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*

CONTENTS

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

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.

(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(**c**),

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

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

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

(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.

(**a**) 1972 c.68.

(**b**) 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).

(**c**) 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.

(**d**) 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.

(**e**) SI 2002/618, as amended by SI 2003/1697, SI 2005/2759 and 2909.

(**f**) SI 2004/1031, as amended by 2005/2754 and 2759 and SI 2006/1928 and 2984.

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(**a**),

"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(**b**), 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(**c**).

Interpretation of other terms

5.—(1) In these Regulations—

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

"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**) OJ L102, 7.4.2004, p.48.
(**b**) OJ L38, 9.2.2006, p.40.
(**c**) OJ L294, 25.10.2006, p.32.
(**d**) 2004 c.30.

(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—

(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).

(4) In its application by virtue of paragraph (2)(c), section 22 of the 2004 Act is to have effect in Scotland as if the reference to the High Court were a reference to the Court of Session.

(5) In its application by virtue of paragraph (2)(d), section 37(1) and (5) of the 2004 Act shall be read—

(a) as if the reference in subsection (1) to Part 2 of the 2004 Act were to these Regulations, and

(b) as if any reference in subsection (5) to a licence were to a licence under Schedule 1 to these Regulations.

(6) In their application by virtue of paragraph (2)(e), paragraphs 7(2)(b) and 9(3) of Schedule 3 to the 2004 Act shall be read as if the reference to section 18 of that Act were to regulation 12 of these Regulations.

(7) In its application by virtue of paragraph (2)(e), paragraph 7(2)(c) of Schedule 3 to the 2004 Act is to be read as including a reference to any relevant third party premises in relation to the licence and to the activity carried on on such premises in connection with the licensed activity.

Extension of other provisions of the 2004 Act to Scotland

9.—(1) Section 15(a), (b), (c)(ii), (d), (e) and (f) (general functions) and section 26(1) and (4) to (8) (preparation of codes) of the 2004 Act shall extend to Scotland (as well as to the rest of the United Kingdom), subject to the modifications specified in paragraph (2), so far as those provisions relate to activities within section 14(1)(h) of that Act.

(2) In its application by virtue of paragraph (1)—

(a) section 15(e) and (f) of the 2004 Act is to be read as including a reference to the Scottish Ministers;

(b) section 26(5) of the 2004 Act is to be read as including a duty to consult the Scottish Ministers if the code of practice relates to Scotland; and

(c) section 26(8) of the 2004 Act is to be read as including a reference to Scotland.

Breach of requirement to hold a licence or to act under a third party agreement

10.—(1) A person who contravenes regulation 7(1) commits an offence unless he reasonably believes—

(a) that what he does is not an activity to which regulation 7(1) applies; or

(b) that he acts under the authority of a licence under Schedule 1.

(2) A person who contravenes regulation 7(2) commits an offence unless he reasonably believes—

(a) that what he does is not an activity to which regulation 7(2) applies; or

(b) that he acts—

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

(ii) in pursuance of a third party agreement, or

(iii) in pursuance of an authorisation under regulation 7(4).

(3) A person guilty of an offence under paragraph (1) or (2) shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum;

(b) on conviction on indictment—

(i) to imprisonment for a term not exceeding 2 years, or

(ii) to a fine, or

(iii) to both.

Preconditions to grant of licence

11.—(1) The Authority may not grant a licence under Schedule 1 unless the following requirements are met.

(2) The proposed designated individual must—

(a) be the applicant for the licence, or

(b) consent to the application for the licence.

(3) The Authority must be satisfied that the proposed designated individual—

(a) is a suitable person to supervise the activity to be authorised by the licence,

(b) will perform the duty imposed by regulation 12,

(c) either—

(i) has a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or

(ii) is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications and practical experience, and

(d) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.

(4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.

(5) The Authority must be satisfied that—

(a) any premises in respect of which the licence is to be granted, and

(b) any premises which are proposed to be relevant third party premises in relation to the licence to be granted,

are suitable for the activity to be authorised by the licence.

(6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by—

(a) the applicant for the licence, and

(b) where different, the proposed designated individual.

(7) In this regulation, references to the proposed designated individual are to the individual whom the application proposes that the licence should designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

Duty of designated individual

12. It shall be the duty of the designated individual to secure—

(a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,

(b) that suitable practices are used in the course of carrying on that activity, and

(c) that—

(i) the conditions of the licence,

(ii) the conditions of third party agreements, in relation to the licensed activities authorised to be carried on under his supervision, and

(iii) the requirements of regulation 13(1),

are complied with.

