STATUTORY INSTRUMENTS

2007 No. 1522

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

Made - - - -	*24th May 2007*
Coming into force	
for the purposes of regulation 1(3)	*25th May 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 [M1] in relation to health protection measures regulating the use of material of human origin [M2];

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:—

Marginal Citations

M1 1972 c.68.

M2 S.I. 2004/3037.

PART 1

INTRODUCTORY

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

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

(3) These Regulations shall come into force on the day after the day on which they are made ("the initial commencement date") 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 under the 1990 Act on the main commencement date.

(4) In these Regulations—

"the 1990 Act" means the Human Fertilisation and Embryology Act 1990 [M3],

and other words and expressions have the same meaning as in the 1990 Act as amended by these Regulations.

Marginal Citations

M3 1990 c.37.

Designation of the competent authority

2. The Human Fertilisation and Embryology Authority (in these Regulations referred to as "the Authority") is designated the competent authority for the purpose of the first, second and third Directives so far as they relate to gametes and embryos.

PART 2

AMENDMENTS TO THE 1990 ACT

Amendments to the 1990 Act

3. The 1990 Act is amended as follows.

Principal terms used in the 1990 Act

4. In section 1 (meaning of "embryo", "gamete" and associated expressions), after subsection (4) insert—

"(5) For the purposes of this Act, sperm is to be treated as partner-donated sperm if the donor of the sperm and the recipient of the sperm declare that they have an intimate physical relationship.".

References to Directives

5. After section 1 insert—

"**1A. Reference to Directives**

In this Act—

"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,

"the second Directive" means 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, and

"the third Directive" means Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council 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."
M4

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Marginal Citations
M4 OJ L102, 7.4.2004, p.48, OJ L38, 9.2.2006, p.40 and OJ L294, 25.10.2006, p.32.

Other terms used in the 1990 Act

6.—(1) Section 2 (other terms) is amended as follows.

(2) In subsection (1), in the appropriate places, insert the following definitions—

""basic partner treatment services" means treatment services that are provided for a woman and a man together without using—

(a) the gametes of any other person, or

(b) embryos created outside the woman's body,",

""competent authority", in relation to an EEA state other than the United Kingdom or in relation to Gibraltar, means an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second and third Directives,",

""distribution", in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,",

""human application" means use in a human recipient,",

""non-medical fertility services" means any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services,",

""processing", in relation to gametes or embryos intended for human application, means any operation involved in their preparation, manipulation or packaging, and related terms are to be interpreted accordingly,",

""procurement", in relation to gametes or embryos intended for human application, means any process by which they are made available, and related terms are to be interpreted accordingly,",

""serious adverse event" means—

(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

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

(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up," ,

""serious adverse reaction" means an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or

non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness,",

""store", in relation to gametes or embryos, means preserve, whether by cryopreservation or in any other way, and "storage" and "stored" are to be interpreted accordingly,", and

""traceability" means the ability—

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) to identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety,".

(3) In subsection (2), for the words from ", whether preserved" onwards substitute " in storage ".

(4) After subsection (2), insert—

"(2A) For the purposes of this Act, a person who, from any premises, controls the provision of services for transporting gametes or embryos is to be taken to distribute gametes or embryos on those premises.

(2B) In this Act, any reference to a requirement of a provision of the first, second or third Directive is a reference to a requirement which that provision requires to be imposed.".

Third party agreements etc.

7. After section 2 insert—

"**2A. Third party agreements**

(1) For the purposes of this Act, a "third party agreement" is an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority 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) procures, tests or processes gametes or embryos (or both), on behalf of the holder of the licence, or

(b) supplies to the holder of the licence any goods or services (including distribution services) which may affect the quality or safety of gametes or embryos.

(2) In this Act—

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

(a) on which a third party procures, tests, processes or distributes gametes or embryos on behalf of any person in connection with activities carried out by that person under a licence, or

(b) from which a third party provides any goods or services which may affect the quality or safety of gametes or embryos to any person in connection with activities carried out by that person under a licence;

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

(3) References in this Act to the persons to whom a third party agreement applies are to—

(a) the third party,

(b) any person designated in the third party agreement as a person to whom the agreement applies, and

(c) any person acting under the direction of a third party or of any person so designated.".

Prohibitions in connection with embryos

8. In section 3 (prohibitions in connection with embryos), for subsection (1) substitute—

"(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except—

(a) in pursuance of a licence, or

(b) in the case of—

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo,

in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.".

