STATUTORY INSTRUMENTS

# 2018 No. 334

# HUMAN FERTILISATION AND EMBRYOLOGY

## The Human Fertilisation and Embryology (Amendment) Regulations 2018

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| *Made - - - -* | *5th March 2018* |
| *Coming into force* | |
| *for the purposes of regulation 1(3)* | *6th March 2018* |
| *for all other purposes* | *1st April 2018* |

The Secretary of State is a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to health protection measures regulating the use of material of human origin.

In accordance with paragraph 2(2) of Schedule 2 to that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of that Act.

**Citation, commencement and interpretation**

**1.**—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Amendment) Regulations 2018.

(2) Except as provided by paragraph (3), these Regulations come into force on 1st April 2018 ("the commencement date").

(3) These Regulations come into force on the day after the day on which they are made so far as necessary to enable anything to be done for the purposes of varying a relevant licence or giving directions to ensure compliance with these Regulations on the commencement date.

(4) In paragraph (3), "relevant licence" has the same meaning as section 8ZB(11) of the 1990 Act as inserted by regulation 4(1) of these Regulations.

(5) In these Regulations—

(a) the "1990 Act" means the Human Fertilisation and Embryology Act 1990(**3**),

(**1**) S.I. 2004/3037.
(**2**) 1972 c.68.
(**3**) 1990 c.37.

(b) "the fourth Directive" has the same meaning as in the 1990 Act, as amended by regulation 3(2) of these Regulations,

(c) "gametes" and "embryos" have the same meaning as in the 1990 Act(**4**).

**Designation of the competent authority**

**2.** The Human Fertilisation and Embryology Authority is designated the competent authority for the purposes of the fourth Directive so far as it relates to gametes and embryos.

**Amendments to definitions in the 1990 Act**

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

(2) In section 1A (reference to Directives)(**5**)—

(a) in the definition of the "second Directive" at the end omit the "and",

(b) in the definition of the "third Directive" at the end insert ", as amended by Commission Directive 2015/565/EU.",

(c) after the definition of "the third Directive" insert—

", and

"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."

(3) In section 2 (other terms)—

(a) in subsection (1)—

(i) in the definition of "competent authority" for "and third" substitute ", third and fourth", and

(ii) in the definition of "distribution" after "delivery" insert "to any person in or outside the United Kingdom for human application",

(b) in subsection (2A) after "transporting gametes or embryos" insert "to any person in or outside the United Kingdom for human application", and

(c) in subsection (2B) for "or third" substitute ", third or fourth".

(4) After section 2A insert—

"**Meaning of "importing licensee", "third country premises" etc**

**2B.**—(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 into the United Kingdom from a third country.

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

(4) "Third country" means a country which is not an EEA state or Gibraltar.

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

(**4**) "Gametes" and "embryos" are defined in section 1 of the 1990 Act.
(**5**) Inserted by S.I.2007/1522, regulation 5.

(a) they are in a third country, and

(b) they are premises on, 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 the United Kingdom.

(6) "Third country supplier" means a person in a third country who has an agreement with an importing licensee for exporting qualifying gametes or embryos intended for import into the United Kingdom.".

**Amendments to the 1990 Act relating to the coding of gametes and embryos**

**4.**—(1) After section 8ZA(**6**) insert—

"**Duties of the Authority in relation to application of the Single European Code**

**8ZB.**—(1) The Authority must allocate to each holder of a relevant licence, one or more unique numbers as the tissue establishment number or numbers in relation to that licence holder in accordance with Annex VII and paragraph 2(a) of Article 10b of the third Directive.

(2) Any number allocated under subsection (1) must be in the format specified in Annex VII.

(3) The Authority must, in relation to each holder of a relevant licence, arrange for the information specified in Annex VIII to be recorded in the EU Tissue Establishment Compendium.

(4) In relation to a person who becomes the holder of a relevant licence before 1st April 2018, the Authority must ensure that the information under subsection (3) is recorded before the end of the period of 10 working days beginning with that day.

(5) In relation to a person who becomes the holder of a relevant licence on or after 1st April 2018, the Authority must ensure that the information under subsection (3) is recorded before the end of the period of 10 working days beginning with the day on which the person becomes the holder of that licence.

(6) Subsection (7) applies if the Authority becomes aware that any information recorded under subsection (3) was incorrectly recorded or requires updating.

(7) The Authority must arrange for the information to be corrected or updated—

(a) in the case of a correction or update which the Authority considers to be a significant change to the information recorded under subsection (3), before the end of the period of 10 working days beginning with the day on which the Authority became aware that the information was incorrectly recorded or required updating;

(b) in any other case, as soon as is reasonably practicable.

(8) Subsection (9) applies if the Authority becomes aware that—

(a) any information recorded in the EU Tissue Establishment Compendium in respect of a tissue establishment in a relevant state was incorrectly recorded or requires updating, or

(b) a tissue establishment in a relevant state has not complied with the requirements of the laws or other measures adopted in that state for the purpose of implementing paragraph 1 of Article 10b of the third Directive and the non-compliance is significant.

(9) The Authority must inform the competent authority in the relevant state in question.

(**6**) Inserted by the Human Fertilisation and Embryology Act 2008 (c.22), section 7.

(10) If the Authority becomes aware that the information recorded in the EU Tissue and Cell Product Compendium requires updating, it must inform the European Commission and the competent authority in the relevant state.

(11) In this section—

"Annex VII" means Annex VII to the third Directive,

"Annex VIII" means Annex VIII to the third Directive,

"EU Tissue and Cell Product Compendium" and "EU Tissue Establishment Compendium" have the same meaning as in Article 2 of the third Directive,

"relevant licence" means a licence granted under any of the following provisions of Schedule 2—

(a) paragraph 1,

(b) paragraph 1A,

(c) paragraph 2, so far as authorising the storage of gametes or embryos intended for human application,

(d) paragraph 3, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application,

"relevant state" means—

(a) an EEA state other than the United Kingdom, or

(b) Gibraltar,

"working day" means any day other than—

(a) a Saturday or Sunday,

(b) Christmas Day or Good Friday, or

(c) a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in any part of the United Kingdom.".

(2) For subsection (12) of section 24 (directions as to particular matters), substitute—

"(12) Directions must specify the systems to be adopted for the identification of gametes and embryos intended for human application which the Authority considers appropriate to secure compliance with the requirements of —

(a) paragraph 1 of Article 25 of the first Directive (coding of information),

(b) paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article,

(c) Article 10a of the third Directive (format of the Single European Code), and

(d) paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).".

(3) After subsection (12) of section 24, insert—

"(12A) Directions must require information to be provided to the Authority which the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive (European coding system).".

(4) Schedule 3A (supplementary licence conditions: human application) is amended as follows.

(5) For paragraph 1 substitute—

"**Traceability system**

**1.** Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).".

(6) Omit paragraph 2.

**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—

"**Inspections of third country premises etc**

**15B.**—(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.