STATUTORY INSTRUMENTS

2018 No. 334

The Human Fertilisation and Embryology (Amendment) Regulations 2018

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

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

"**8ZB Duties of the Authority in relation to application of the Single European Code**

(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.

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

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

(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.