DRAFT STATUTORY INSTRUMENTS

2018 No.

The Human Fertilisation and Embryology (Amendment) Regulations 2018

Amendments to the 1990 Act relating to the import of gametes and embryos

5.—(1) The 1990 Act is amended as follows.

(2) After section 15A insert—

"**15B Inspections of third country premises etc**

(1) This section applies where—

(a) qualifying gametes or embryos are imported into the United Kingdom from a third country by an importing licensee,

(b) the gametes or embryos are distributed in an EEA state other than the United Kingdom or in Gibraltar, and

(c) the competent authority in that state or in Gibraltar 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

(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 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.

15C Third country premises and third country suppliers: report of inspections etc

(1) This section applies where the European Commission or a competent authority in an EEA state other than the United Kingdom or in Gibraltar 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."

(3) In section 18(2) (revocation of licence otherwise than on application)—

(a) omit "or" at the end of paragraph (h), and

(b) after paragraph (i) insert—

"or

(j) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that qualifying gametes or embryos imported from a third country by the holder of the licence meet standards of quality and safety laid down in this Act.".

(4) In section 24 (directions as to particular matters)—

(a) in subsection (4A)—

(i) for the words from "import" to "such a country" substitute "export from the United Kingdom to a third country", and

(ii) in paragraph (a) omit "imports or",

(b) after subsection (4A) insert the following subsections—

"(4AA) Directions must, in accordance with paragraph 1 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make qualifying imports (other than a one-off import) must comply before the Authority gives any directions under subsection (4) authorising the person to make qualifying imports.

(4AB) Directions must, in accordance with paragraph 2 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make a qualifying import which is a one-off import must comply before the Authority gives any directions under subsection (4) authorising the person to make the import.

(4AC) In giving any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, the Authority must include the directions specified in paragraph 3 of Schedule 3AA.

(4AD) Where the Authority gives any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, it must provide that person with a certificate in the form set out in Annex II to the fourth Directive.

(4AE) In subsections (4AA) and (4AB) a reference to a one-off import, in relation to gametes or embryos, is to gametes or embryos imported for the purposes of providing services to a particular person or persons on one occasion only.

(4AF) In subsections (4AA) to (4AD) and Schedule 3AA "qualifying import" means the import into the United Kingdom from a third country of gametes or embryos intended for human application.".

(5) In section 47 (index) insert the following entries in the appropriate places—

"Fourth Directive	Section 1A"
"Importing licensee	Section 2B(2)"
"Qualifying gametes or embryos	Section 2B(3)"
"Third country	Section 2B(4)"
"Third country premises	Section 2B(5)"
"Third country supplier	Section 2B(6)"

(6) After Schedule 3A insert—

"Schedule 3AA Section 24(4AA), (4AB) and (4AC)

REQUIREMENTS WHERE GAMETES OR EMBRYOS IMPORTED FROM THIRD COUNTRY

1. A direction given under section 24(4AA) must require the person to whom the licence applies to—

(a) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act,

(b) provide the Authority with any information specified in the direction for the purposes of securing compliance with the requirements of Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments),

(c) provide the Authority with any documents specified in the direction for the purposes of securing compliance with the requirements of Part F of Annex I to the fourth Directive (documentation to be provided by importing tissue establishments),

(d) do the following—

(i) make available for inspection any documents specified in the direction for the purposes of securing compliance with the requirements of Parts A and B of Annex III to the fourth Directive (availability and provision of documentation) and,

(ii) if requested by the Authority, provide the Authority with any such documents,

(e) enter into a written agreement with any proposed third country supplier which complies with the requirements specified in the direction for the purposes of securing compliance with the requirements of Article 7(2) and (3) of the fourth Directive (written agreements), and

(f) provide the Authority with a copy of the written agreement mentioned in sub-paragraph (e).

2. A direction given under section 24(4AB) must require the person to whom the licence applies to —

(a) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act,

(b) provide the Authority with any information specified in the direction for the purposes of securing compliance with the requirements of Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments), and

(c) provide the Authority with any information or documents specified in the direction for the purposes of securing compliance with the requirements of Articles 5(2) and 7(1) of the fourth Directive (requirements in relation to one-off imports).

3. The following requirements must be specified in directions under section 24(4) authorising any person to whom a licence applies to make any qualifying imports—

(a) a requirement that the person must not make any substantial changes in connection with any qualifying imports made by the person unless the Authority approves those changes in writing,

(b) a requirement that the person must notify the Authority if the person ceases to make qualifying imports,

(c) a requirement that the person must—

(i) notify the Authority of any serious adverse events or serious adverse reactions notified to the person by the person's third country supplier (including events or reactions which that supplier suspects are serious adverse events or reactions), and

(ii) provide any information specified in the direction which the Authority requires for the purposes of securing compliance with the requirements of Article 6(2) of the fourth Directive (updated information), and

(d) a requirement that the person must notify the Authority of any changes in circumstances of the person's third country supplier of which the person is aware.

4. In this Schedule—

"changes of circumstances" means any changes in circumstances of the description specified in the direction in question in accordance with the provision made in Article 6(3) of the fourth Directive (notification of revocation of third country's authorisation),

"substantial changes" means changes of the description specified in the direction in question in accordance with the provision as to the meaning of substantial changes made in Article 3(3) of the fourth Directive (requirements where substantial changes made to import activities).".

(7) Schedule 3B (inspection, entry, search and seizure) is amended as follows.

(8) After paragraph 1 insert—

"**Inspection of documents held by an importing licensee**

1A.—(1) This paragraph applies 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 other than the United Kingdom or in Gibraltar, and

(c) the competent authority in that state or in Gibraltar 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.

(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.".

(9) After paragraph 4 insert—

"**4A.**—(1) This paragraph applies 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 other than the United Kingdom or in Gibraltar, and

(c) the competent authority in that state or in Gibraltar 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.".

(10) In paragraph 8(2)(b), after "any" insert "relevant documents or".

(11) After paragraph 8(3) insert—

"(4) 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.".

(12) After paragraph 9(3) insert—

"(4) Sub-paragraph (5) applies if the European Commission or a competent authority in an EEA state other than the United Kingdom or in Gibraltar 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) 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.".