

Draft Regulations laid before Parliament under paragraph 2(2) of Schedule 2 to the European Communities Act 1972, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2018 No. 0000

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology
(Amendment) Regulations 2018

Made - - - - - ***** 2018**

Coming into force

*for the purposes of
regulation 1(3)*

***** 2018**

for all other purposes

1st April 2018

The Secretary of State is a Minister designated⁽¹⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽²⁾ in relation to health protection measures regulating the use of material of human origin.

In accordance with paragraph 2(2) of Schedule 2 to that Act, a draft of this instrument was laid before Parliament and approved by a resolution of each House of Parliament.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of that Act.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Amendment) Regulations 2018.

(2) Except as provided by paragraph (3), these Regulations come into force on 1st April 2018 (“the commencement date”).

(3) These Regulations come into force on the day after the day on which they are made so far as necessary to enable anything to be done for the purposes of varying a relevant licence or giving directions to ensure compliance with these Regulations on the commencement date.

(4) In paragraph (3), “relevant licence” has the same meaning as section 8ZB(11) of the 1990 Act as inserted by regulation 4(1) of these Regulations.

(1) S.I. 2004/3037.

(2) 1972 c.68.

(5) In these Regulations—

- (a) the “1990 Act” means the Human Fertilisation and Embryology Act 1990⁽³⁾,
- (b) “the fourth Directive” has the same meaning as in the 1990 Act, as amended by regulation 3(2) of these Regulations,
- (c) “gametes” and “embryos” have the same meaning as in the 1990 Act⁽⁴⁾.

Designation of the competent authority

2. The Human Fertilisation and Embryology Authority is designated the competent authority for the purposes of the fourth Directive so far as it relates to gametes and embryos.

Amendments to definitions in the 1990 Act

3.—(1) The 1990 Act is amended as follows.

(2) In section 1A (reference to Directives)⁽⁵⁾—

- (a) in the definition of the “second Directive” at the end omit the “and”,
- (b) in the definition of the “third Directive” at the end insert “, as amended by Commission Directive 2015/565/EU.”,
- (c) after the definition of “the third Directive” insert—
“, and

“the fourth Directive” means Commission Directive 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.”

(3) In section 2 (other terms)—

- (a) in subsection (1)—
 - (i) in the definition of “competent authority” for “and third” substitute “, third and fourth”, and
 - (ii) in the definition of “distribution” after “delivery” insert “to any person in or outside the United Kingdom for human application”,
- (b) in subsection (2A) after “transporting gametes or embryos” insert “to any person in or outside the United Kingdom for human application”, and
- (c) in subsection (2B) for “or third” substitute “, third or fourth”.

(4) After section 2A insert—

“2B Meaning of “importing licensee”, “third country premises” etc

- (1) This section applies for the purposes of this Act.
- (2) “Importing licensee” means a person—
 - (a) to whom a licence applies, and
 - (b) who is authorised by directions under section 24(4) to import qualifying gametes or embryos into the United Kingdom from a third country.
- (3) “Qualifying gametes or embryos” means gametes or embryos intended for human application.

(3) 1990 c.37.

(4) “Gametes” and “embryos” are defined in section 1 of the 1990 Act.

(5) Inserted by S.I.2007/1522, regulation 5.

- (4) “Third country” means a country which is not an EEA state or Gibraltar.
- (5) Premises are “third country premises” if—
 - (a) they are in a third country, and
 - (b) they are premises on, 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 the United Kingdom.
- (6) “Third country supplier” means a person in a third country who has an agreement with an importing licensee for exporting qualifying gametes or embryos intended for import into the United Kingdom.”.

Amendments to the 1990 Act relating to the coding of gametes and embryos

- 4.—(1) After section 8ZA(6) insert—

“8ZB Duties of the Authority in relation to application of the Single European Code

(1) The Authority must allocate to each holder of a relevant licence, one or more unique numbers as the tissue establishment number or numbers in relation to that licence holder in accordance with Annex VII and paragraph 2(a) of Article 10b of the third Directive.

(2) Any number allocated under subsection (1) must be in the format specified in Annex VII.

