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.**]**

[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,

"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, **[**F7as amended by Commission Directive 2012/39/EU,**]**F8...

[F9"the third Directive" means—

(a) in the application of this Act in relation to Great Britain, 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 ("the 2006 Directive"), as it had effect immediately before 29 April 2015 (which is the date on which the amendments made by Commission Directive 2015/565/EU came into force), and

(b) in the application of this Act in relation to Northern Ireland, the 2006 Directive as amended by Commission Directive 2015/565/EU,**]**

"the fourth Directive" means Commission Directive 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported 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**

F7 Words in s. 1A inserted (15.12.2014) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2014 (S.I. 2014/2884), regs. 1, **2**

F8 Word in s. 1A omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **3(2)(a)**

F9 Words in s. 1A substituted (31.12.2020) by S.I. 2019/482, **reg. 2(2)** (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **3**); 2020 c. 1, **Sch. 5 para. 1(1)**

2 Other terms.

(1) In this Act—

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

[F10"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,**]**

[F10"competent authority", in relation to an EEA state F11..., means an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second**[**F12, third and fourth**]** Directives,**]**

"directions" means directions under section 23 of this Act,

[F10**]**"distribution", in relation to gametes or embryos intended for human application, means transportation or delivery **[**F13**]**to any person in or outside the United Kingdom for human application**]**, and related terms are to be interpreted accordingly,**]**

[F10**]**"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

[F10**]**"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,**]**

[F14**]**"nuclear DNA", in relation to an embryo, includes DNA in the pronucleus of the embryo,**]**

[F10**]**"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,**]**

[F10**]**"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,**]**

[F10**]**"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,**]**

[F10**]**"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,**]**

[F10**]**"store", in relation to gametes**[**F15**]**, embryos or human admixed embryos**]**, means preserve, whether by cryopreservation or in any other way, and "storage" and "stored" are to be interpreted accordingly,**]**

[F16**]**"tissue establishment" means a tissue bank or a unit of a hospital or another body which procures, tests, processes, preserves, stores or distributes human gametes or embryos,**]**

[F10**]**"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**[**F17, gametes or human admixed embryos **]**, include keeping while preserved **[**F18in storage**]**.

[F19(2A) For the purposes of this Act, a person who, from any premises, controls the provision of services for transporting gametes or embryos **[**F20to any person in or outside the United Kingdom for human application**]** is to be taken to distribute gametes or embryos on those premises.

[F21(2B) Any reference in this Act to a requirement of a provision of the first, second, third or fourth Directive—

(a) in the application of this Act in relation to Great Britain, is to be read as a reference to a requirement which that provision would require to be imposed if the provision formed part of the law of England and Wales or Scotland, and

(b) in the application of this Act in relation to Northern Ireland, is to be read as 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

F10 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)**

F11 Words in s. 2 omitted (31.12.2020) by S.I. 2019/482, **reg. 2(3)(a)(i)** (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Words in s. 2(1) substituted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **3(3)(a)(i)**

F13 Words in s. 2(1) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **3(3)(a)(ii)**

F14 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)

F15 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)

F16 Words in s. 2(1) inserted (31.12.2020) by S.I. 2019/482, regs. 1, **2(3)(a)(ii)** (as amended by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 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)

F18 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)**

F19 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)

F20 Words in s. 2(2A) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **3(3)(b)**

F21 S. 2(2B) substituted (31.12.2020) by S.I. 2019/482, regs. 1, **2(3)(b)** (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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)**

[F22 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.

F23 **[** (1A) For the purposes of subsection (1), as it applies in relation to Great Britain, Article 24 of the first Directive is to be read subject to the modifications set out in paragraph 11A(8) of Schedule 3A.**]**

(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

F22 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**

F23 S. 2A(1A) inserted (31.12.2020) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/482), regs. 1, **2(4)** (as amended by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **5**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F24 2B Meaning of "importing licensee", "third country premises" etc

(1) This section applies for the purposes of this Act.

(2) "Importing licensee" means a person—

(a) to whom a licence applies, and

(b) who is authorised by directions under section 24(4) to import qualifying gametes or embryos F25... from a third country.

(3) "Qualifying gametes or embryos" means gametes or embryos intended for human application.

[F26(4) "Third country" means—

(a) in relation to the import of qualifying gametes or embryos into, or the export of qualifying gametes or embryos from, Great Britain, a country other than the United Kingdom,

(b) in relation to the import of qualifying gametes or embryos into Northern Ireland, a country other than Northern Ireland or an EEA state, and

(c) in relation to the export of qualifying gametes or embryos from Northern Ireland, a country other than the United Kingdom or an EEA state.

(5) Premises are "third country premises" if—

(a) in relation to Great Britain—

(i) they are in a country other than the United Kingdom, and

(ii) they are premises in or from which a third country supplier, or a person providing services to a third country supplier, procures, tests, processes, stores, distributes or exports qualifying gametes or embryos intended for import into Great Britain, and

(b) in relation to Northern Ireland—

(i) they are in a country other than Northern Ireland or an EEA state, and

(ii) they are premises in or from which a third country supplier, or a person providing services to a third country supplier, procures, tests, processes, stores, distributes or exports qualifying gametes or embryos intended for import into Northern Ireland.

(6) "Third country supplier" means—

(a) in relation to qualifying gametes or embryos intended for import into Great Britain, a person in a country other than the United Kingdom who has an agreement with an importing licensee for exporting such gametes or embryos into Great Britain, and

(b) in relation to qualifying gametes or embryos intended for import into Northern Ireland, a person in a country other than Northern Ireland or an EEA state who has an agreement with an importing licensee for exporting such gametes or embryos into Northern Ireland.]]

Textual Amendments

F24 S. 2B inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **3(4)**

F25 Words in s. 2B(2)(b) omitted (31.12.2020) by S.I. 2019/482, **reg. 2(5)** (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

F26 S. 2B(4)-(6) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(5)** (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Principal terms used.