SCHEDULES

[F1SCHEDULE 3A

Section 14A

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**

[F2Traceability system]

Textual Amendments

F2 Sch. 3A para. 1 substituted (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), **4(5)** (with reg. 6(2)(3))

1 **[F2**Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).**]**

2 **[F3**Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.**]**

Textual Amendments

F3 Sch. 3A para. 2 omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), **4(6)** (with reg. 6(2)(3))

Serious adverse events and serious adverse reactions

3 Licence conditions shall require such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and

Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Third party agreements and termination of licensed activities

4 For the purpose of securing compliance with the requirements of Articles 21(5) (tissue and cell storage conditions) and 24 (relations between tissue establishments and third parties) of the first Directive, licence conditions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Requirements for procurement of gametes and embryos

5 Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Selection criteria and laboratory tests required for donors of reproductive cells

6 In relation to partner-donated sperm which is not intended to be used without processing or storage, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 2 (partner donation (not direct use)) of Annex III (selection criteria and laboratory tests required for donors of reproductive cells) to the second Directive.

7 In relation to donations of gametes or embryos other than partner-donated sperm or partner-created embryos, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 3 (donations other than by partners) of Annex III to the second Directive.

8 Licence conditions shall require that the laboratory tests required by sections 2 and 3 of Annex III to the second Directive to be carried out for the purpose of selecting gametes or embryos for donation, meet the requirements of section 4 (general requirements to be met for determining biological markers) of Annex III to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

9 In relation to—

(a) donation and procurement procedures, and

(b) the reception of gametes and embryos at the premises to which a licence relates or at relevant third party premises,

licence conditions shall require compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the second Directive
1. Donation and procurement procedures	
Consent and donor identification (record of consent, method of identification, donor interview)	Annex IV, point 1.1
Donor evaluation: other than partner-donated sperm and partner-created embryos and autologous donors (assessment of donor's medical and behavioural information)	Annex IV, point 1.2
Procurement procedures for gametes and embryos (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of the procured gametes and embryos (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. Reception of tissues and cells at the tissue establishment	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, points 2.1 to 2.3
Registration of data (other than in respect of partner-donated sperm and partner-created embryos)	Annex IV, point 2.4
Registration of data (partner-donated sperm and partner-created embryos)	Annex IV, point 2.5

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C

Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence for gametes and embryo preparation processes

11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Interpretation of this Schedule

12 In this Schedule, "partner-created embryos" means embryos created using the gametes of a man and a woman who declare that they have an intimate physical relationship.**]**

Status:
Point in time view as at 06/03/2018.

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