(3) The Authority must, in relation to each holder of a relevant licence, arrange for the information specified in Annex VIII to be recorded in the EU Tissue Establishment Compendium.

(4) In relation to a person who becomes the holder of a relevant licence before 1st April 2018, the Authority must ensure that the information under subsection (3) is recorded before the end of the period of 10 working days beginning with that day.

(5) In relation to a person who becomes the holder of a relevant licence on or after 1st April 2018, the Authority must ensure that the information under subsection (3) is recorded before the end of the period of 10 working days beginning with the day on which the person becomes the holder of that licence.

(6) Subsection (7) applies if the Authority becomes aware that any information recorded under subsection (3) was incorrectly recorded or requires updating.

(7) The Authority must arrange for the information to be corrected or updated—

- (a) in the case of a correction or update which the Authority considers to be a significant change to the information recorded under subsection (3), before the end of the period of 10 working days beginning with the day on which the Authority became aware that the information was incorrectly recorded or required updating;
- (b) in any other case, as soon as is reasonably practicable.

(8) Subsection (9) applies if the Authority becomes aware that—

- (a) any information recorded in the EU Tissue Establishment Compendium in respect of a tissue establishment in a relevant state was incorrectly recorded or requires updating, or
- (b) a tissue establishment in a relevant state has not complied with the requirements of the laws or other measures adopted in that state for the purpose of implementing

paragraph 1 of Article 10b of the third Directive and the non-compliance is significant.

(9) The Authority must inform the competent authority in the relevant state in question.

(10) If the Authority becomes aware that the information recorded in the EU Tissue and Cell Product Compendium requires updating, it must inform the European Commission and the competent authority in the relevant state.

(11) In this section—

“Annex VII” means Annex VII to the third Directive,

“Annex VIII” means Annex VIII to the third Directive,

“EU Tissue and Cell Product Compendium” and “EU Tissue Establishment Compendium” have the same meaning as in Article 2 of the third Directive,

“relevant licence” means a licence granted under any of the following provisions of Schedule 2—

(a) paragraph 1,

(b) paragraph 1A,

(c) paragraph 2, so far as authorising the storage of gametes or embryos intended for human application,

(d) paragraph 3, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application,

“relevant state” means—

(a) an EEA state other than the United Kingdom, or

(b) Gibraltar,

“working day” means any day other than—

(a) a Saturday or Sunday,

(b) Christmas Day or Good Friday, or

(c) a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in any part of the United Kingdom.”.

(2) For subsection (12) of section 24 (directions as to particular matters), substitute—

“(12) 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 secure compliance with the requirements of—

(a) paragraph 1 of Article 25 of the first Directive (coding of information),

(b) paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article,

(c) Article 10a of the third Directive (format of the Single European Code), and

(d) paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).”.

(3) After subsection (12) of section 24, insert—

“(12A) Directions must require information to be provided to the Authority which the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive (European coding system).”.

(4) Schedule 3A (supplementary licence conditions: human application) is amended as follows.

(5) For paragraph 1 substitute—

“Traceability system

1. Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).”.

(6) Omit paragraph 2.

Amendments to the 1990 Act relating to the import of gametes and embryos

5.—(1) The 1990 Act is amended as follows.

(2) After section 15A insert—

“15B Inspections of third country premises etc

(1) This section applies where—

- (a) qualifying gametes or embryos are imported into the United Kingdom from a third country by an importing licensee,
- (b) the gametes or embryos are distributed in an EEA state other than the United Kingdom or in Gibraltar, and
- (c) the competent authority in that state or in Gibraltar requests the Authority to carry out any of the following activities—
 - (i) arranging for an inspection of any third country premises to be carried out on behalf of the Authority,
 - (ii) arranging for an inspection of any relevant documents held by a third country supplier to be carried out on behalf of the Authority,
 - (iii) exercising the Authority’s powers under section 18(2) to revoke a licence held by an importing licensee,
 - (iv) exercising the Authority’s powers under section 18A(3) to vary a licence held by an importing licensee,
 - (v) exercising the Authority’s powers under section 19C(1) to suspend a licence held by an importing licensee, and
 - (vi) other appropriate control measures.

