Draft Regulations laid before Parliament under paragraphs 1 and 8F of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2020 No. 0000

EXITING THE EUROPEAN UNION

HUMAN FERTILISATION AND EMBRYOLOGY

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

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C of the European Union (Withdrawal) Act 2018(**a**) and section 41(1) of the European Union (Withdrawal Agreement) Act 2020.

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 1 and 8F(**b**) of Schedule 7 to the European Union (Withdrawal) Act 2018.

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 and come into force immediately before IP completion day.

Amendment of the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019

2. The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019(**c**) are amended as follows.

Substitution of regulation 2(2)

3. For regulation 2(2) substitute—

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

""the third Directive" means—

(**a**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1) (the "2020 Act"). Section 8C was inserted by section 21 of that Act.
(**b**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.
(**c**) 2019/482.

(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,",".

Amendment of regulation 2(3)

4. In regulation 2(3)—

(a) for sub-paragraph (a)(i) substitute—

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

(b) in sub-paragraph (a)(ii), in the inserted definition of "tissue establishment", for "tissues and cells" substitute "gametes or embryos";

(c) for sub-paragraph (b) substitute—

"(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.".".

Amendment of regulation 2(4)

5. In regulation 2(4), in the new subsection (1A) inserted by that provision into section 2 of the Human Fertilisation and Embryology Act 1990(**a**), after "subsection (1)," insert "as it applies in relation to Great Britain,".

Substitution of regulation 2(5)

6. For regulation 2(5) substitute—

"(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

(**a**) 1990 c. 37. Relevant amendments to the Human Fertilisation and Embryology Act 1990 were made by the Human Fertilisation and Embryology Act 2008 (c. 22), S.I. 2007/1522, 2018/334 and 2018/1413.

(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.".".

Substitution of regulation 2(6)

7. For regulation 2(6) substitute—

"(6) In section 8ZB(**a**) (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";

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

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

(**a**) Section 8ZB was inserted by S.I. 2018/334.

Substitution of regulation 2(7)

8. For regulation 2(7) substitute—

"(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".".

Substitution of regulation 2(8)

9. For regulation 2(8) substitute—

"(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".".

Substitution of regulation 2(9)

10. For regulation 2(9) substitute—

"(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".".

Substitution of regulation 2(10)

11. For regulation 2(10) substitute—

"(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".".

Substitution of regulation 2(11)

12. For regulation 2(11) substitute—

"(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".".

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).".

Substitution of regulation 2(13)

14. For regulation 2(13) substitute—

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

Amendment of regulation 2(14)

15. In section 42A as inserted by regulation 2(14), at the end insert—

"(6) The Secretary of State may only make regulations under this section in relation to Great Britain.".

Amendment of regulation 2(17)

16. In regulation 2(17)—

(a) in the new paragraph A1 inserted by sub-paragraph (a), after "this Act," insert "as it applies in relation to Great Britain,";

(b) for sub-paragraph (b) substitute—

"(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) in the new paragraph 11A inserted by sub-paragraph (c), in sub-paragraph (2)(a)(ii) for "in the United Kingdom" substitute "in Great Britain".

Amendment of regulation 2(18)

17. In regulation 2(18)—

(a) in the new paragraph A1 inserted by sub-paragraph (a), after "this Act," insert "as it applies in relation to Great Britain,";

(b) for the new paragraph 2(c) substituted by sub-paragraph (b), substitute—

"(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) in the new paragraph 3A(3) inserted by sub-paragraph (c), for "the United Kingdom" substitute "Great Britain".

Substitution of regulation 2(19)

18. For regulation 2(19) substitute—

"(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".".

Substitution of regulation 3

19. For regulation 3 (amendment of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007) substitute—

"**3.** In regulation 2 of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007(**a**)—

(a) for the heading substitute "Designation of the competent authority: Northern Ireland";

(b) for "The Human Fertilisation and Embryology Authority" substitute "In relation to Northern Ireland, the Human Fertilisation and Embryology Authority".".

Amendment of regulation 4

20. In regulation 4(1) (transitional provision)—

(a) for "exit day" substitute "IP completion day";

(b) in sub-paragraphs (a) and (b), for "the United Kingdom" substitute "Great Britain".

Name
Parliamentary Under Secretary of State
Department for Health and Social Care

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in section 8(1) and 8C 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) of that Act) arising from the withdrawal of the United Kingdom from the European Union, and in order to give effect to the Protocol on Ireland/Northern Ireland in the withdrawal agreement respectively.

They amend the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/482) so as to enable the provision amended by those Regulations to continue to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day.

(**a**) S.I. 2007/1522.

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

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