Prohibitions in connection with gametes

9.—(1) Section 4 (prohibition in connection with gametes) is amended as follows.

(2) In subsection (1), for paragraph (b) substitute—

"(b) in the course of providing treatment services for any woman, use—

(i) any sperm, other than partner-donated sperm which has been neither processed nor stored,

(ii) the woman's eggs after processing or storage, or

(iii) the eggs of any other woman, or".

(3) After subsection (1), insert—

"(1A) No person shall procure, test, process or distribute any gametes intended for human application except in pursuance of a licence or a third party agreement.".

Duties of the Authority

10. After section 8 (general functions of the Authority), insert—

"**8A. Duty of Authority to communicate with competent authorities of other EEA states**

The Authority shall communicate to the competent authorities of EEA states other than the United Kingdom or of Gibraltar, and to the European Commission, such information in relation to serious adverse events and serious adverse reactions as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the

withdrawal from use of gametes and embryos that are intended for human application but are known or suspected to be unsuitable for such application.".

Inspection of licensed and other premises

11.—(1) Section 9 (licence committees and other committees) is amended as follows.

(2) After subsection (7), insert—

"(7A) Before considering such an application, the licence committee may also arrange for—

(a) any premises that will be relevant third party premises for the purposes of the application to be inspected on its behalf, and

(b) a report on the inspection to be made to it.".

(3) For subsection (8) substitute—

"(8) A licence committee shall arrange for any premises to which a licence relates to be inspected on its behalf at intervals not exceeding two years, and for a report on the inspection to be made to it.".

(4) Omit subsection (9).

(5) In subsection (10) , for "one year" substitute " two years ".

(6) After subsection (10), insert—

"(10A) A licence committee may arrange for any relevant third party premises to be inspected on its behalf and for a report on the inspection to be made to it.".

(7) In subsection (11), for "(7) or (8)" substitute " (7), (7A), (8) or (10A) ".

Licences for treatment, storage and research

12. In section 11 (licences for treatment, storage and research), after subsection (1)(a) insert—

"(aa) licences under paragraph 1A of that Schedule authorising activities in the course of providing non-medical fertility services,".

General conditions

13.—(1) Section 12 (general conditions) is amended as follows.

(2) Make the existing provision subsection (1).

(3) In that subsection—

(a) in paragraph (a), for "that the activities authorised by the licence" substitute " except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities ",

(b) after paragraph (a) insert—

"(aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,", and

(c) at the beginning of paragraph (c) insert " except in relation to the use of gametes in the course of providing basic partner treatment services or non-medical fertility services, ".

(4) After that subsection, insert—

"(2) Subsection (3) applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2, and

(b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application.

(3) It shall be a condition of every licence to which this subsection applies that—

(a) such information as is necessary to facilitate the traceability of gametes and embryos, and

(b) any information relating to the quality or safety of gametes or embryos,

shall be recorded and provided to the Authority upon request.".

Conditions of licences for treatment

14. In section 13 (conditions of licences for treatment), in subsection (5), after "treatment services" insert " , other than basic partner treatment services, ".

Conditions of licences for non-medical fertility services

15. After section 13, insert—

"**13A. Conditions of licences for non-medical fertility services**

(1) The following shall be conditions of every licence under paragraph 1A of Schedule 2.

(2) The requirements of section 13(2) to (4) and (7) shall be complied with.

(3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.

(4) Donors of sperm, other than partner-donated sperm, shall be provided with such information as the Authority shall specify in directions for the purpose of securing compliance with the requirements of Part A of the Annex to the first Directive (information to be provided on the donation of reproductive cells).".

Conditions of storage licences

16. In section 14(1)(a) (conditions of storage licences), after "licence", in the first and third places it occurs, insert " or third party agreement ".

Supplementary licence conditions: human application

17. After section 14 (conditions of storage licences), insert—

"**14A. Conditions of licences: human application**

(1) This section applies to—

(a) every licence under paragraph 1 or 1A of Schedule 2, and

(b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application.

(2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.

(3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.

(4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.".

Serious adverse events and serious adverse reactions

18. After section 15 (conditions of research licences), insert—

"**15A. Duties of the Authority in relation to serious adverse events and serious adverse reactions**

(1) The Authority shall investigate serious adverse events and serious adverse reactions and take appropriate control measures.

