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STATUTORY INSTRUMENTS

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**2018 No. 334**

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

**Amendments to definitions in the 1990 Act**

- 3.—(1) The 1990 Act is amended as follows.
- (2) In section 1A (reference to Directives)(1)—
- (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—

**“2B Meaning of “importing licensee”, “third country premises” etc**

- (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—
- (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.”.