

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, SCHEDULE 3B. (See end of Document for details)

SCHEDULES

[^{F1}SCHEDULE 3B

INSPECTION, ENTRY, SEARCH AND SEIZURE

Textual Amendments

- F1** Sch. 3B inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), s. 68(2), [Sch. 5](#); [S.I. 2009/2232](#), art. 2(x)

Inspection of statutory records

- 1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—
- (a) in a visible and legible form, or
 - (b) in a form from which they can be readily produced in a visible and legible form.
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

[^{F2}Inspection of documents held by an importing licensee

Textual Amendments

- F2** Sch. 3B para. 1A 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\(8\)](#)

- 1A. (1) This paragraph applies [^{F3}in relation to Northern Ireland] where—
- (a) qualifying gametes or embryos are imported from a third country by an importing licensee,
 - (b) the gametes or embryos are distributed in an EEA state ^{F4}..., and
 - (c) the competent authority in that state ^{F5}... requests the Authority to arrange for an inspection of any relevant documents held by an importing licensee to be carried out.
- (2) The Authority must arrange for an inspection of the documents in question to be carried out by a duly authorised person, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.

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- (3) Where relevant documents are stored in any electronic form, a duly authorised person may require an importing licensee to make the documents available for inspection—
- (a) in a visible and legible form, or
 - (b) in a form from which they can be readily produced in a visible and legible form.
- (4) A duly authorised person may take copies of any relevant documents inspected in pursuance of a requirement under this paragraph.
- (5) In this paragraph “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

- F3** Words in Sch. 3B para. 1A(1) inserted (31.12.2020) by S.I. 2019/482, **reg. 2(19)(a)(i)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F4** Words in Sch. 3B para. 1A(1)(b) omitted (31.12.2020) by virtue of S.I. 2019/482, **reg. 2(19)(a)(ii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F5** Words in Sch. 3B para. 1A(1)(c) omitted (31.12.2020) by virtue of S.I. 2019/482, **reg. 2(19)(a)(iii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**)

Arranging inspections

- 2 (1) Where a person—
- (a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or
 - (b) has made a relevant application to the Authority which the Authority has not yet considered,
- the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).
- (2) For the purposes of sub-paragraph (1) a “relevant application” means—
- (a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or
 - (b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.
- (3) The premises referred to in sub-paragraph (1) are—
- (a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;
 - (b) any premises that will be relevant third party premises for the purposes of any application.
- (4) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

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Entry and inspection of premises

- 3 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.
- (2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.
- 4 (1) Subject to sub-paragraph (2), the Authority shall arrange for any premises to which a licence relates to be inspected under paragraph 3 by a duly authorised person at intervals not exceeding two years.
- (2) The Authority need not comply with sub-paragraph (1) where the premises in question have been inspected in pursuance of paragraph 2 or 3 at any point within the previous two years.
- ^I
^{F6}4A. (1) This paragraph applies [^{F7}in relation to Northern Ireland] where—
- (a) any activity governed by this Act is carried out in relation to qualifying gametes or embryos imported from a third country on any premises—
- (i) to which a licence held by an importing licensee relates, or
- (ii) which are relevant third party premises in relation to an importing licensee,
- (b) the gametes or embryos are distributed in an EEA state ^{F8}..., and
- (c) the competent authority in that state ^{F9}... requests the Authority to arrange for an inspection of the premises to be carried out.
- (2) The Authority must arrange for an inspection of the premises in question to be carried out under paragraph 3 by a duly authorised person, unless the Authority 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 sub-paragraph (2) the Authority must—
- (a) make arrangements with the requesting authority for it to participate in the inspection, or
- (b) notify the requesting authority that the Authority has decided that it is not appropriate for the requesting authority to participate in the inspection and give reasons for that decision.
- (4) In this paragraph, “requesting authority” means the competent authority which made the request under sub-paragraph (1) for the Authority to arrange for the inspection to be carried out.]

