



Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

Licence conditions

12 General conditions.

[^{F1}(1)] The following shall be conditions of every licence granted under this Act—

- (a) [^{F2}except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities] shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,
- [^{F3}(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,]
- (b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),
- (c) [^{F4}except in relation to the use of gametes in the course of providing basic partner treatment services ^{F5}... ,] that the provisions of Schedule 3 to this Act shall be complied with,
- (d) that proper records shall be maintained in such form as the Authority may specify in directions,
- (e) that no money or other benefit shall be given or received in respect of any supply of gametes[^{F6}, embryos or human admixed embryos] unless authorised by directions,
- (f) that, where gametes[^{F7}, embryos or human admixed embryos] are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions, and
- (g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify.

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

[^{F8}(2) Subsection (3) applies to—

- (a) every licence under paragraph 1 or 1A of Schedule 2, ^{F9}...
- (b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application[^{F10}, and
- (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are 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.]

Textual Amendments

- F1** S. 12 renumbered as s. 12(1) (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, **13(2)**
- F2** Words in s. 12(1)(a) 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, **13(3)(a)**
- F3** S. 12(1)(aa) 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, **13(3)(b)**
- F4** Words in s. 12(1)(c) 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, **13(3)(c)**
- F5** Words in s. 12(1)(c) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 12(2)(a), 68(2), **Sch. 8 Pt. 1**; S.I. 2009/2232, art. 2(c)
- F6** Words in s. 12(1)(e) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. **12(2)(b)**, 68(2); S.I. 2009/2232, art. 2(c)
- F7** Words in s. 12(1)(f) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. **12(2)(b)**, 68(2); S.I. 2009/2232, art. 2(c)
- F8** S. 12(2)(3) 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, **13(4)**
- F9** Word in s. 12(2)(a) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 12(3)(a), 68(2), **Sch. 8 Pt. 1**; S.I. 2009/2232, art. 2(c)
- F10** S. 12(2)(c) and word inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. **12(3)(b)**, 68(2); S.I. 2009/2232, art. 2(c)

Commencement Information

- I1** S. 12 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, **art. 2(2)**

13 Conditions of licences for treatment.

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (2) Such information shall be recorded as the Authority may specify in directions about the following—
 - (a) the persons for whom services are provided in pursuance of the licence,
 - (b) the services provided for them,

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
 - (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
 - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
 - (f) such other matters as the Authority may specify in directions.
- (3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.
- (4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (5) A woman shall not be provided with treatment services ^{F11}... unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for [^{F12}supportive parenting]), and of any other child who may be affected by the birth.
- [^{F13}(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- (6B) The reference in subsection (6A) to the intended second parent is a reference to—
- (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned in subsection (6A), and
 - (b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in subsection (6A).
- (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about—
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
 - (b) suitable methods of informing such a child of that fact.
- (6D) Where the person responsible receives from a person (“X”) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X’s withdrawal of consent to X being treated as

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the parent of any child resulting from the provision of treatment services to a woman (“W”), the person responsible—

- (a) must notify W in writing of the receipt of the notice from X, and
- (b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.

(6E) Where the person responsible receives from a woman (“W”) who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person (“X”) being treated as a parent of any child resulting from the provision of treatment services to W—

- (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W’s consent, or
- (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X,

the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).]

(7) Suitable procedures shall be maintained—

- (a) for determining the persons providing gametes or from whom embryos are taken for use in pursuance of the licence, and
- (b) for the purpose of securing that consideration is given to the use of practices not requiring the authority of a licence as well as those requiring such authority.

[^{F14}(8) Subsections (9) and (10) apply in determining any of the following—

- (a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question;
- (b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo;
- (c) which of two or more embryos to place in a woman.

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop—

- (a) a serious physical or mental disability,
- (b) a serious illness, or
- (c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

(10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop—

- (a) a gender-related serious physical or mental disability,
- (b) a gender-related serious illness, or
- (c) any other gender-related serious medical condition,

must not be preferred to those that are not known to carry such a risk.

(11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if—

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (a) it affects only one sex, or
 - (b) it affects one sex significantly more than the other.
- (12) No embryo appropriated for the purpose mentioned in paragraph 1(1)(ca) of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.
- (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.]

Textual Amendments

- F11** Words in s. 13(5) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 14(2)(a), 68(2), [Sch. 8 Pt. 1](#); S.I. 2009/2232, art. 2(d)
- F12** Words in s. 13(5) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 14(2)(b), 68(2) (with s. 14(6)); S.I. 2009/2232, art. 2(d)
- F13** S. 13(6)-(6E) substituted for s. 13(6) (6.4.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 14(3), 68(2); S.I. 2009/479, art. 4(a) (with art. 7Sch.)
- F14** S. 13(8)-(13) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 14(4), 68(2); S.I. 2009/2232, art. 2(d)

Commencement Information

- I2** S. 13 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400](#), art. 2(2)

[^{F15}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.