Information and confidentiality

13.—(1) It shall be a condition of every licence under Schedule 1 that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in relation to the licence—

(a) is available for the purpose of tracing donations;

(b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and

(c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications or transfer of information.

(2) Any information which is collected in pursuance of a licence under Schedule 1 or a third party agreement, and from which a donor (living or deceased) or recipient of tissue or cells may be identified, shall not be disclosed except where such disclosure—

(a) is of information which has been rendered anonymous so that neither the donor nor recipient is identifiable,

(b) is made in accordance with an order of a court,

(c) is otherwise required by law,

(d) is made to a person as a member or employee of the Authority,

(e) is made to a person who is otherwise acting on behalf of the Authority in the exercise of its functions under these Regulations, including in particular its functions under Part 5 of these Regulations,

(f) is made to a tissue establishment for the purpose of tracing a donation from donor to recipient or recipient to donor,

(g) is made to a licence holder or a person to whom a licence applies for the purposes of his functions under the licence,

(h) is made to a third party in relation to a licence for the purposes of his functions under a third party agreement,

(i) is made pursuant to any consent to disclosure given by the person, being the donor or recipient of the tissue or cells, whose identity would be disclosed,

(j) is necessary—

(i) for any purpose preliminary to proceedings,

(ii) for the purpose of, or in connection with, any proceedings,

(iii) for the purpose of reporting a suspected offence,

(iv) for the purpose of cooperating with a police investigation,

(v) for the purpose of investigating a serious adverse event or serious adverse reaction,

(k) is made by a licence holder or designated individual in accordance with directions given to that person by the Authority under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8, or

(l) is of information which has been lawfully made available to the public before the disclosure is made.

(3) References to proceedings in paragraph (2)(j) include any formal procedure for dealing with a complaint.

(4) Where a disclosure is made to a person pursuant to paragraph (2)(d) or (e), that person shall not further disclose the information received unless the disclosure—

(a) is made in accordance with paragraph (2), or

(b) is made by the Authority for the purpose of its obligations under regulations 17 and 20.

Breach of confidentiality requirement

14.—(1) Any person who discloses any information in breach of regulation 13(2) or (4) shall be guilty of an offence.

(2) A person guilty of an offence under paragraph (1) shall be liable—

(a) on summary conviction—

(i) to a fine not exceeding the statutory maximum, or

(ii) to imprisonment for a term not exceeding three months, or

(iii) to both;

(b) on conviction on indictment—

(i) to a fine, or

(ii) to imprisonment for a term not exceeding two years, or

(iii) to both.

(3) In any proceedings for an offence under paragraph (1), it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

PART 3

REGULATION OF LICENSED ACTIVITIES

Import and export of tissue and cells

15.—(1) The Authority shall give such directions to licence holders or designated individuals under section 23(1) of the 2004 Act, as applied by regulation 8, as it considers necessary for the purpose of securing that all imports of tissue and cells intended for human application from countries which are not EEA states meet standards of quality and safety equivalent to those provided for in these Regulations.

(2) In giving any directions for the purposes of paragraph (1) the Authority shall have regard to ensuring traceability.

Directions: compliance with the first, second and third Directives

16.—(1) The Authority shall give directions to licence holders or designated individuals under section 23(1) of the 2004 Act, as applied by regulation 8, in accordance with Schedule 2 for the purpose of securing compliance with the requirements of the first, second and third Directives.

(2) The Authority shall give such other directions to licence holders or designated individuals under section 23(1) of that Act, as applied by regulation 8, as it considers necessary for securing compliance by licence holders and third parties with any requirements of the first, second and third Directives.

PART 4

OBLIGATIONS OF THE AUTHORITY

Requirement for the Authority to provide information

17.—(1) The Secretary of State may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales or Northern Ireland.

(2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland.

(3) The Authority shall upon receipt of a notice under paragraph (1) or (2) provide the information requested within the period specified in the notice.

Register of licences

18.—(1) The Authority shall maintain a register recording the grant, suspension or revocation of every licence granted under Schedule 1.

(2) The register shall contain the following information—

(a) the name of the licence holder,

(b) the activities authorised, and

(c) any variation of the information referred to in sub-paragraph (a) or (b).

