

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

SCHEDULES

[^{F1}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)**

[^{F2}Directions]

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\(1\)](#))

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

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- (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.]

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