^{F16}(4)]

Textual Amendments

- F15** S. 13A 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, 15
- F16** S. 13A(4) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 5](#), [Sch. 8 Pt. 1](#); S.I. 2009/2232, art. 2(y)

14 Conditions of storage licences.

- (1) The following shall be conditions of every licence [^{F17}authorising the storage of gametes, embryos or human admixed embryos]—
 - [^{F18}(a) that gametes of a person shall be placed in storage only if—
 - (i) received from that person,

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person's consent to the storage is not required, or
 - (iii) acquired from a person to whom a licence or third party agreement applies,
 - (aa) that an embryo taken from a woman shall be placed in storage only if—
 - (i) received from that woman, or
 - (ii) acquired from a person to whom a licence or third party agreement applies,
 - (ab) that an embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,
 - (ac) that a human admixed embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,]
 - (b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,
 - [^{F19}(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,]
 - [^{F20}(c) that the requirements of subsection (3) (maximum storage periods) are met,]
 - [^{F21}(ca) that any gametes, embryos or human admixed embryos that have been kept in storage pursuant to the licence must, once they may no longer lawfully be so kept, be removed from storage and disposed of, and]
 - (d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.
- (2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.
- [^{F22}(3) The requirements referred to in subsection (1)(c) are as follows—
- (a) gametes must not be kept in storage for longer than such period not exceeding 55 years beginning with the day on which they are first placed in storage as the licence may specify;
 - (b) an embryo must not be kept in storage for treatment purposes for longer than such period not exceeding 55 years beginning with the day on which it is first so kept as the licence may specify;
 - (c) an embryo that is kept in storage for the research or training purpose but not for treatment purposes must not be so kept for longer than such period not exceeding 10 years beginning with the day on which consent was given under Schedule 3 to the storage of the embryo for that purpose as the licence may specify;
 - (d) a human admixed embryo must not be kept in storage for longer than such period not exceeding 10 years beginning with the day on which it is first placed in storage as the licence may specify.

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (4) Where under Schedule 3 consent is given to the storage of an embryo for the training or research purpose by different persons on different days, the reference in subsection (3) (c) to the day on which consent was given is to be taken as a reference to the last of those days.
- (5) For the purposes of this section—
 - (a) “treatment purposes” are purposes referred to in paragraph 2(1)(a) or (b) of Schedule 3;
 - (b) the “training purpose” is the purpose referred to in paragraph 2(1)(ba) of that Schedule;
 - (c) the “research purpose” is the purpose referred to in paragraph 2(1)(c) of that Schedule.]

Textual Amendments

- F17** Words in s. 14(1) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 15\(2\)\(a\)](#), [68\(2\)](#); [S.I. 2009/2232](#), [art. 2\(e\)](#)
- F18** S. 14(1)(a)-(ac) substituted for s. 14(1)(a) (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 15\(2\)\(b\)](#), [68\(2\)](#); [S.I. 2009/2232](#), [art. 2\(e\)](#)
- F19** S. 14(1)(ba) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 15\(2\)\(c\)](#), [68\(2\)](#); [S.I. 2009/2232](#), [art. 2\(e\)](#)
- F20** S. 14(1)(c) substituted (1.7.2022) by [Health and Care Act 2022 \(c. 31\)](#), [s. 186\(3\)](#), [Sch. 17 para. 2\(2\)](#) (with [Sch. 17 Pt. 2](#))
- F21** S. 14(1)(ca) inserted (1.7.2022) by [Health and Care Act 2022 \(c. 31\)](#), [s. 186\(3\)](#), [Sch. 17 para. 5](#) (with [Sch. 17 Pt. 2](#))
- F22** S. 14(3)-(5) substituted (1.7.2022) by [Health and Care Act 2022 \(c. 31\)](#), [s. 186\(3\)](#), [Sch. 17 para. 2\(3\)](#) (with [Sch. 17 Pt. 2](#))

Commencement Information

- I3** S. 14 wholly in force; s. 14 not in force at Royal Assent see [s. 49\(2\)](#); [s. 14\(5\)](#) in force for certain purposes at [8.7.1991](#) and s. 14 fully in force at [1.8.1991](#) by [S.I. 1991/1400](#), [art. 2\(1\)\(a\)\(2\)](#)

[^{F23}14A Conditions of licences: human application

- (1) This section applies to—
 - (a) every licence under paragraph 1 or 1A of Schedule 2, ^{F24}...
 - (b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application^{F25}, and
 - (c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are 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 [^{F26}Northern Ireland from an EEA State], 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.

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (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.]

Textual Amendments

- F23** S. 14A 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, **17**
- F24** Word in s. 14A(1)(a) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 6\(a\)](#), [Sch. 8 Pt. 1](#); S.I. 2009/2232, art. 2(y)
- F25** S. 14A(1)(c) and word inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 6\(b\)](#); S.I. 2009/2232, art. 2(y)
- F26** Words in s. 14A(3) substituted (31.12.2020) by S.I. 2019/482, [reg. 2\(8\)](#) (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **9**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

15 Conditions of research licences.

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.
- (3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.
- [^{F27}(5) If by virtue of paragraph 20 of Schedule 3 (existing cells or cell lines) qualifying cells, as defined by paragraph 20(2) of that Schedule, of a person (“P”) are used to bring about the creation *in vitro* of an embryo or human admixed embryo without P’s consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P.]

