STATUTORY INSTRUMENTS

2019 No. 482

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

PART 2

Amendment of primary legislation

Amendment of the Human Fertilisation and Embryology Act 1990

2.—(1) The Human Fertilisation and Embryology Act 1990 [M1] is amended as follows.

[[F1](2) In section 1A (reference to Directives), for the definition of "the third Directive" substitute—

""the third Directive" means—

(a) in the application of this Act in relation to Great Britain, Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells ("the 2006 Directive"), as it had effect immediately before 29 April 2015 (which is the date on which the amendments made by Commission Directive 2015/565/EU came into force), and

(b) in the application of this Act in relation to Northern Ireland, the 2006 Directive as amended by Commission Directive 2015/565/EU,",**]**

(3) [M2]In section 2 (other terms)—

(a) in subsection (1) —

[[F2](i) in the definition of "competent authority" omit "other than the United Kingdom or in relation to Gibraltar";**]**

(ii) at the appropriate place, insert—

""tissue establishment" means a tissue bank or a unit of a hospital or another body which procures, tests, processes, preserves, stores or distributes human **[**[F3]gametes or embryos**]**,";

[[F4](b) for subsection (2B) substitute—

"(2B) Any reference in this Act to a requirement of a provision of the first, second, third or fourth Directive—

(a) in the application of this Act in relation to Great Britain, is to be read as a reference to a requirement which that provision would require to be imposed if the provision formed part of the law of England and Wales or Scotland, and

(b) in the application of this Act in relation to Northern Ireland, is to be read as a reference to a requirement which that provision requires to be imposed.".**]**

(4) In section 2A [M3] (third party agreements) after subsection (1) insert—

"(1A) For the purposes of subsection (1), **[**F5as it applies in relation to Great Britain,**]** Article 24 of the first Directive is to be read subject to the modifications set out in paragraph 11A(8) of Schedule 3A.".

[F6(5) In section 2B (meaning of "importing licensee", "third country premises" etc)—

(a) in subsection (2)(b) omit "into the United Kingdom";

(b) for subsections (4), (5) and (6) substitute—

"(4) "Third country" means—

(a) in relation to the import of qualifying gametes or embryos into, or the export of qualifying gametes or embryos from, Great Britain, a country other than the United Kingdom,

(b) in relation to the import of qualifying gametes or embryos into Northern Ireland, a country other than Northern Ireland or an EEA state, and

(c) in relation to the export of qualifying gametes or embryos from Northern Ireland, a country other than the United Kingdom or an EEA state.

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

(a) in relation to Great Britain—

(i) they are in a country other than the United Kingdom, and

(ii) they are premises in 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 Great Britain, and

(b) in relation to Northern Ireland—

(i) they are in a country other than Northern Ireland or an EEA state, and

(ii) they are premises in 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 Northern Ireland.

(6) "Third country supplier" means—

(a) in relation to qualifying gametes or embryos intended for import into Great Britain, a person in a country other than the United Kingdom who has an agreement with an importing licensee for exporting such gametes or embryos into Great Britain, and

(b) in relation to qualifying gametes or embryos intended for import into Northern Ireland, a person in a country other than Northern Ireland or an EEA state who has an agreement with an importing licensee for exporting such gametes or embryos into Northern Ireland.".**]**

[F7(6) In section 8ZB (duties of the Authority in relation to the application of the Single European Code)—

(a) for the heading substitute "Duties of the Authority in relation to the Single European Code: Northern Ireland";

(b) in subsection (1), after "The Authority" insert " in relation to Northern Ireland,";

(c) for subsection (3) substitute—

"(3) In relation to Northern Ireland, the Authority must take steps to enable the information specified in Annex VIII to be recorded in the EU Tissue Establishment Compendium in relation to each holder of a relevant licence.";

(d) omit subsection (4);

(e) for subsection (5) substitute—

"(5) The Authority must take the steps mentioned in subsection (3) to enable the information mentioned in that subsection to be recorded before the end of the period of 10 working days beginning with the day on which the person becomes the holder of a relevant licence.";

(f) in subsection (7), for the words before paragraph (a) substitute "The Authority must take steps to enable the information to be corrected or updated";

(g) in subsection (11), for the definition of "relevant state" substitute—

""relevant state" means an EEA State,".**]**

[F8(7) In section 8A (duty of Authority to communicate with competent authorities of other EEA states)—