(2) The Authority must carry out the activity in question in subsection (1)(c), unless it considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Before an inspection of any premises is carried out in pursuance of subsection (2), the Authority must—

- (a) make arrangements with the competent authority which made the request under subsection (1) for it to participate in the inspection, or
- (b) notify the competent authority which made the request under subsection (1) that the Authority has decided that it is not appropriate for it to participate in the inspection and give reasons for that decision.

(4) For the purposes of ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act, the Authority may arrange for either or both of the following to be carried out on its behalf—

- (a) an inspection of any third country premises,

(b) an inspection of any relevant documents held by a third country supplier.

(5) The Authority may arrange for a report to be made on any inspection carried out in pursuance of subsection (2) or (4).

(6) Any inspection carried out on behalf of the Authority in pursuance of subsection (2) or (4) must be carried out by a person authorised by the Authority to act for the purposes of this section.

(7) References in this section to carrying out an inspection of any premises include, in particular—

- (a) inspecting any equipment found on the premises,
- (b) inspecting and taking copies of any relevant documents or records found on the premises, and
- (c) observing the carrying on of any activity relevant to ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.

(8) In this section, “relevant document” means a document relevant for the purposes of ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.

15C Third country premises and third country suppliers: report of inspections etc

(1) This section applies where the European Commission or a competent authority in an EEA state other than the United Kingdom or in Gibraltar requests the Authority to provide it with—

- (a) a copy of a report or information on any inspection of third country premises or relevant documents carried out in pursuance of section 15B(2) or (5),
- (b) information on any exercise of the Authority’s powers under section 18(2), 18A(3) or 19C(1) in relation to a licence held by an importing licensee (whether in pursuance of section 15B(2) or otherwise), or
- (c) information on any appropriate control measures carried out by the Authority (whether in pursuance of section 15B(2) or otherwise).

(2) The Authority must provide the report or information in question to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.”

(3) In section 18(2) (revocation of licence otherwise than on application)—

- (a) omit “or” at the end of paragraph (h), and
- (b) after paragraph (i) insert—

“or

- (j) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that qualifying gametes or embryos imported from a third country by the holder of the licence meet standards of quality and safety laid down in this Act.”.

(4) In section 24 (directions as to particular matters)—

- (a) in subsection (4A)—
 - (i) for the words from “import” to “such a country” substitute “export from the United Kingdom to a third country”, and
 - (ii) in paragraph (a) omit “imports or”,

(b) after subsection (4A) insert the following subsections—

“(4AA) Directions must, in accordance with paragraph 1 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make qualifying imports (other than a one-off import) must comply before the Authority gives any directions under subsection (4) authorising the person to make qualifying imports.

(4AB) Directions must, in accordance with paragraph 2 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make a qualifying import which is a one-off import must comply before the Authority gives any directions under subsection (4) authorising the person to make the import.

(4AC) In giving any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, the Authority must include the directions specified in paragraph 3 of Schedule 3AA.

(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 provide that person with a certificate in the form set out in Annex II to the fourth Directive.

(4AE) In subsections (4AA) and (4AB) a reference to a one-off import, in relation to gametes or embryos, is to gametes or embryos imported for the purposes of providing services to a particular person or persons on one occasion only.

(4AF) In subsections (4AA) to (4AD) and Schedule 3AA “qualifying import” means the import into the United Kingdom from a third country of gametes or embryos intended for human application.”.

(5) In section 47 (index) insert the following entries in the appropriate places—

“Fourth Directive	Section 1A”
“Importing licensee	Section 2B(2)”
“Qualifying gametes or embryos	Section 2B(3)”
“Third country	Section 2B(4)”
“Third country premises	Section 2B(5)”
“Third country supplier	Section 2B(6)”

(6) After Schedule 3A insert—

“Schedule 3AA Section 24(4AA), (4AB) and (4AC)