Textual Amendments

- F27** S. 15(5) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 7 para. 7](#); S.I. 2009/2232, art. 2(y)

Commencement Information

- I4** S. 15 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, [art. 2\(2\)](#)

[^{F28}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.

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Licence conditions. (See end of Document for details)

- (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) [^{F29}If the Authority, in relation to Northern Ireland, receives a request from a competent authority in an EEA state] 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.]

Textual Amendments

- F28** S. 15A 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, 18
- F29** Words in s. 15A(3) substituted (31.12.2020) by [S.I. 2019/482](#), [reg. 2\(9\)](#) (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 10); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

[^{F30}15B [^{F31}Inspection of third country premises etc.: Northern Ireland]

- (1) This section applies where—
 - (a) qualifying gametes or embryos are imported into [^{F32}Northern Ireland] from a third country by an importing licensee,
 - (b) the gametes or embryos are distributed in an EEA state ^{F33}..., and
 - (c) the competent authority in that state ^{F34}... requests the Authority to carry out any of the following activities—
 - (i) arranging for an inspection of any third country premises to be carried out on behalf of the Authority,
 - (ii) arranging for an inspection of any relevant documents held by a third country supplier to be carried out on behalf of the Authority,
 - (iii) exercising the Authority's powers under section 18(2) to revoke a licence held by an importing licensee,
 - (iv) exercising the Authority's powers under section 18A(3) to vary a licence held by an importing licensee,
 - (v) exercising the Authority's powers under section 19C(1) to suspend a licence held by an importing licensee, and
 - (vi) other appropriate control measures.
- (2) The Authority must carry out the activity in question in subsection (1)(c), unless it considers that it would be inappropriate to do so in the particular circumstances of the case.
- (3) Before an inspection of any premises is carried out in pursuance of subsection (2), the Authority must—
 - (a) make arrangements with the competent authority which made the request under subsection (1) for it to participate in the inspection, or

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- (b) notify the competent authority which made the request under subsection (1) that the Authority has decided that it is not appropriate for it to participate in the inspection and give reasons for that decision.
- (4) For the purposes of ascertaining whether qualifying gametes or embryos imported [^{F35}into Northern Ireland] from a third country meet standards of quality and safety equivalent to those laid down in this Act, the Authority may arrange for either or both of the following to be to be carried out on its behalf—
 - (a) an inspection of any third country premises,
 - (b) an inspection of any relevant documents held by a third country supplier.
- (5) The Authority may arrange for a report to be made on any inspection carried out in pursuance of subsection (2) or (4).
- (6) Any inspection carried out on behalf of the Authority in pursuance of subsection (2) or (4) must be carried out by a person authorised by the Authority to act for the purposes of this section.
- (7) References in this section to carrying out an inspection of any premises include, in particular—
 - (a) inspecting any equipment found on the premises,
 - (b) inspecting and taking copies of any relevant documents or records found on the premises, and
 - (c) observing the carrying on of any activity relevant to ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.
- (8) In this section, “relevant document” means a document relevant for the purposes of ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.

Textual Amendments

- F30** Ss. 15B, 15C 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), 5(2)
- F31** S. 15B heading substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(10)(a)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 11); 2020 c. 1, **Sch. 5 para. 1(1)**
- F32** Words in s. 15B(1)(a) substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(10)(b)(i)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 11); 2020 c. 1, **Sch. 5 para. 1(1)**
- F33** Words in s. 15B(1)(b) omitted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(10)(b)(ii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 11); 2020 c. 1, **Sch. 5 para. 1(1)**
- F34** Words in s. 15B(1)(c) omitted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(10)(b)(iii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 11); 2020 c. 1, **Sch. 5 para. 1(1)**
- F35** Words in s. 15B(4) inserted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(10)(c)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 11); 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: Licence conditions. (See end of Document for details)

15C [F36 Third country premises and third country suppliers: report of inspections etc: Northern Ireland]

- (1) [F37 This section applies in relation to Northern Ireland where the European Commission or a competent authority in an EEA state] requests the Authority to provide it with—
- (a) a copy of a report or information on any inspection of third country premises or relevant documents carried out in pursuance of section 15B(2) or (5),
 - (b) information on any exercise of the Authority's powers under section 18(2), 18A(3) or 19C(1) in relation to a licence held by an importing licensee (whether in pursuance of section 15B(2) or otherwise), or
 - (c) information on any appropriate control measures carried out by the Authority (whether in pursuance of section 15B(2) or otherwise).
- (2) The Authority must provide the report or information in question to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.]

Textual Amendments

- F30** Ss. 15B, 15C 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), 5(2)
- F36** S. 15C heading substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(11)(a)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 12); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F37** Words in s. 15C(1) substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(11)(b)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 12); 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: Licence conditions.