(a) for the heading substitute "Duty of Authority to communicate with competent authorities of EEA states: Northern Ireland";

(b) for the words from "The Authority" to "Gibraltar" substitute "The Authority must, in relation to Northern Ireland, communicate to the competent authorities of EEA states".**]**

[F9(8) In section 14A (conditions of licences: human application), in subsection (3), for the words from "the United Kingdom" to "Gibraltar" substitute "Northern Ireland from an EEA State".**]**

[F10(9) In section 15A (duties of the Authority in relation to serious adverse events and serious adverse reactions), in subsection (3), for the words from "If the Authority" to "Gibraltar" substitute "If the Authority, in relation to Northern Ireland, receives a request from a competent authority in an EEA state".**]**

[F11(10) In section 15B (inspection of third country premises etc.)—

(a) for the heading substitute "Inspection of third country premises etc.: Northern Ireland";

(b) in subsection (1)—

(i) in paragraph (a), for "the United Kingdom" substitute "Northern Ireland";

(ii) in paragraph (b), omit "other than the United Kingdom or in Gibraltar";

(iii) in paragraph (c), omit "or in Gibraltar";

(c) in subsection (4), after "imported" insert "into Northern Ireland".**]**

[F12(11) In section 15C (third country premises and third country suppliers: report of inspections etc.)—

(a) for the heading substitute "Third country premises and third country suppliers: report of inspections etc: Northern Ireland";

(b) in subsection (1), for the words from "This section" to "Gibraltar" substitute "This section applies in relation to Northern Ireland where the European Commission or a competent authority in an EEA state".**]**

(12) M4In section 24 (directions as to particular matters)—

(a) in subsection (3A)—

[F13(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,";**]**

(ii) in paragraph (d) for "country which is not an EEA state" substitute " third country ";

[F14(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.";**]**

[F15(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";**]**

[F16(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";**]**

[F17(d) in subsection (12A), for "Directions must" substitute "In relation to Northern Ireland, directions must";

(e) omit subsection (14).**]**

[F18(13) In section 33A (disclosure of information), in subsection (2)(m), at the beginning insert "in relation to Northern Ireland,".**]**

(14) Before section 43 (but after the heading "Miscellaneous and General") insert—

"**Powers to make regulations in relation to standards of quality and safety**

42A.—(1) The Secretary of State may by regulations make provision specifying requirements to be met for the purposes of ensuring traceability.

(2) The Secretary of State may by regulations make provision in relation to the notification of serious adverse events and serious adverse reactions (whether to the Authority or such other person as may be specified in the regulations).

(3) The Secretary of State may by regulations make provision specifying requirements to be met for the purposes of verifying that standards of quality and safety equivalent to those required pursuant to this Act apply in relation to imports by tissue establishments of gametes and embryos from third countries.

(4) The Secretary of State may by regulations make provision specifying technical requirements in relation to the following—

(a) the licensing or authorisation of tissue establishments;

(b) the procurement of gametes or embryos;

(c) selection criteria for donors of gametes and embryos;

(d) laboratory tests required for donors;

(e) procedures for the reception of gametes and embryos at the tissue establishment;

(f) the gamete and embryo preparation process;

(g) gamete and embryo processing, storage and distribution.

(5) The provision that may be made in regulations under this section includes provision amending this Act and may modify, or further modify, the provisions of the second, third and fourth Directives as they apply by virtue of this Act.

[F19(6) The Secretary of State may only make regulations under this section in relation to Great Britain.”**]**.

(15) In section 45(4A) (regulations) M5, insert at the appropriate place— “ section 42A; ”;

(16) In section 47 M6 (Index)—

(a) omit the entry relating to “Competent authority”;

(b) at the appropriate place insert—

“Tissue establishment	Section 2(1)”.

(17) In Schedule 3A M7 (supplementary licence conditions: human application)—

(a) before the italic heading above paragraph 1 insert—

“**A1.** For the purposes of this Act, **[**F20as it applies in relation to Great Britain,**]** the first, second and third Directives are to be read subject to the modifications set out in paragraphs 11A to 11C.”;

[F21(b) in paragraph 3—

(i) in the heading, at the end insert “: Great Britain”;

(ii) for “Licence” substitute “In relation to Great Britain, licence”;

(iii) in the words following sub-paragraph (b), for the words from “are necessary” to the end substitute “the Authority considers appropriate”;

(ba) after paragraph 3 insert—

“**Serious adverse events and serious adverse reactions: Northern Ireland**

3A. In relation to Northern Ireland, licence conditions shall require such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.”**]**.

