Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2019 No. XXX

EXITING THE EUROPEAN UNION
HUMAN FERTILISATION AND EMBRYOLOGY

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

Made - - - - 2019

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**).

A draft of these Regulations was laid before Parliament in accordance with paragraph 1(1) of Schedule 7 to that Act and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

(**1**) 2018 c. 16.

PART 2

Amendment of primary legislation

Amendment of the Human Fertilisation and Embryology Act 1990

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

(2) In section 1A(**3**) (references to Directives) in the definition of "the third Directive", for "as amended by Commission Directive 2015/565/EU" substitute "as it had effect immediately before 29 April 2015 (the date on which the amendments made by Commission Directive 2015/565/EU came into force)".

(3) In section 2(**4**) (other terms)—

(a) in subsection (1) —

(i) omit the definition of "competent authority";

(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 tissues and cells,";

(b) in subsection (2B), for the words from "is a reference" to the end substitute "is to be read as a reference to a requirement which that provision would require to be imposed if the provision formed part of domestic law".

(4) In section 2A(**5**) (third party agreements) after subsection (1) insert—

"(1A) For the purposes of subsection (1), Article 24 of the first Directive is to be read subject to the modifications set out in paragraph 11A(8) of Schedule 3A.".

(5) In section 2B(**6**) (meaning of "importing licensee", "third country premises" etc) for subsection (4) substitute—

"(4) "Third country" means any country other than the United Kingdom.".

(6) Omit section 8ZB(**7**) (duties of the Authority in relation to application of the Single European Code).

(7) Omit section 8A(**8**) (duty of Authority to communicate with competent authorities of other EEA states).

(8) In section 14A(**9**) (conditions of licences: human application) omit subsections (3) and (4).

(9) In section 15A(**10**) (duties of the Authority in relation to serious adverse events and serious adverse reactions) omit subsection (3).

(10) Omit section 15B(**11**) (inspections of third country premises etc).

(**2**) 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.
(**3**) Section 1A was inserted by S.I. 2007/1522 and amended by S.I. 2014/2884 and 2018/334.
(**4**) 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.
(**5**) Section 2A was inserted by S.I. 2007/1522.
(**6**) Section 2B was inserted by S.I. 2018/334.
(**7**) Section 8ZB was inserted by S.I. 2018/334.
(**8**) Section 8A was inserted by S.I. 2007/1522.
(**9**) Section 14A was inserted by S.I. 2007/1522 and amended by section 65 of, and paragraph 6 of Schedule 7 to, the Human Fertilisation and Embryology Act 2008.
(**10**) Section 15A was inserted by S.I. 2007/1522.
(**11**) Section 15B was inserted by S.I. 2018/334.

(11) Omit section 15C(**12**) (third country premises and third country suppliers: report of inspections etc).

(12) In section 24(**13**) (directions as to particular matters)—

(a) in subsection (3A)—

(i) omit paragraph (c) (but not the "or" at the end);

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

(b) in subsection (4AD) for "in the form set out in Annex II to the fourth Directive" substitute "of authority in such form as the Authority considers appropriate";

(c) in subsection (12) for the words from " to secure compliance with" to the end, substitute "to facilitate traceability";

(d) omit subsections (12A) and (14).

(13) In section 33A(**14**) (disclosure of information), omit subsection (2)(m).

(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.".

(15) In section 45(4A) (regulations)(**15**), insert at the appropriate place—

"section 42A;";

(**12**) Section 15C was inserted by S.I. 2018/334.
(**13**) Section 24 was amended by section 22 of the Human Fertilisation and Embryology Act 2008 and by S.I. 2007/1522 and 2018/334.
(**14**) Section 33A was inserted by section 25 of the Human Fertilisation and Embryology Act 2008.
(**15**) Section 45 was amended by section 30 of the Human Fertilisation and Embryology Act 2008.

(16) In section 47(**16**) (Index)—

(a) omit the entry relating to "Competent authority";

(b) at the appropriate place insert—

"Tissue establishment	Section 2(1)".

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

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

"**A1.** For the purposes of this Act, the first, second and third Directives are to be read subject to the modifications set out in paragraphs 11A to 11C.";

(b) in paragraph 3, for the words from "are necessary" to the end substitute "the Authority considers appropriate";

(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 "in the United Kingdom";

(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—

(**16**) 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.

(**17**) Schedule 3A was inserted by S.I. 2007/1522 and amended by S.I. 2018/334.

(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"(**18**);

(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(**19**) (requirements where gametes or embryos imported from third country) —

(a) before paragraph 1, insert—

"**A1.** For the purposes of this Act, the fourth Directive is to be read subject to the modifications set out in paragraph 3A.

Directions";

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

(**18**) S.I. 2002/618.
(**19**) Schedule 3AA was inserted by S.I. 2018/334.

"(c) provide the Authority with any information or documents specified in the direction for the purposes of demonstrating—

(i) traceability; and

(ii) that the import is a one-off import within the meaning given by section 24(4AE).";

(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 "the United Kingdom".

(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"(**20**);

(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".

(19) In Schedule 3B(**21**) (inspection, entry, search and seizure)—

(a) omit paragraph 1A and the italic heading preceding it;

(b) omit paragraph 4A;

(c) in paragraph 9, omit sub-paragraphs (4) and (5).

PART 3

Amendment of subordinate legislation

Amendment of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

3. In the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007(**22**), omit regulation 2 (designation of the competent authority).

(**20**) 2018 c. 12.
(**21**) Schedule 3B was inserted by section 28(2) of, and Schedule 5 to, the Human Fertilisation and Embryology Act 2008, and amended by S.I. 2018/334.
(**22**) S.I. 2007/1522.

PART 4

Transitional provision

Transitional provision

4.—(1) For a period of six months beginning with exit day, the requirements of the provisions listed in paragraph (2) do not apply to—

(a) an import of gametes or embryos into the United Kingdom from an EEA state or Gibraltar; or

(b) an export of gametes or embryos from the United Kingdom into an EEA state or Gibraltar,

provided that the Authority is satisfied that the import or, as the case may be, export, meets requirements of traceability and standards of quality and safety equivalent to those laid down in the Act.

(2) The provisions referred to in paragraph (1) are—

(a) subsections (4A) to (4AD) of section 24 of the Act;

(b) Schedule 3AA to the Act.

(3) In this regulation—

(a) "the Act" means the Human Fertilisation and Embryology Act 1990 (as amended by these Regulations); and

(b) the terms "the Authority", "embryo", "gamete" and "traceability" have the same meanings as they have in the Act.

Signed by authority of the Secretary of State for Health and Social Care.

Name
Parliamentary Under-Secretary of State,
Department of Health and Social Care

Address
Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (f) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to legislation concerning gametes and embryos intended for use in human application. In particular, they amend legislation relating to technical requirements for the storage, procurement, testing, processing or distribution of gametes and embryos, and the import of gametes and embryos into, and their export from, the United Kingdom. Part 2 amends primary legislation, Part 3 amends subordinate legislation, and Part 4 makes transitional provision.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.