DRAFT STATUTORY INSTRUMENTS

2007 No.

The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

PART 2

AMENDMENTS TO THE 1990 ACT

Directions as to particular matters

22.—(1) Section 24 (directions as to particular matters) is amended as follows.

(2) In subsection (1), after "treatment services" insert ", other than basic partner treatment services,".

(3) In subsection (2), after "paragraph 1" insert "or 1A".

(4) In subsection (3), at the beginning insert "In relation to gametes or embryos that are not intended for human application,".

(5) After subsection (3) insert—

"(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage—

(a) between premises to which licences relate,

(b) between such premises and relevant third party premises,

(c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or

(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4),

in such circumstances and subject to such conditions as may be specified in the directions.".

(6) After subsection (4), insert—

"(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in this Act, and

(b) have regard to ensuring traceability.".

(7) At the end insert—

"(12) Directions may require a unique code to be assigned to each donation of gametes and embryos intended for human application received pursuant to a licence.

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of–

(a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application,

(b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or

(c) any misidentification or mix-up of gametes or embryos intended for human application.

(14) In this section, "tissue establishment" has the meaning given by Article 3(o) of the first Directive.".