(c) after paragraph 11 insert—

"**Modifications to the first, second and third Directives**

11A.—(1) The modifications to the first Directive are as follows.

(2) Article 8 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "on their territory" there were substituted "**[**F22in Great Britain**]**";

(b) paragraphs 2, 3 5 and 6 were omitted.

(3) Article 14 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "within the scope of this Directive" there were substituted " in accordance with the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph 2, the reference to Member States were a reference to the Authority;

(c) in paragraph 3—

(i) the first reference to Member States were a reference to the Authority;

(ii) "in Member States" were omitted.

(4) Article 15 is to be read as if paragraphs 1, 2 and 4 were omitted.

(5) Article 19(5) is to be read as if the words "in accordance with Article 8" were omitted.

(6) Article 20 is to be read as if in paragraph 1, the reference to Article 28(h) were a reference to the requirements of Annex 2 to the third Directive listed in paragraph 11 of this Schedule.

(7) Article 21 is to be read as if—

(a) in paragraph 4, for "laid down in this Directive" there were substituted " of the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph 5—

(i) the first reference to Member States were a reference to the Authority;

(ii) the reference to a tissue establishment accredited, designated, authorised or licensed in accordance with Article 6 were a reference to a tissue establishment authorised or licensed in accordance with the provisions of this Act;

(iii) for the words "Member States' legislation" there were substituted " legislation ".

(8) Article 24 is to be read as if—

(a) in paragraph 2, for "laid down in this Directive" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority.

(9) The Annex is to be read as if—

(a) in paragraph B.1, for "legislation in force in Member States" there were substituted " requirements of Schedule 3 to the Human Fertilisation and Embryology Act 1990 ";

(b) paragraph B.2 were omitted.

11B.—(1) The modifications to the second Directive are as follows.

(2) Article 2 is to be read as if, in paragraph 1, the reference to Member States were a reference to the Authority.

(3) Articles 3, 4 and 5 are to be read as if any reference to the competent authority or authorities were a reference to the Authority.

(4) Annex 1 is to be read as if, in the first paragraph, for "responsible person as defined in Article 17 of Directive 2004/23/EC" there were substituted " person responsible in accordance with section 17 of the Human Fertilisation and Embryology Act 1990 ".

(5) Annex 2 is to be read as if, in paragraph 2.1, the reference to the competent authority in the Member State were a reference to the Authority.

(6) Annex 3 is to be read as if, in paragraph 3.6, for "in force in Member States" there were substituted " of the Human Fertilisation and Embryology Act 1990 ".

(7) Annex 4 is to be read as if—

(a) in paragraphs 1.1.1 and 1.2.1, the reference to an authorised person were to—

(i) the person responsible in accordance with section 17 of this Act, or

(ii) a person authorised by the person responsible or the Authority to carry out the specified tasks;

(b) in paragraph 1.1.1(a), for "Article 13 of Directive 2004/23/EC" there were substituted " the Human Fertilisation and Embryology Act 1990 ";

(c) in paragraph 1.4.4, the reference to the competent authority were a reference to the Authority.

11C.—(1) The modifications to the third Directive are as follows.

(2) Annex 1 is to be read as if—

(a) in paragraph A.1—

(i) for "responsible person" there were substituted " person responsible ";

(ii) for "as provided in Article 17 of Directive 2004/23/EC" there were substituted " in accordance with the requirements of sections 16 and 17 of the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph A.4, for "laid down in this Directive" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(c) in paragraph C.6, for the words from "requirements of Council" to the end there were substituted " requirements of the Medical Devices Regulations 2002 "[M8] ;

(d) in paragraph D.1, for "laid down in this Directive" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(e) in paragraph E.1, for "laid down in this Directive" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(f) in paragraph E.8, the reference to the competent authority were a reference to the Authority.