(3) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Register of serious adverse events and serious adverse reactions

19.—(1) The Authority shall keep a register containing information provided to it under these Regulations about any serious adverse event or serious adverse reaction.

(2) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Duties of the Authority in relation to serious adverse events and serious adverse reactions

20.—(1) The Authority shall put in place procedures for communicating such information in relation to any serious adverse event or serious adverse reaction to—

(a) any person in the United Kingdom carrying-on procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application,

(b) any person in the United Kingdom, of whom it is aware, using such tissue or cells for that purpose,

(c) the competent authorities in EEA states other than the United Kingdom and in Gibraltar, and

(d) the European Commission,

as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of tissue and cells that are intended for human application but are known or suspected to be unsuitable for human application.

(2) The Authority shall investigate serious adverse events and serious adverse reactions and carry out appropriate control measures.

(3) The duty under paragraph (2) includes a duty to investigate any serious adverse event or serious adverse reaction which has occurred in the United Kingdom, and to carry out appropriate control measures, at the request of a competent authority in an EEA state other than the United Kingdom or in Gibraltar.

PART 5

INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of documents

21.—(1) A duly authorised person may require a person to produce for inspection any documents relevant to compliance with these Regulations.

(2) Where records or documents to which paragraph (1) applies are stored in any electronic form, the power under this regulation includes power to require the records or documents to be made available for inspection in a visible and legible form or in a form from which they can readily be produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any documents produced for inspection in pursuance of a requirement under paragraph (1).

Entry and inspection of premises

22.—(1) The Authority may arrange for any premises in respect of which a licence is in force, or any relevant third party premises, to be inspected on its behalf, and for a report on the inspection to be made to it, for any of the purposes referred to in paragraph (6).

(2) The Authority shall arrange for an inspection under paragraph (1) of any premises in respect of which a licence is in force not less than once in every interval of two years.

(3) The Authority may arrange for any premises to be inspected on its behalf, and for a report on the inspection to be made to it, for the purpose of satisfying itself under regulation 11(5) that—

(a) the premises are suitable for use for the carrying-on of a licensed activity, or

(b) the premises are suitable to be relevant third party premises in relation to a licence.

(4) If associated with any licensed activity there occurs any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for any premises to which the licence

relates and any relevant third party premises to be inspected on its behalf and for a report on the inspection to be made.

(5) For the purpose of carrying out an inspection under paragraph (1), (3) or (4), a duly authorised person may at any reasonable time enter and inspect—

(a) any premises specified, or proposed to be specified, in the licence as premises where the licensed activities are authorised to be carried on; or

(b) any relevant third party premises or any premises proposed to be such premises.

(6) The purposes for which an inspection may be carried out under paragraph (1) are for—

(a) ensuring compliance by the licence holder with—

(i) these Regulations,

(ii) the conditions of the licence, or

(iii) directions given under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8;

(b) ensuring compliance by the designated individual with the duty under regulation 12; or

(c) ensuring compliance by a third party with a third party agreement.

Entry and search in connection with suspected offence

23.—(1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath or, in Scotland, by evidence on oath that there are reasonable grounds for believing—

(a) that an offence under these Regulations is being, or has been, committed on any premises, and

(b) that any of the conditions in paragraph (2) is met in relation to the premises,

he may by signed warrant authorise a duly authorised person to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this regulation has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this regulation shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) The powers exercisable by a justice of the peace under paragraph (1) are also exercisable in Scotland by a sheriff.

Execution of warrants

24.—(1) Entry and search under a warrant under regulation 23 is unlawful if any of paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give him—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give him—

(i) a copy of the warrant,

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In paragraphs (3)(b)(ii) and (4)(b)(ii) the references to an appropriate statement are to a statement in writing containing the information set out in Schedule 3.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under regulation 23 is executed are unoccupied, or the occupier is temporarily absent and no other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant, shall, when leaving the premises, leave them as effectively secured as he found them.

Seizure in the course of inspection or search

25.—(1) A duly authorised person entering and inspecting premises under this Part may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority's functions relating to the grant, revocation, variation and suspension of licences under Schedule 1 and to the investigation of serious adverse events and serious adverse reactions.

(2) A duly authorised person entering and searching premises under a warrant under regulation 23 may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under these Regulations.

