



Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

Principal terms used

1 Meaning of “embryo”, “gamete” and associated expressions.

- [^{F1}(1) In this Act (except in section 4A or in the term “human admixed embryo”)—
- (a) embryo means a live human embryo and does not include a human admixed embryo (as defined by section 4A(6)), and
 - (b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.]
- (2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—
- [^{F2}(a) references to embryos the creation of which was brought about *in vitro* (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there, and]
 - (b) references to embryos taken from a woman do not include embryos whose creation was brought about *in vitro*.
- (3) This Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.
- [^{F3}(4) In this Act (except in section 4A)—
- (a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,
 - (b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and
 - (c) references to gametes are to be read accordingly.]

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- [^{F4}(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.]
- [^{F5}(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) “embryo”, “eggs”, “sperm” or “gametes” includes things specified in the regulations which would not otherwise fall within the definition.
- (7) Regulations made by virtue of subsection (6) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes.]

Textual Amendments

- F1** S. 1(1) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), ss. 1\(2\), 68\(2\)](#); [S.I. 2009/2232, art. 2\(a\)](#)
- F2** S. 1(2)(a) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), ss. 1\(3\), 68\(2\)](#); [S.I. 2009/2232, art. 2\(a\)](#)
- F3** S. 1(4) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), ss. 1\(4\), 68\(2\)](#); [S.I. 2009/2232, art. 2\(a\)](#)
- F4** S. 1(5) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\), regs. 1, {4}](#)
- F5** S. 1(6)(7) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), ss. 1\(5\), 68\(2\)](#); [S.I. 2009/2232, art. 2\(a\)](#)

Modifications etc. (not altering text)

- C1** S. 1(1) applied (1.4.2005 for certain purposes, 20.10.2005 for certain further purposes, 7.4.2006 for certain further purposes, 31.7.2006 for certain further purposes and 1.9.2006 otherwise) by [Human Tissue Act 2004 \(c. 30\), s. 54\(6\)](#) (with transitional provisions in s. 58); [S.I. 2005/919, {art. 3}, Sch.](#) (with transitional provisions in art. 2); [S.I. 2005/2792, art. 2\(d\)](#); [S.I. 2006/404, art. 3\(3\)](#), [Sch.](#) (subject to art. 4); [S.I. 2006/1997, art. 2\(1\)\(2\)](#), 3(1)(2), [Sch.](#) (subject to arts. 4, 7, 8) (as that S.I. is amended by [S.I. 2006/2169, art. 2](#))
- C2** S. 1(4) applied (1.4.2005 for certain purposes, 20.10.2005 for certain further purposes, 7.4.2006 for certain further purposes, 31.7.2006 for certain further purposes and 1.9.2006 otherwise) by [Human Tissue Act 2004 \(c. 30\), s. 54\(6\)](#) (with transitional provisions in s. 58); [S.I. 2005/919, {art. 3}, Sch.](#) (with transitional provisions in art. 2); [S.I. 2005/2792, art. 2\(d\)](#); [S.I. 2006/404, art. 3\(3\)](#), [Sch.](#) (subject to art. 4); [S.I. 2006/1997, art. 2\(1\)\(2\)](#), 3(1)(2), [Sch.](#) (subject to arts. 4, 7, 8) (as that S.I. is amended by [S.I. 2006/2169, art. 2](#))

Commencement Information

- I1** S. 1 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

[^{F6}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,

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“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.]

Textual Amendments

- F6** S. 1A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, 5

2 Other terms.

(1) In this Act—

“the Authority” means the Human Fertilisation and Embryology Authority established under section 5 of this Act,

[^{F7}“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,]

[^{F7}“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,]

“directions” means directions under section 23 of this Act,

[^{F7}“distribution”, in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,]

[^{F7}“human application” means use in a human recipient,]

“licence” means a licence under Schedule 2 to this Act and, in relation to a licence, “the person responsible” has the meaning given by section 17 of this Act, and

[^{F7}“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,]

[^{F8}“nuclear DNA”, in relation to an embryo, includes DNA in the pronucleus of the embryo,]

[^{F7}“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,]

[^{F7}“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,]

[^{F7}“serious adverse event” means—

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(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.]

[^{F7}“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,]

[^{F7}“store”, in relation to gametes[^{F9}, embryos or human admixed embryos], means preserve, whether by cryopreservation or in any other way, and “storage” and “stored” are to be interpreted accordingly,]

[^{F7}“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,]

“treatment services” means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

(2) References in this Act to keeping, in relation to embryos[^{F10}, gametes or human admixed embryos], include keeping while preserved [^{F11}in storage].

[^{F12}(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.]

(3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted.

Textual Amendments

F7 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, **6(2)**

F8 Words in s. 2(1) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 2, 68(2); S.I. 2009/2232, art. 2(a)

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- F9** Words in s. 2(1) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 2\(a\)](#); S.I. 2009/2232, art. 2(y)
- F10** Words in s. 2(2) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 2\(b\)](#); S.I. 2009/2232, art. 2(y)
- F11** Words in s. 2(2) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, 6(3)
- F12** S. 2(2A)(2B) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), [regs. 1](#), 6(4)

Commencement Information

- I2** S. 2 wholly in force at 1.8.1991 see s. 49(2), S.I. 1990/2165 and [S.I. 1991/1440](#), [art. 2\(2\)](#)

[^{F13}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.]

Textual Amendments

- F13** S. 2A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), [regs. 1](#), 7

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