(3) Annex 2 is to be read as if—

(a) in the first paragraph, the reference to the competent authority were a reference to the Authority;

(b) in paragraph A, for the words from "the tissues and cells must" to the end there were substituted " tissue establishment procedures must ensure that the licence conditions in paragraph 9 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 are met ";

(c) in paragraph B.3, for the words from "the standards" to the end there were substituted " the requirements of paragraph 10 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 ";

(d) in paragraph B.8, the second sentence were omitted;

(e) in paragraph C.2, for "laid down in this Directive" there were substituted " of Schedule 3A to the Human Fertilisation and Embryology Act 1990 ";

(f) in paragraphs C.4 and C.5, any reference to the responsible person as defined or specified in Article 17 of Directive 2004/23/EC were a reference to the person responsible in accordance with section 17 of this Act;

(g) in paragraph D.5, the reference to the competent authority were a reference to the Authority;

(h) in paragraph E.2(h), for "as set out in Articles 5 to 6" there were substituted " in accordance with paragraph 3 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 ".".

(18) In Schedule 3AA [M9] (requirements where gametes or embryos imported from third country) —

(a) before paragraph 1, insert—

"**A1.** For the purposes of this Act, **[**[F23]as it applies in relation to Great Britain,**]** the fourth Directive is to be read subject to the modifications set out in paragraph 3A.

Directions ";

(b) for sub-paragraph 2(c), substitute—

[[F24]"(c) provide the Authority—

(i) in relation to Great Britain, with any information or documents specified in the direction for the purposes of demonstrating traceability, and that the import is a one-off import within the meaning given by section 24(4AE),

(ii) in relation to Northern Ireland, with any information or documents specified in the direction for the purposes of securing compliance with the requirements of Articles 5(2) and 7(1) of the fourth Directive (requirements in relation to one-off imports)."**]**;

(c) after paragraph 3, insert—

"**Modifications to the fourth Directive**

3A.—(1) The modifications to the fourth Directive are as follows.

(2) The Directive is to be read as if references to a third country were references to any country other than the United Kingdom.

(3) Article 2 is to be read as if for "the Union", in each place where it occurs, there were substituted "**[**[F25]Great Britain**]**".

(4) Article 5(1) is to be read as if—

(a) for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(b) the references to the competent authority or authorities were references to the Authority.

(5) Article 6 is to be read as if—

(a) in paragraph 2—

(i) the reference to the competent authority or authorities were a reference to the Authority;

(ii) the words from "The information laid out" to the end were omitted;

(b) in paragraph 3—

(i) the first reference to the competent authority or authorities were a reference to the Authority;

(ii) the reference to the competent authority or authorities in sub-paragraph (b) were a reference to the authority or authorities in the third country concerned responsible for regulating tissue establishments in that country.

(6) Article 7 is to be read as if—

(a) in paragraph 2, for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph 3, the reference to the competent authority or authorities were a reference to the Authority.

(7) Annex 1 is to be read as if—

(a) in paragraph A.4, for "TE compendium code" there were substituted " reference number previously allocated to the tissue establishment by the Authority ";

(b) in paragraph B.4, the reference to the Responsible Person were a reference to the person responsible in accordance with section 17 of this Act;

(c) in paragraph C.2, the words "(where applicable, in accordance with the EU generic list") were omitted;

(d) in paragraph F.3, the references to a third country competent authority or authorities were references to the authority or authorities in the third country responsible for regulating tissue establishments in that country.

(8) Annex 3 is to be read as if—

(a) in the first paragraph, the reference to the competent authority or authorities were a reference to the Authority;

(b) in paragraph A.1, for "as laid down in Directive 2004/23EC" there were substituted " in accordance with sections 16 and 17 of the Human Fertilisation and Embryology Act 1990 ";

(c) in paragraph A.3, the words "applying the Single European Code," were omitted;

(d) in paragraph B.7, the reference to a third country competent authority or authorities were a reference to the authority or authorities in the third country responsible for regulating tissue establishments in that country.

(9) Annex 4 is to be read as if—

(a) in paragraph 1, for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Fertilisation and Embryology Act 1990 ";

(b) in paragraph 4, the reference to a third country competent authority or authorities were a reference to the authority or authorities in the third country responsible for regulating tissue establishments in that country;

(c) in paragraph 5, the reference to the competent authority or authorities were to the Authority;

(d) in paragraph 7, for "EU data protection rules" there were substituted " data protection legislation within the meaning of section 3(9) of the Data Protection Act 2018 "[M10] ;

(e) in paragraph 8, for the words from "requirements" to the end there were substituted " quality and safety standards required by the Human Fertilisation and Embryology Act 1990 ".