(2) In investigating any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for—

(a) any premises to which a licence relates and any relevant third party premises to be inspected on its behalf, and

(b) a report on the inspection to be made to it.

(3) If the Authority receives a request from a competent authority in an EEA state other than the United Kingdom or in Gibraltar to carry out an inspection in relation to a serious adverse event or serious adverse reaction, the Authority must arrange for such an inspection to be carried out, for a report to be made of the inspection and for appropriate control measures to be taken.".

Grant of licence

19. In section 16 (grant of licence), in subsection (2), for paragraph (c) substitute—

"(c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application, that the individual—

(i) possesses a diploma, certificate or other evidence of formal qualifications in the field 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 is otherwise considered by the licence committee to be suitably qualified on the basis of academic qualifications in the field of nursing, and

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

(ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes or embryos not intended for human application or a licence under paragraph 3 of that Schedule, that the licence committee is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,

(cb) that the licence committee is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act.".

The person responsible

20. In section 17 (the person responsible), in subsection (1), after paragraph (d) omit the word "and" and after paragraph (e) add—

"(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and

(g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.".

Revocation and variation of licence

21. In section 18 (revocation and variation of licence), in subsection (1), after paragraph (b) insert—

"(ba) that any premises which are relevant third party premises in relation to the licence are not suitable for the activities entrusted to the third party by the person who holds the licence,".

Directions as to particular matters

22.—(1) Section 24 (directions as to particular matters) is amended as follows.

(2) In subsection (1), after "treatment services" insert " , other than basic partner treatment services, ".

(3) In subsection (2), after "paragraph 1" insert " or 1A ".

(4) In subsection (3), at the beginning insert " In relation to gametes or embryos that are not intended for human application, ".

(5) After subsection (3) insert—

"(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage—

(a) between premises to which licences relate,

(b) between such premises and relevant third party premises,

(c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or

(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4),

in such circumstances and subject to such conditions as may be specified in the directions.".

(6) After subsection (4), insert—

"(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in this Act, and

(b) have regard to ensuring traceability.".

(7) At the end insert—

"(12) Directions may require a unique code to be assigned to each donation of gametes and embryos intended for human application received pursuant to a licence.

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of—

(a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application,

(b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or

(c) any misidentification or mix-up of gametes or embryos intended for human application.

(14) In this section, "tissue establishment" has the meaning given by Article 3(o) of the first Directive.".

The Authority's register of information

23.—(1) Section 31 (the Authority's register of information) is amended as follows.

(2) In subsection (2)—

(a) for paragraph (a) substitute—

"(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,",

(b) after paragraph (a) insert—

"(aa) the procurement or distribution, in the course of providing non-medical fertility services for any identifiable individual, of any sperm (other than partner-donated sperm which has not been stored),",

(c) in paragraph (b), omit "or use",

(d) after paragraph (b) insert—

"(ba) the use, otherwise than for the purposes of basic partner treatment services, of gametes of an identifiable individual, or

(bb) the use of an embryo taken from any identifiable woman,", and

(e) for "was, or may have been, born in consequence of treatment services" substitute " is a relevant individual ".

(3) In subsection (3)(a), for "was, or may have been, born in consequence of treatment services" substitute " is a relevant individual ".

(4) In subsection (6)(a), for "was, or may have been, born in consequence of treatment services" substitute " is a relevant individual ".

(5) After subsection (7) add—

"(8) In this section "relevant individual" means an individual who was, or may have been, born in consequence of—

(a) treatment services other than basic partner treatment services, or

(b) the procurement or distribution, in the course of providing non-medical fertility services, of any sperm (other than partner-donated sperm which has not been stored).".

Other registers to be kept by the Authority

24. After section 31, insert—

"**31A. The Authority's register of licences**

(1) The Authority shall keep a register recording the grant, suspension or revocation of—

(a) every licence under paragraph 1 or 2 of Schedule 2 authorising activities in relation to gametes or embryos intended for use for human application, and

(b) every licence under paragraph 1A of Schedule 2.

(2) The register shall specify, in relation to each such licence—

(a) the activities authorised,

(b) the address of the premises to which the licence relates,

(c) the name of the person responsible and, if applicable, the nominal licensee, and

(d) any variations made.

(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.

31B. The Authority's register of serious adverse events and serious adverse reactions

(1) The Authority shall keep a register containing information provided to it under this Act 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.".

