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 FERTILISATION AND EMBRYOLOGY

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

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

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

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

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

PART 1

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").

(**1**) 1972 c.68.
(**2**) S.I. 2004/3037.

(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(**3**),

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

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

(**3**) 1990 c.37.

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."(**4**).

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—

(**4**) OJ L102, 7.4.2004, p.48, OJ L38, 9.2.2006, p.40 and OJ L294, 25.10.2006, p.32.

(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—