Textual Amendments

- F6** Sch. 3B para. 4A 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(9)
- F7** Words in Sch. 3B para. 4A(1) inserted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(19)(b)(i)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 18); 2020 c. 1, **Sch. 5 para. 1(1)**)
- F8** Words in Sch. 3B para. 4A(1)(b) omitted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(19)(b)(ii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, 18); 2020 c. 1, **Sch. 5 para. 1(1)**)

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- F9** Words in Sch. 3B para. 4A(1)(c) omitted (31.12.2020) by S.I. 2019/482, reg. 2(19)(b)(iii) (as substituted by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, 18); 2020 c. 1, Sch. 5 para. 1(1)

Entry and search in connection with suspected offence

- 5 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—
- (a) that an offence under this Act is being, or has been committed on any premises, and
 - (b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,
- the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.
- (2) The conditions referred to are—
- (a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;
 - (b) that the premises are unoccupied;
 - (c) that the occupier is temporarily absent;
 - (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.
- (3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.
- (4) In relation to Scotland—
- (a) any reference in sub-paragraph (1) to a justice of the peace includes a reference to a sheriff, and
 - (b) the reference in that sub-paragraph to “on sworn information” is to be read as a reference to “by evidence on oath”.

Execution of warrants

- 6 (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
- (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
- (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—
- (a) produce the warrant to the occupier, and
 - (b) give the occupier—
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement.

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- (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—
 - (a) produce the warrant to that other person,
 - (b) give that other person—
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement, and
 - (c) leave a copy of the warrant in a prominent place on the premises.
- (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.
- (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.
- (7) Where the premises in relation to which a warrant under paragraph 5 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.

Seizure in the course of inspection or search

- 7 (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for—
 - (a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or
 - (b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.
- (2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.
- (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.
- (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
- (5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

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Supplementary provision

- 8 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
- (2) Power under this Schedule to inspect or search any premises includes, in particular—
- (a) power to inspect any equipment found on the premises,
 - (b) power to inspect and take copies of any [^{F10}relevant documents or] records found on the premises, and
 - (c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.
- (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

[In this paragraph “relevant document” means a document relevant for the purposes of ^{F11}(4) 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

- F10** Words in Sch. 3B para. 8(2)(b) 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(10)**
- F11** Sch. 3B para. 8(4) 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(11)**

- 9 (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.
- (2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—
- (a) prepare a written report of the inspection, or as the case may be, the inspection and search, and
 - (b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.
- (3) In sub-paragraph (2), the “appropriate person” means—
- (a) in relation to premises to which a licence relates, the person responsible, or
 - (b) in relation to any other premises, the occupier.
- [Sub-paragraph (5) applies [^{F13}in relation to Northern Ireland] if the European ^{F12}(4) Commission or a competent authority in an EEA state ^{F14}... requests the Authority to provide it with a copy of a report or information on—
- (a) any inspection under paragraph 1 or 1A of records or documents,
 - (b) any inspection under paragraph 2 where the person to whom an application for authorisation relates also seeks a direction under section 24(4)

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- authorising that person to import qualifying gametes or embryos into the United Kingdom from a third country, or
- (c) any inspection under paragraph 3 of premises to which a licence held by an importing licensee relates or which are relevant third party premises in relation to an importing licensee.
- (5) The Authority must give a copy of the report or information 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

- F12** Sch. 3B para. 9(4)(5) 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(12)**
- F13** Words in Sch. 3B para. 9(4) inserted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(19)(c)(i)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F14** Words in Sch. 3B para. 9(4) omitted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(19)(c)(ii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

Enforcement

- 10 A person who—
- (a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or
- (b) intentionally obstructs the exercise of any right under this Schedule,
- is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

- 11 In this Schedule—
- (a) “duly authorised person”, in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and
- (b) “licensed activity”, in relation to a licence, means the activity which the licence authorises to be carried on.]

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