Disclosure of information and confidentiality

25.—(1) Section 33 (restrictions on disclosure of information) is amended as follows.

(2) In subsection (5) after "a person to whom a licence applies" insert " , no person who is or has been a person to whom a third party agreement applies, ".

(3) After subsection (6)(b), insert—

"(ba) to a person to whom a third party agreement applies for the purposes of his functions under the third party agreement,".

(4) In subsection (7), for "paragraph (a) or (b)" substitute " paragraphs (a) to (bb) ".

Powers of members and employees of Authority

26. In section 39 (powers of members and employees of Authority), in subsection (1)—

(a) after "to which a licence relates" insert " , or relevant third party premises, ", and

(b) in paragraph (a)—

(i) omit the word "or" at the end of sub-paragraph (i), and

(ii) after sub-paragraph (i) insert—

"(ia) for the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction, or".

Offences

27.—(1) Section 41 (offences) is amended as follows.

(2) In subsection (2)(a), after "section 3(1)" insert " or (1A) ".

(3) In subsection (2)(b), omit "or uses" and "or (b)".

(4) After subsection (2)(b) insert—

"(ba) uses any gametes in contravention of section 4(1)(b),".

(5) After subsection (2) insert—

"(2A) A person who contravenes section 3(1B) or 4(1A) is guilty of an offence.".

(6) In subsection (4), after "(3) above" insert " , other than an offence to which subsection (4B) applies, ".

(7) After subsection (4) insert—

"(4A) Subsection (4B) applies to—

(a) an offence under subsection (2)(ba) or (d) or (3) committed in the course of providing basic partner treatment services or non-medical fertility services, or

(b) an offence under subsection (2A).

(4B) A person guilty of an offence to which this subsection applies is liable—

(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and

(b) on summary conviction, to imprisonment for a term not exceeding three months or a fine not exceeding the statutory maximum or both.".

(8) In subsection (11)(a), after the word "licence" insert " or third party agreement ".

Index

28.—(1) Section 47 (index) is amended as follows.

(2) In the table in that provision—

(a) in the entry beginning "Store" for "Section 2(2)" substitute " Section 2(1) ", and

(b) insert the following entries at the appropriate places—

"Basic partner treatment services"	"Section 2(1)",
"Competent authority"	"Section 2(1)",
"Distribution, in relation to gametes or embryos intended for human application"	"Section 2(1)",
"First Directive"	"Section 1A",
"Human application"	"Section 2(1)",
"Non-medical fertility services"	"Section 2(1)",
"Partner-donated sperm"	"Section 1(5)",
"Person to whom a third party agreement applies"	"Section 2A(3)",
"Processing, in relation to gametes or embryos intended for human application"	"Section 2(1)",

"Procurement, in relation to gametes or embryos intended for human application"	"Section 2(1)",
"Relevant third party premises, in relation to a licence"	"Section 2A(2)",
"Second Directive"	"Section 1A",
"Serious adverse event"	"Section 2(1)",
"Serious adverse reaction"	"Section 2(1)",
"Third Directive"	"Section 1A",
"Third party"	"Section 2A(2)",
"Third party agreement"	"Section 2A(1)",
"Traceability"	"Section 2(1)".

Activities for which licences may be granted: Schedule 2 to the 1990 Act

29. In Schedule 2 (activities for which licences may be granted)—

(a) in paragraph 1(1)—

(i) for sub-paragraphs (b) and (c) substitute—

"(b) procuring, keeping, testing, processing or distributing embryos,

(c) procuring, testing, processing, distributing or using gametes", and

(ii) at the beginning of sub-paragraph (d) insert " other ",

(b) after paragraph 1 insert—

"**Licences for non-medical fertility services**

1A.—(1) A licence under this paragraph may authorise any of the following in the course of providing non-medical fertility services—

(a) procuring sperm, and

(b) distributing sperm.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.",

(c) for paragraph 4(1), substitute—

"(1) A licence under this Schedule can only authorise activities to be carried on—

(a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and

(b) under the supervision of an individual designated in the licence.

(1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.",

(d) omit paragraph 4(2)(a), and

(e) for paragraph 4(2)(d) substitute—

"(d) apply to premises of the person who holds the licence in different places.".

