STATUTORY INSTRUMENTS

2020 No. 1307

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020

Amendment of regulation 2(12)

- **13.** In regulation 2(12)—
 - (a) for sub-paragraph (a)(i) substitute—
 - "(i) for paragraph (c) (but not including the "or" that follows it) substitute—
 - "(c) in relation to Northern Ireland, 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 which implement the first, second and third Directives,";";
 - (b) after sub-paragraph (a) insert—
 - "(aa) for subsection (4) substitute—
 - "(4) Directions may authorise any person to whom a licence applies to—
 - (a) receive gametes, embryos or human admixed embryos—
 - (i) from outside the United Kingdom, and
 - (ii) in respect of Northern Ireland, from Great Britain, or
 - (b) send gametes, embryos or human admixed embryos outside the United Kingdom,

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

- (4ZA) Directions made by virtue of subsection (4) may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.";";
- (c) for sub-paragraph (b) substitute—
 - "(b) for subsection (4AD) substitute—
 - "(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—
 - (a) in relation to Great Britain, provide that person with a certificate of authority in such form as the Authority considers appropriate; and
 - (b) in relation to Northern Ireland, provide that person with a certificate in the form set out in Annex II to the fourth Directive.";
 - (ba) in subsection (4AF), omit "into the United Kingdom";";
- (d) for sub-paragraph (c) substitute—
 - "(c) after subsection (11) insert—

- "(11A) In relation to Great Britain, 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 facilitate traceability.";
- (ca) in subsection (12), for "Directions must" substitute "In relation to Northern Ireland, directions must";";
- (e) for sub-paragraph (d) substitute—
 - "(d) in subsection (12A), for "Directions must" substitute "In relation to Northern Ireland, directions must";
 - (e) omit subsection (14).".