Interpretation of this Schedule ".

[[F26](19) In Schedule 3B (inspection, entry, search and seizure)—

(a) in paragraph 1A—

(i) in sub-paragraph (1), in the words before paragraph (a), after "This paragraph applies" insert "in relation to Northern Ireland";

(ii) in sub-paragraph (1)(b) omit "other than the United Kingdom or in Gibraltar";

(iii) in sub-paragraph (1)(c) omit "or in Gibraltar";

(b) in paragraph 4A—

(i) in sub-paragraph (1), in the words before paragraph (a), after "This paragraph applies" insert "in relation to Northern Ireland";

(ii) in sub-paragraph (1)(b) omit "other than the United Kingdom or in Gibraltar";

(iii) in sub-paragraph (1)(c) omit "or in Gibraltar";

(c) in paragraph 9(4), in the words before paragraph (a)—

(i) after "Sub-paragraph (5) applies" insert "in relation to Northern Ireland";

(ii) omit "other than the United Kingdom or in Gibraltar".**]**

F1 Reg. 2(2) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **3**

F2 Reg. 2(3)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(a)**

F3 Words in reg. 2(3)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(b)**

F4 Reg. 2(3)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **4(c)**

F5 Words in reg. 2(4) inserted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **5**

F6 Reg. 2(5) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **6**

F7 Reg. 2(6) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **7**

F8 Reg. 2(7) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **8**

F9 Reg. 2(8) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **9**

F10 Reg. 2(9) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **10**

F11 Reg. 2(10) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **11**

F12 Reg. 2(11) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **12**

F13 Reg. 2(12)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **13(a)**

F14 Reg. 2(12)(aa) inserted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **13(b)**

F15 Reg. 2(12)(b)(ba) substituted for reg. 2(12)(b) (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **13(c)**

F16 Reg. 2(12)(c)(ca) substituted for reg. 2(12)(c) (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **13(d)**

F17 Reg. 2(12)(d)(e) substituted for reg. 2(12)(d) (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **13(e)**

F18 Reg. 2(13) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **14**

F19 Words in reg. 2(14) inserted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **15**

F20 Words in reg. 2(17)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **16(a)**

F21 Reg. 2(17)(b)(ba) substituted for reg. 2(17)(b) (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **16(b)**

F22 Words in reg. 2(17)(c) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **16(c)**

F23 Words in reg. 2(18)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(a)**

F24 Words in reg. 2(18)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(b)**

F25 Words in reg. 2(18)(c) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(c)**

F26 Reg. 2(19) substituted (31.12.2020 immediately before IP completion day) by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **18**

Commencement Information

I1 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 1990 c. 37. Relevant amendments have been made by sections 2, 22, 25, 28, 30 and 65 of, and Schedules 5 and 7 to, the Human Fertilisation and Embryology Act 2008 (c. 22) and by S.I. 2007/1522, 2014/2884 and 2018/334.

M2 Section 2 was amended by sections 2 and 65 of, and paragraph 2 of Schedule 7 to, the Human Fertilisation and Embryology Act 2008 and by S.I. 2007/1522 and 2018/334.

M3 Section 2A was inserted by S.I. 2007/1522.

M4 Section 24 was amended by section 22 of the Human Fertilisation and Embryology Act 2008 and by S.I. 2007/1522 and 2018/334.

M5 Section 45 was amended by section 30 of the Human Fertilisation and Embryology Act 2008.

M6 Section 47 was amended by sections 65 of, and paragraph 13 of Schedule 7 to, the Human Fertilisation and Embryology Act 2008 and by S.I. 2007/1522 and 2018/334.

M7 Schedule 3A was inserted by S.I. 2007/1522 and amended by S.I. 2018/334.

M8 S.I. 2002/618.

M9 Schedule 3AA was inserted by S.I. 2018/334.

M10 2018 c. 12; section 3(9) was amended by S.I. 2019/419.

Changes to legislation:
There are currently no known outstanding effects for the The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019, PART 2.