New Schedule to the 1990 Act

30. After Schedule 3 (consents to use of gametes or embryos) insert—

"SCHEDULE 3A Section 14A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Traceability and coding system

1. Licence conditions shall require that all persons to whom a licence applies 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. Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

Serious adverse events and serious adverse reactions

3. Licence conditions shall require 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,

to be in place 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

4. For the purpose of securing compliance with the requirements of Articles 21(5) (tissue and cell storage conditions) and 24 (relations between tissue establishments and third parties) of the first Directive, licence conditions 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.

Requirements for procurement of gametes and embryos

5. Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply 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.

Selection criteria and laboratory tests required for donors of reproductive cells

6. In relation to partner-donated sperm which is not intended to be used without processing or storage, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 2 (partner donation (not direct use)) of Annex III (selection criteria and laboratory tests required for donors of reproductive cells) to the second Directive.

7. In relation to donations of gametes or embryos other than partner-donated sperm or partner-created embryos, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 3 (donations other than by partners) of Annex III to the second Directive.

8. Licence conditions shall require that the laboratory tests required by sections 2 and 3 of Annex III to the second Directive to be carried out for the purpose of selecting gametes or embryos for donation, meet the requirements of section 4 (general requirements to be met for determining biological markers) of Annex III to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

9. In relation to—

(a) donation and procurement procedures, and

(b) the reception of gametes and embryos at the premises to which a licence relates or at relevant third party premises,

licence conditions shall require 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 partner-donated sperm and partner-created embryos and autologous donors (assessment of donor's medical and behavioural information)	Annex IV, point 1.2
Procurement procedures for gametes and embryos (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 gametes and embryos (minimum labelling requirements)	Annex IV, point 1.6

Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. Reception of tissues and cells at the tissue establishment	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, points 2.1 to 2.3
Registration of data (other than in respect of partner-donated sperm and partner-created embryos)	Annex IV, point 2.4
Registration of data (partner-donated sperm and partner-created embryos)	Annex IV, point 2.5

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

10. Licence conditions shall require 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 for gametes and embryo preparation processes

11. In respect of gametes and embryos preparation processes, licence conditions shall require 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 gametes and embryos at the tissue establishment	Annex II, Part A

Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo 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

Interpretation of this Schedule

12. In this Schedule, "partner-created embryos" means embryos created using the gametes of a man and a woman who declare that they have an intimate physical relationship.".

PART 3

TRANSITORY PROVISIONS

Basic partner treatment services: inspections

31.—(1) This regulation applies where—

(a) immediately before the initial commencement date, a person who was before that date using gametes for the purpose of providing basic partner treatment services either—

(i) does not hold a licence under paragraph 1 of Schedule 2 to the 1990 Act, or

(ii) holds a licence under that paragraph which would not authorise the use of gametes for that purpose after the main commencement date, and

(b) before the main commencement date, that person applies for a licence under that paragraph authorising the use of gametes for that purpose, or a variation of a licence that will authorise the use of gametes for that purpose.

(2) In a case to which this regulation applies, section 9(7) (licence committees and other committees) of the 1990 Act (which requires a licence committee to arrange for an inspection of premises where a licensable activity is to be carried out before considering a licence application) shall be read as providing the Authority with power to inspect such premises before granting or varying a licence before the main commencement date, but not as placing a duty on it to do so.

(3) Where, in a case to which this regulation applies—

(a) either—

(i) a licence is granted under paragraph 1 of Schedule 2 to the 1990 Act, or

(ii) a licence granted under paragraph 1 of Schedule 2 to the 1990 Act is varied,

before the main commencement date, and

(b) any premises on which the activities governed by the 1990 Act are carried out were not inspected on behalf of a licence committee before the licence was so granted or varied,

a licence committee shall arrange for such premises to be inspected on its behalf before the end of the period of two years beginning with the day the licence or variation (as the case may be) is granted.

Basic partner treatment services: licence committees

32.—(1) This regulation applies where a person who, before the initial commencement date, was not using gametes for the purpose of providing basic partner treatment services applies, before the main commencement date, for a licence under paragraph 1 of Schedule 2 to the 1990 Act authorising the use of gametes for that purpose.

(2) In a case to which this regulation applies, the Authority may provide for any of its functions relating to the granting of licences which are discharged by a licence committee in accordance with section 9(1) of the 1990 Act, to be discharged prior to the main commencement date by a member of the Authority.

(3) Where, in accordance with paragraph (2), the Authority has provided for any of its functions in relation to the grant of licences to be discharged by a member of the Authority, any such function which has been properly discharged by any such member shall be treated as having been properly discharged by the Authority for the purposes of the 1990 Act.

