

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

SCHEDULES

[^{F1}SCHEDULE 3A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments

- F1** Sch. 3A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs 1, **30**

[^{F2}Modifications to the first, second and third Directives

Textual Amendments

- F2** Sch. 3A paras. 11A-11C and cross-heading inserted (31.12.2020) by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/482\)](#), regs. 1, **2(17)(c)** (with reg. 4) (as amended by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **16(c)**); 2020 c. 1, Sch. 5 para. 1(1)

- 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 Great Britain”;
 - (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.

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- (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—
 - (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;

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- (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 ”;
- (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 ”.]]

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