REQUIREMENTS WHERE GAMETES OR EMBRYOS IMPORTED FROM THIRD COUNTRY

1. A direction given under section 24(4AA) must require the person to whom the licence applies to—

(a) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act,

- (b) provide the Authority with any information specified in the direction for the purposes of securing compliance with the requirements of Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments),
 - (c) provide the Authority with any documents specified in the direction for the purposes of securing compliance with the requirements of Part F of Annex I to the fourth Directive (documentation to be provided by importing tissue establishments),
 - (d) do the following—
 - (i) make available for inspection any documents specified in the direction for the purposes of securing compliance with the requirements of Parts A and B of Annex III to the fourth Directive (availability and provision of documentation) and,
 - (ii) if requested by the Authority, provide the Authority with any such documents,
 - (e) enter into a written agreement with any proposed third country supplier which complies with the requirements specified in the direction for the purposes of securing compliance with the requirements of Article 7(2) and (3) of the fourth Directive (written agreements), and
 - (f) provide the Authority with a copy of the written agreement mentioned in subparagraph (e).
2. A direction given under section 24(4AB) must require the person to whom the licence applies to —
- (a) comply with measures specified in the direction for the purposes of ensuring that any qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act,
 - (b) provide the Authority with any information specified in the direction for the purposes of securing compliance with the requirements of Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments), and
 - (c) provide the Authority 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).
3. The following requirements must be specified in directions under section 24(4) authorising any person to whom a licence applies to make any qualifying imports—
- (a) a requirement that the person must not make any substantial changes in connection with any qualifying imports made by the person unless the Authority approves those changes in writing,
 - (b) a requirement that the person must notify the Authority if the person ceases to make qualifying imports,
 - (c) a requirement that the person must—
 - (i) notify the Authority of any serious adverse events or serious adverse reactions notified to the person by the person’s third country supplier (including events or reactions which that supplier suspects are serious adverse events or reactions), and
 - (ii) provide any information specified in the direction which the Authority requires for the purposes of securing compliance with the requirements of Article 6(2) of the fourth Directive (updated information), and
 - (d) a requirement that the person must notify the Authority of any changes in circumstances of the person’s third country supplier of which the person is aware.
4. In this Schedule—

“changes of circumstances” means any changes in circumstances of the description specified in the direction in question in accordance with the provision made in Article 6(3) of the fourth Directive (notification of revocation of third country’s authorisation),

“substantial changes” means changes of the description specified in the direction in question in accordance with the provision as to the meaning of substantial changes made in Article 3(3) of the fourth Directive (requirements where substantial changes made to import activities).”.

(7) Schedule 3B (inspection, entry, search and seizure) is amended as follows.

(8) After paragraph 1 insert—

“Inspection of documents held by an importing licensee

1A.—(1) This paragraph applies where—

- (a) qualifying gametes or embryos are imported from a third country by an importing licensee,
- (b) the gametes or embryos are distributed in an EEA state other than the United Kingdom or in Gibraltar, and
- (c) the competent authority in that state or in Gibraltar requests the Authority to arrange for an inspection of any relevant documents held by an importing licensee to be carried out.

(2) The Authority must arrange for an inspection of the documents in question to be carried out by a duly authorised person, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Where relevant documents are stored in any electronic form, a duly authorised person may require an importing licensee to make the documents available for inspection—

- (a) in a visible and legible form, or
- (b) in a form from which they can be readily produced in a visible and legible form.

(4) A duly authorised person may take copies of any relevant documents inspected in pursuance of a requirement under this paragraph.

(5) In this paragraph “relevant document” means a document relevant for the purposes of ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.”.

(9) After paragraph 4 insert—

“4A.—(1) This paragraph applies where—

- (a) any activity governed by this Act is carried out in relation to qualifying gametes or embryos imported from a third country on any premises--
 - (i) to which a licence held by an importing licensee relates, or
 - (ii) which are relevant third party premises in relation to an importing licensee,
- (b) the gametes or embryos are distributed in an EEA state other than the United Kingdom or in Gibraltar, and
- (c) the competent authority in that state or in Gibraltar requests the Authority to arrange for an inspection of the premises to be carried out.