(3) Where a person has power under paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(4) The power under paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of paragraph (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

Powers: supplementary

26.—(1) Any power under this Part to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Any power under regulation 22 or 23 to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises,

(c) in the case of premises in respect of which a licence under Schedule 1 is in force, power to observe the carrying-on on the premises of the licensed activity, and

(d) in the case of relevant third party premises in respect of which a third party agreement is in force, power to observe the carrying-on on the premises of the activity carried on pursuant to such agreement.

(3) Any power under this Part to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

Requirements when exercising power of inspection or search

27.—(1) A person's right to exercise a power under this Part is subject to his producing evidence of his entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Part to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection or search, and

(b) if requested to do so by the appropriate person, give him a copy of the report.

(3) In paragraph (2), the "appropriate person" means—

(a) in relation to premises in respect of which a licence is in force, the designated individual;

(b) in relation to any relevant third party premises, the occupier.

Enforcement

28.—(1) A person commits an offence if—

(a) he fails without reasonable excuse to comply with a requirement under regulation 21 or regulation 26(3), or

(b) he intentionally obstructs the exercise of any right under this Part.

(2) A person guilty of an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Meaning of duly authorised person

29. In this Part, "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision.

PART 6

AMENDMENTS TO THE 2004 ACT

Remit of the Authority

30.—(1) Section 14 (remit) of the 2004 Act is amended as follows.

(2) At the end of subsection (1) insert—

"(h) the procurement, processing, preservation, testing, storage, distribution, import or export of tissue or cells, in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (g).".

(3) After subsection (2) insert—

"(2A) Expressions used in paragraph (h) of subsection (1) and in the 2007 Regulations have the same meaning in that paragraph as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.".

Exclusion from licensing requirement of section 16

31.—(1) Section 16 of the 2004 Act is amended as follows.

(2) After subsection (2), insert—

"(2A) This section does not apply to the procurement, testing, processing, preservation, storage, distribution, import or export of tissue and cells intended for human application in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies.

(2B) Expressions used in subsection (2A) and in the 2007 Regulations have the same meaning in that subsection as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.".

Interpretation of Part 2 of the 2004 Act

32. In section 41 (interpretation of Part 2) of the 2004 Act, before the definition of "anatomical specimen" insert—

""the 2007 Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007;".

Applications under Schedule 3 to the 2004 Act

33. In paragraph 13(1) of Schedule 3 to the 2004 Act, after "Schedule", insert "and Schedule 1 to the 2007 Regulations".

PART 7

GENERAL

Offences by bodies corporate

34.—(1) Where an offence under these Regulations is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of—

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person who was purporting to act in any such capacity,

he (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) Where an offence under these Regulations is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, he (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly.

(4) In paragraph (3), "partner" includes a person purporting to act as a partner.

Transitional arrangements: storage licences

35.—(1) This regulation applies where, immediately before the commencement date, a licence granted under Schedule 3 to the 2004 Act authorises the carrying-on of the activity described in section 16(2)(e)(ii) of the 2004 Act for use for transplantation.

(2) A licence referred to in paragraph (1) shall, from the commencement date, also be treated as a licence granted pursuant to Schedule 1 to these Regulations in respect of the storage of tissue or cells for human application and shall authorise the carrying-on of the activities to which regulation 7(2) applies.

(3) Where any premises to which a licence referred to in paragraph (1) relates have not been inspected on behalf of the Authority since the licence was granted, the Authority shall arrange for such premises to be inspected on its behalf before the end of the period of two years beginning with the commencement date.

Signed by authority of the Secretary of State for Health

Name
Minister of State
Date Department of Health

SCHEDULE 1

Regulation 7

Licences for the purposes of regulation 7

Power to grant licence

1. The Authority may on application grant a licence for the purposes of regulation 7.

Characteristics of licences

2. A licence under this Schedule may authorise the carrying-on of any of the activities to which regulation 7(1) or (2) applies.

3. A licence—

(a) shall designate an individual as the designated individual, and

(b) shall not authorise the licensed activities to be carried on under the supervision of more than one such individual.

4. A licence —

(a) shall specify the premises (other than relevant third party premises) where the licensed activity is authorised to be carried on, and

(b) shall not authorise the licensed activity to be carried on on premises (other than relevant third party premises in the case of activities to which regulation 7(2) applies) at different places.