Treatment services and storage licences: the person responsible

33.—(1) This regulation applies to any case where—

(a) immediately before the initial commencement date a person was carrying on activities pursuant to—

(i) a licence under paragraph 1 of Schedule 2 to the 1990 Act, or

(ii) a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application, and

(b) the person responsible in respect of such licence does not meet the requirement specified in section 16(2)(c)(i) of the 1990 Act, as inserted by regulation 19.

(2) That requirement does not prevent the person mentioned in paragraph (1)(a) from continuing to act as the responsible person in relation to—

(a) the activities authorised by the licence, and

(b) where before the initial commencement date persons to whom the licence applies were using gametes for the purpose of providing basic partner treatment services, the continued use of gametes for that purpose if that use is authorised by a variation of the licence taking effect on the main commencement date,

for a period of six months beginning with the main commencement date.

Signed by authority of the Secretary of State for Health

Department of Health
24th May 2007

Caroline Flint
Minister of State

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, in relation to gametes and embryos intended for use in a human recipient, 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 [M5], as well as Commission Directive 2006/17/EC[M6] and Commission Directive 2006/86/EC[M7] laying down technical requirements in relation to Directive 2004/23/EC ("the Directives"). They do so by amending the Human Fertilisation and Embryology Act 1990 ("the 1990 Act").

Regulation 2 appoints the Human Fertilisation and Embryology Authority ("the Authority") as the competent authority in relation to the Directives. Regulations 4 to 7 insert new definitions in sections 1 and 2 of the 1990 Act and inserts a new section 2A (which relates to interpretation).

Regulations 8 and 9 amend sections 3 and 4 (prohibitions in connection with embryos and gametes). The licence requirement in section 4(1)(b) is expanded to include treatment services provided to persons together where there is no third party donor. Sections 3 and 4 have been amended to expressly prohibit the procurement, processing or distribution of any embryo or gametes, and the testing of any gametes, intended for human application except pursuant to either a licence or an agreement with a licence holder which complies with certain requirements of the Directives.

Regulations 10 (which inserts a new section 8A (duty of Authority to communicate with competent authorities of other EEA states)), 18 (which inserts a new section 15A (duties of the Authority in relation to serious adverse events and serious adverse reactions)) and 20 (which amends section 17) impose additional duties on the Authority and the person responsible (in relation to a licence). Regulation 11 amends section 9 of the 1990 Act (licence committees and other committees) to make further provision in relation to the inspection of premises, including premises of third parties.

Regulation 12 amends section 11 of the 1990 Act (licences for treatment, storage and research) to provide for a new licence in relation to non-medical fertility services. Regulation 29 amends Schedule 2 to the 1990 Act (activities for which licences may be granted) by inserting a new paragraph 1A to make provision in relation to such licences.

Regulations 13 to 17 amend sections 12 to 14 of the 1990 Act and insert new sections 13A and 14A (which relate to licence conditions) to make further provision in relation to licence conditions. In particular, licences are to contain conditions required by a new Schedule 3A (supplementary licence conditions: human application) to the 1990 Act (inserted by regulation 30), to secure compliance with requirements of the Directives. Regulation 19 amends section 16 (grant of licence) to require persons responsible in relation to a licence to have minimum qualifications and experience.

Regulation 21 amends section 18 (revocation and variation of licence) of the 1990 Act to permit licence revocations or variations if premises of third parties providing services are not suitable.

Regulation 22 amends section 24 (directions as to particular matters) to expand the Authority's powers of direction. Regulations 23 to 25 amend sections 31 to 33 (which relate to information to be kept by the Authority and disclosure of such information), in particular by inserting new sections 31A and 31B to require the Authority to keep registers of licences and of serious occurrences affecting donors or recipients.

Regulation 26 amends section 39 (powers of members and employees of Authority) of the 1990 Act to extend the Authority's enforcement powers to cover third party premises and serious occurrences. Regulation 27 amends section 41 (offences) to provide for maximum penalties for the new offences created by the amendments to sections 3 and 4 of the 1990 Act.

Regulations 31 to 33 make transitory provision in relation to licences under the 1990 Act.
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 Assisted Reproduction Team, Department of Health, Room 609, Wellington House, 133-155 Waterloo Road, London SE1 8UG.

Status:
Point in time view as at 25/05/2007.

Changes to legislation:
There are currently no known outstanding effects for the The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.