

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Paragraph 1. (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)**

[^{F1}Directions]

Textual Amendments

- F1** 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).]

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