

**Changes to legislation:** There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Modifications to the fourth Directive. (See end of Document for details)

## SCHEDULES

### [<sup>F1</sup>SCHEDULE 3AA

#### 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)**

#### *[<sup>F2</sup>Modifications to the fourth Directive*

##### Textual Amendments

- F2** 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 subparagraph (b) were a reference to the authority or authorities in the third country concerned responsible for regulating tissue establishments in that country.

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(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”.]]

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