(2) The Authority must arrange for an inspection of the premises in question to be carried out under paragraph 3 by a duly authorised person, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Before an inspection of any premises is carried out in pursuance of sub-paragraph (2) the Authority must—

- (a) make arrangements with the requesting authority for it to participate in the inspection, or
- (b) notify the requesting authority that the Authority has decided that it is not appropriate for the requesting authority to participate in the inspection and give reasons for that decision.

(4) In this paragraph, “requesting authority” means the competent authority which made the request under sub-paragraph (1) for the Authority to arrange for the inspection to be carried out.”.

(10) In paragraph 8(2)(b), after “any” insert “relevant documents or”.

(11) After paragraph 8(3) insert—

“(4) In this paragraph “relevant document” means a document relevant for the purposes of ascertaining whether qualifying gametes or embryos imported from a third country meet standards of quality and safety equivalent to those laid down in this Act.”.

(12) After paragraph 9(3) insert—

“(4) Sub-paragraph (5) applies if the European Commission or a competent authority in an EEA state other than the United Kingdom or in Gibraltar requests the Authority to provide it with a copy of a report or information on—

- (a) any inspection under paragraph 1 or 1A of records or documents,
- (b) any inspection under paragraph 2 where the person to whom an application for authorisation relates also seeks a direction under section 24(4) authorising that person to import qualifying gametes or embryos into the United Kingdom from a third country, or
- (c) any inspection under paragraph 3 of premises to which a licence held by an importing licensee relates or which are relevant third party premises in relation to an importing licensee.

(5) The Authority must give a copy of the report or information to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.”.

Transitional provisions

6.—(1) A licence to which section 14A of the 1990 Act applies (conditions of licence: human application) which is in force immediately before the commencement date, is to be treated as subject to the conditions in Schedule 3A to the 1990 Act as amended by these Regulations.

(2) Paragraph (3) applies in respect of qualifying gametes or embryos which were in storage on 29th October 2016 and which are transported or delivered to any person in or outside the United Kingdom at any time before 30th October 2021.

(3) Where this paragraph applies, the amendments made by regulation 4(2) to (6) do not apply.

(4) Paragraph (5) applies in respect of qualifying gametes or embryos which either—

- (a) were in storage on 29th October 2016, and are transported or delivered to any person in or outside the United Kingdom on or after 30th October 2021; or
- (b) were placed in storage after 29th October 2016, and are in storage on the commencement date (irrespective of when they are transported or delivered to any person in or outside the United Kingdom).

(5) Where this paragraph applies—

- (i) the amendments made by regulation 4(2) do not apply; and
 - (ii) directions given by the Authority must specify the systems to be adopted for the identification of qualifying gametes or embryos to which this paragraph applies which the Authority considers appropriate to secure compliance with the requirements of paragraph 1(f) of Article 10b of the third Directive (requirements as to labelling).
- (6) In this regulation, “the Authority”, “the third Directive” and “qualifying gametes or embryos” have the same meaning as in the 1990 Act, as amended by these Regulations.

Signed by authority of the Secretary of State for Health.

Date

Name
Parliamentary Under-Secretary of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Fertilisation and Embryology Act 1990 (“the 1990 Act”) to implement Directive 2015/565 (“the coding Directive”) of the European Commission, laying down technical requirements for the coding of tissues and cells and Directive 2015/566 (“the fourth Directive”) of the European Commission, setting out procedures for verifying standards of quality and safety of imported tissues and cells. These Regulations apply in relation to gametes and embryos intended for use in human application.

Regulation 2 appoints the Human Fertilisation and Embryology Authority (“the Authority”) as the competent authority in relation to the fourth Directive.

Regulations 3 to 5 amend the 1990 Act. Regulation 3 amends definitions. Regulation 3(2) amends section 1A to ensure that all references in the 1990 Act to the “third Directive” include amendments made to that Directive by the coding Directive. It also amends that section to incorporate the definition of the fourth Directive. Regulation 3(3) clarifies the meaning of “distribution”. Regulation 3(4) inserts new section 2B to define “importing licensee”, “qualifying gametes or embryos”, “third country”, “third country premises” and “third country supplier” for the purposes of that Act.