5. It shall be a condition of a licence under this Schedule—

(a) that the licensed activities shall be carried on only under the supervision of the designated individual;

(b) that the licensed activity shall be carried on only on the premises specified in the licence or, in the case of activities to which regulation 7(2) applies, on relevant third party premises.

Fees

6. In determining the amounts of any fees to be charged under paragraph 13 of Schedule 3 to the 2004 Act, as applied by regulation 8, the Authority shall have regard to its costs in connection with the consideration of applications for licences under this Schedule.

SCHEDULE 2

Regulation 16

Directions for securing compliance with the first, second and third Directives

Traceability and coding system

1. Directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive; and

(b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.

2. Directions given for the purposes of paragraph 1 shall include directions requiring designated individuals to ensure that third parties responsible for human application retain the information listed in Annex VI (information on the minimum donor/recipient data set to be kept) and Annex VII (information contained in the European coding system) to the third Directive.

Reporting obligations

3. Directions under paragraph 2(4)(c) to (e) of Schedule 3 to the 2004 Act (as applied by regulation 8) shall specify the information to be recorded, the form in which it is to be recorded, the period for which such information is to be kept and the persons to whom any specified information is to be provided for the purpose of securing compliance with the requirements of Article 10(1) (register of tissue establishments and reporting obligations) of the first Directive.

Serious adverse events and serious adverse reactions

4. Directions shall require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Third party agreements and termination of licensed activities

5. For the purpose of securing compliance with the requirements of Article 21(5) (tissue and cell storage conditions) and Article 24 (relations between tissue establishments and third parties) of the first Directive, directions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Procurement and use of tissue or cells

6. Directions shall specify the requirements to be met by all licence holders authorised to procure tissue or cells to secure compliance with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

7. Directions shall be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

8. In giving directions for the purposes of paragraph 7, the Authority shall, in particular, impose a requirement on designated individuals to ensure that records are retained, and the Authority and tissue establishments are notified without delay, of any serious adverse event and any serious adverse reaction.

Selection criteria and laboratory tests required for donors of tissues and cells

9. In relation to donors of tissues or cells who are deceased at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to all such donors, point 1.1 (general criteria for exclusion), and

(b) in relation to such donors who are children, point 1.2 (additional exclusion criteria for deceased child donors),

of Annex I (selection criteria for donors of tissue or cells) to the second Directive.

10. In relation to donors of tissues or cells who are alive at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to autologous donors, point 2.1 (autologous living donor),

(b) in relation to allogeneic donors, point 2.2 (allogeneic living donor),

of Annex I to the second Directive.

11. Directions shall, in respect of all donors of tissues or cells, deal with the biological tests to be performed and carried out, in accordance with the requirements of section 1 (biological tests required for donors) and section 2 (general requirements to be met for determining biological markers) of Annex II (laboratory tests required for donors) to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

12. In respect of—

(a) donation and procurement procedures, and

(b) the reception of tissue and cells at premises specified in a licence under Schedule 1,

directions shall be given for the purpose of securing compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the second Directive
1. **Donation and procurement procedures**	
Consent and donor identification (record of consent, method of identification, donor interview)	Annex IV, point 1.1
Donor evaluation: other than autologous donors (assessment of donor's medical and behavioural information and physical examinations)	Annex IV, point 1.2
Procurement procedures for tissue and cells (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of the procured tissue and cells (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. **Reception of tissue and cells at the tissue establishment**	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, point 2.1 to 2.3
Registration of data	Annex IV, point 2.4

Requirements for holding a licence under Schedule 1

13. Directions shall be given for the purpose of securing compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C
Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence under Schedule 1 for tissue and cell preparation processes

14. In respect of tissue and cell preparation processes, directions shall be given for the purpose of securing compliance with—

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of tissue and cells at the tissue establishment	Annex II, Part A
Processing of tissue and cells (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of tissue and cells (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of tissue and cells (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of tissue and cells containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

SCHEDULE 3

Regulation 24

Appropriate statements

An appropriate statement for the purposes of regulation 24 must contain the following information—

(a) a statement that the duly authorised person has been authorised by the Authority for the purposes of regulation 23;

(b) a statement that the duly authorised person's rights of entry and search are subject to his producing evidence of his entitlement to exercise them, if required;

(c) a statement that the duly authorised person is entitled, if need be, to enter the premises by force;

(d) a description of the duly authorised person's powers under regulation 25(2) to (4) of inspection and seizure of property;

