party agreement.

PART 2

LICENSING OF ACTIVITIES RELATING TO THE USE OF TISSUE FOR HUMAN APPLICATION

Licensing requirement

7.—(1) No person shall store tissue or cells intended for human application otherwise than under the authority of a licence under Schedule 1.

(2) Subject to paragraphs (4) and (6), no person shall do an activity to which this paragraph applies otherwise than—

(a) under the authority of a licence under Schedule 1, or

(b) in pursuance of a third party agreement.

(3) Paragraph (2) applies to the procurement, testing, processing, distribution, import or export of tissue and cells intended for human application.

(4) The Authority may authorise any person to distribute, import or export tissue or cells directly from where the procurement takes place to an organisation responsible for human application for immediate human application.

(5) The Authority may not authorise distribution, import or export under paragraph (4) unless—

(a) the authorisation relates to tissue or cells specified for the purposes of Article 6(5) of the first Directive, and

(b) the Authority is satisfied—

(i) that the distribution, import or export is necessary for clinical reasons, and

(ii) that the case is one of emergency.

(6) Paragraph (2) shall not apply to the distribution to or from, or to the import from or the export to, tissue establishments which are accredited, designated, authorised or licensed under the laws or other measures adopted in an EEA state other than the United Kingdom or in Gibraltar for the purpose of implementing the first, second and third Directives.

(7) Schedule 1 shall apply in relation to licences for the purposes of this regulation.

Application of the 2004 Act in relation to licences under Schedule 1

8.—(1) The provisions of the 2004 Act mentioned in paragraph (2) shall apply, subject to the modifications specified in paragraphs (4) to (7), in relation to a licence under Schedule 1 as they apply in relation to licences under paragraph 1 of Schedule 3 (licences for the purposes of section 16) to that Act.

(2) The provisions mentioned in paragraph (1) are—

(a) section 17 (persons to whom licence applies),

(b) section 19(1), (2), (5) and (7) (right to reconsideration of licensing decisions),

(c) sections 20 to 24 (which relate to appeals and powers to give directions),

(d) section 37(1) to (5) (directions), and

(e) paragraphs 2(4)(c) to (f) and (5), 5, 7 to 11, and 13 of Schedule 3 (licences for the purposes of section 16).

(3) In their application by virtue of this regulation, those provisions extend to Scotland (as well as to the rest of the United Kingdom).