SCHEDULES

[F1SCHEDULE 3AA

Section 24(4AA), (4AB) and (4AC)

REQUIREMENTS WHERE GAMETES OR EMBRYOS IMPORTED FROM THIRD COUNTRY

Textual Amendments

F1 Sch. 3AA inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **5(6)**

[F2A1 For the purposes of this Act, as it applies in relation to Great Britain, the fourth Directive is to be read subject to the modifications set out in paragraph 3A.

Textual Amendments

F2 Sch. 3AA para. A1 and cross-heading inserted (31.12.2020) S.I. 2019/482, regs. 1, **2(18)(a)** (with reg. 4) (as amended by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**)

Directions]

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 sub-paragraph (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

[[F3](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).**]**

Textual Amendments

F3 Sch. 3AA para. 2(c) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(18)(b)** (as amended by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(b)**)

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.

[F4 Modifications to the fourth Directive

Textual Amendments

F4 Sch. 3AA para. 3A and cross-headings inserted (31.12.2020) by S.I. 2019/482, regs. 1, **2(18)(c)** (with reg. 4) (as amended by The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1307), regs. 1, **17(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**)

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 "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 ";

(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***]**

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).**]**

Changes to legislation:
There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, SCHEDULE 3AA.