(e) a description of the requirement under paragraph 25(5) for the duly authorised person to leave a statement giving particulars of what he has seized and stating that he has seized it;

(f) a description of the powers of the duly authorised person—

(i) under regulation 26(1), to bring with him such other persons and equipment as he considers necessary;

(ii) under regulation 26(2), to inspect equipment and inspect and take copies of records, and in the case of premises in respect of which a licence under Schedule 1 is in force, or relevant third party premises in respect of which a third party agreement is in force, to observe the carrying-on of licensed activity or activity pursuant to such agreement;

(g) a description of the duly authorised person's obligations under regulation 27(2) to prepare a written report of the search and, if requested to do so by the appropriate person, give him a copy of the report;

(h) a statement that a person commits an offence under regulation 28 if—

(i) he fails without reasonable excuse to comply with a requirement under regulation 26(3), or

(ii) he intentionally obstructs the exercise of any right under Part 5.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement in part 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, as well as Commission Directive 2006/17/EC and Commission Directive 2006/86/EC laying down technical requirements in relation to Directive 2004/23/EC ("the Directives"). These Regulations impose safety and quality requirements in relation to human tissue and cells intended for human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos outside the human body, organs and blood.

These Regulations extend to the whole of the United Kingdom, except Part 6 which does not extend to Scotland.

Regulation 3 appoints the Human Tissue Authority ("the Authority") as the competent authority for the purposes of the Directives.

Regulation 7 prohibits the storage of tissue or cells, which are intended to be applied in or on a human, otherwise than under a licence granted under Schedule 1 to these Regulations. It also prohibits the procurement, testing, processing, distribution, import or export of such tissue or cells otherwise than under a licence, or under an agreement with a licence holder which complies with certain requirements of the Directives. Regulation 11 makes it an offence to breach such prohibition and provides for maximum penalties. Schedule 1 provides for the grant of licences and regulation 8 applies a number of provisions of the Human Tissue Act 2004 ("the 2004 Act") to such licences, including the procedures to be followed in respect of an application for a licence and powers to impose fees. These provisions, as well as other relevant provisions of the 2004 Act (regulation 9), are extended to Scotland in so far as they relate to the activities covered by these Regulations. Regulation 7(4) provides power for the Authority to authorise any person to distribute, import or export tissue or cells directly from where procurement takes place for immediate transplantation to humans.

Regulation 11 imposes preconditions to the grant of licences. Regulation 12 imposes a duty on the individual designated under a licence with responsibility for supervising the licensed activities to ensure that only suitable persons participate in carrying-on the activities, that suitable practices are used in doing so, and that the conditions of the licence and of agreements with third parties in relation to such activities are complied with.

Regulation 13 imposes restrictions on the disclosure of information obtained under the Regulations. Regulation 14 makes it an offence to breach such restrictions and imposes maximum penalties.

Regulations 15 and 16 make provision in relation to the giving of directions by the Authority in relation to the import or export of tissue or cells and in relation to the carrying-on of licensed activities. In particular, licence holders are required to comply with directions given by the Authority in accordance with Schedule 2 to the Regulations for the purpose of securing compliance with the requirements of the Directives.

Regulations 17 to 20 impose obligations on the Authority, including requirements to keep registers of licences and of serious occurrences affecting donors and recipients of tissue or cells, and to notify other EEA states of such occurrences.

Regulations 21 to 29 and Schedule 3 provide for enforcement and related matters, including powers of inspection. Regulations 30 to 33 make consequential amendments to the Human Tissue Act 2004.

Regulation 34 provides that an officer of a body corporate, or a partner in a Scottish partnership, commits an offence when it is proved that such body or partnership committed an offence under these Regulations with the consent or connivance of that officer or partner, or it was attributable to neglect on his part.

Regulation 35 makes transitional provision in relation to licences under the 2004 Act which authorised the storage of material (other than blood) which has come from a human body for use for transplantation.

Such licences shall also be treated as licences under Schedule 1 to these Regulations on the commencement date (5 July 2007).

A Regulatory Impact Assessment and a Transposition Note have been prepared for these Regulations and a copy of each has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment and the Transposition Note can be obtained from the Organ and Tissue Transplantation Team, Department of Health, Room 611, 6th floor North, Wellington House, 133-155 Waterloo Road, London SE1 8UG.

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.

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