Regulation 4(1) inserts new section 8ZB which requires the Authority to take steps to ensure compliance with requirements imposed by the coding Directive relating to the application of a Single European Code (“SEC”) to gametes and embryos intended for human application. Regulation 4(2) amends section 24(12) to require the Authority to issue directions to licence holders requiring the application of the SEC to gametes and embryos intended for human application and regulation 4(3) inserts new subsection (12A) requiring the Authority to issue directions relating to information licence holders must provide relating to the SEC. Regulation 4(5) amends paragraph 1 of Schedule 3A to remove the requirement for conditions relating to coding since the requirements relating to application of the new SEC will be conveyed in directions to licence holders issued by the Authority. Regulation 4(6) omits paragraph 2 of Schedule 3A which is no longer required.

Regulation 5 makes amendments relating to the import of gametes and embryos. Regulation 5(2) inserts new section 15B to allow the Authority to carry out inspections of third country premises or documents held by a third country supplier, or to take control measures in relation to importing licensees, where appropriate, following a request from another competent authority in whose country the gametes or embryos have been distributed. Provision is made for the Authority to agree how it will participate in any inspection or to give reasons for refusing to allow such participation.

Regulation 5(2) also inserts new section 15C to make provision requiring the Authority to provide where it is appropriate, a report or information on any inspection of third country premises or documents held by a third country supplier or information on any appropriate control measures carried out following a request from the European Commission or another competent authority.

Regulation 5(3) amends section 18 to add to the list of grounds upon which the Authority may revoke a licence otherwise than on application, to include where the Authority is not satisfied that third country premises are suitable for carrying out activities in a manner which will meet standards of safety and quality laid out in the Act.

Regulation 5(4) amends section 24. This section relates to directions to import and inserts new subsections (4AA) to (4AD), the detail of which is set out in new Schedule 3AA which reflects the requirements of the fourth Directive. Subsection (4AA) and paragraph 1 of Schedule 3AA require the Authority to ensure that certain conditions in the fourth Directive are met before issuing any

directions enabling a licence holder to import gametes or embryos for human application from a third country. Subsection (4AB) together with paragraph 2 of Schedule 3AA set out the requirements which must be satisfied before directions can be given authorising a one-off import of such gametes or embryos from a third country. Subsection (4AC) together with paragraph 3 of Schedule 3AA sets out further requirements which must be specified in directions authorising the import of gametes or embryos from a third country. Subsection (4AD) provides that when authorising a licence holder to import gametes or embryos from a third country, the Authority must provide that licence holder with the certificate set out in Annex II to the fourth Directive.

Regulation 5(5) amends section 47 to update the index. Regulation 5(6) inserts Schedule 3AA.

Regulation 5(8) and (9) amend Schedule 3B to allow the Authority to carry out where appropriate an inspection of relevant documents held by an importing licensee and premises where any activity governed by this Act is carried out in relation to gametes or embryos imported from a third country and intended for human application. Regulation 5(12) makes provision requiring the Authority to provide a report or information as appropriate on inspections of documents or premises which the Authority has carried out under Schedule 3B.

Regulation 6 makes transitional provision. Regulation 6(1) makes provision to the effect that existing licences to which section 14A of the 1990 Act applies will be deemed from the commencement date to be subject to the revised conditions in Schedule 3A.

Regulation 6(2) and (3) provide that, where gametes or embryos are in storage on 29th October 2016 and are transported or delivered to any person in or outside the United Kingdom within 5 years of that date, the licence holder will be exempted from applying the requirements of the Single European Code. Regulation 6(4) and (5) provide that where gametes or embryos were in storage on 29th October 2016 and are transported or delivered to any person on or after 30th October 2021, the procedures in the coding Directive which relating to gametes or embryos with small labels will apply. Similarly, these procedure apply to gametes or embryos which were placed in storage after 29th October 2016 but which are in storage on the commencement date, irrespective of when they are transported or delivered.

A Regulatory Impact Assessment and a Transposition Note have been prepared for these Regulations and a copy of each has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment and the Transposition Note can be obtained from the Health Ethics Team (Assisted Reproduction and Embryology), Department of Health, 6th Floor, 39 Victoria Street, London SW1H 0EU.