STATUTORY INSTRUMENTS

2024 No. 1091

RETAINED EU LAW REFORM

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Amendment) Regulations 2024

Made - - - -	*31st October 2024*
Coming into force - -	*28th November 2024*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 42A(4) and (5) and 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990(**a**) and section 8C(1)(c), (2) and (5) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**b**).

A draft of this instrument has been laid before and approved by a resolution of each House of Parliament, in accordance with section 45(4) and (4A)(**c**) of the Human Fertilisation and Embryology Act 1990 and paragraph 8F(1)(**d**) of Schedule 7 to the European Union (Withdrawal) Act 2018.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Amendment) Regulations 2024.

(2) These Regulations come into force on the 28th day after the day on which they are made.

(3) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendments to the Human Fertilisation and Embryology Act 1990

2.—(1) Schedule 3A(**e**) to the Human Fertilisation and Embryology Act 1990 is amended as follows.

(2) After paragraph A1 insert—

(**a**) 1990 c. 37; Section 42A was inserted by S.I. 2019/482; section 45(3A) was inserted by section 30 of the Human Fertilisation and Embryology Act 2008 (c. 22).

(**b**) 2018 c. 16; section 8C was inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 (c. 1) ("the 2020 Act"). There are further amendments to section 8C but none is relevant. Paragraph 21 of Schedule 7 was amended by paragraph 53(2) of Schedule 5 to the 2020 Act and paragraph 8(14) of Schedule 2 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28).

(**c**) Subsection (4A) was inserted by section 30(5) of the Human Fertilisation and Embryology Act 2008 (c. 22) and amended by S.I. 2019/482.

(**d**) Paragraph 8F was inserted by paragraphs 38 and 51 of Schedule 5 to the 2020 Act.

(**e**) Schedule 3A was inserted by S.I. 2007/1522. There are amendments to Schedule 3A but none is relevant.

"Modification of the definition of partner donation in the second Directive

B1. For the purpose of this Schedule, Article 1 of the second Directive is to be read as if for paragraph (b) there were substituted—

"(b) "partner donation" means the donation of reproductive cells between—

(i) a man and a woman; or

(ii) a woman and a woman,

who declare that they have an intimate physical relationship;".".

(3) In paragraph 6, after "which is not" insert ", or partner-donated eggs which are not,".

(4) In paragraph 7—

(a) for "In", substitute "Subject to paragraph 7A, in";

(b) after "partner-donated sperm" insert ", partner-donated eggs".

(5) After paragraph 7 insert—

"7A.—(1) In relation to a donation within paragraph 7 which meets the conditions in this paragraph, licence conditions must not include the requirement in section 3.2 of Annex III to the second Directive, that donors must be negative for HIV.

(2) The first condition is the donor has a plasma HIV RNA load of no more than 200 copies per millilitre on—

(a) a date no more than 6 months and no less than 21 days before the date of the donation; and

(b) a date no more than 7 days before the date of the donation.

(3) The second condition is the donor has been receiving antiretroviral treatment for a period of at least 6 months up to and including the date of the donation.

(4) The third condition is the donor and the recipient declare that they have a qualifying relationship.

(5) "Qualifying relationship" means a relationship between—

(a) friends;

(b) family; or

(c) persons who have been introduced to each other by a third party for the purpose of conceiving.

(6) The fourth condition is the recipient declares that they—

(a) reasonably believe, on the facts known to them at the time, that the donor has tested positive for HIV;

(b) understand the health risks involved in being treated with the donation; and

(c) consent to being treated with the donation in light of the matters referred to in paragraphs (a) and (b).".

(6) In paragraph 9, in the table, after "partner-donated sperm" (in each place it occurs) insert ", partner-donated eggs".

(7) For paragraph 12 substitute—

"12. In this Schedule—

"HIV" means human immunodeficiency virus, type 1 and type 2;

"partner-created embryos" means embryos created using the gametes of a man and a woman who declare that they have an intimate physical relationship;

"partner-donated eggs" means eggs donated between a woman and a woman who declare that they have an intimate physical relationship;

"RNA" means ribonucleic acid.".

Merron
Parliamentary Under Secretary of State
Department of Health and Social Care

31st October 2024

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend Schedule 3A to the Human Fertilisation and Embryology Act 1990 (c. 37) ("the 1990 Act"). Schedule 3A relates to the technical requirements for the donation, procurement and testing of human tissues and cells.

The amendments—

(a) enable female same sex couples donating eggs to one another to undergo less stringent selection and testing criteria set out in paragraph 6 of Schedule 3A to the 1990 Act, as opposed to more stringent screening under paragraph 7 of Schedule 3A to the 1990 Act; and

(b) enable people diagnosed with HIV to donate gametes and embryos to family, friends or persons who have been introduced to the donor by a third party for the purpose of conceiving, where donors can demonstrate that they have a sustained undetectable HIV viral load of no more than 200 copies per millilitre and have been undergoing antiretroviral therapy for at least 6 months prior to the date of donation.

Regulation 2 amends Schedule 3A to the 1990 Act to—

(a) modify the definition of partner donation in the Directive;

(b) require conditions of licences issued under the Act ("licence conditions") to require partner-donated eggs to comply with the selection criteria for donors and the requirements for laboratory tests in section 2 of Annex III to Commission Directive 2006/17/EC of 8 February 2006 ("the Directive");

(c) except partner-donated eggs from being required by licence conditions to comply with the selection criteria for donors and the requirements for laboratory tests in section 3 of Annex III to the Directive;

(d) prohibit licence conditions, in Section 3.2 of Annex III to the Directive requiring donors to be HIV negative, if the donation is within paragraph 7 and meets the conditions in sub-paragraphs 7A(2), (3), (4) and (6). The donor must demonstrate that they have a sustained undetectable HIV viral load of no more than 200 copies per millilitre (regulation 7A(2)) and be receiving antiretroviral therapy for at least 6 months up to and including the date of donation (regulation 7A(3)). The donation must be to family, friends, or to persons who have been introduced to the donor by a third party for the purpose of conceiving (regulation 7A(4)). The recipient of the donation must be aware of the HIV diagnosis, understand the health risks of being treated with the donation and consent to the donation (regulation 7A(6)).

Regulation 2(6) amends Schedule 3A to similarly except partner-donated eggs from requirements under the Directive in relation to donation and procurement procedures and reception of tissue and cells at the tissue establishment.

Regulation 2(7) inserts the following new definitions; "HIV", "partner-donated eggs" and "RNA".

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

© Crown Copyright 2024

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Saul Nassé,

Controller of His Majesty's Stationery Office and King's Printer of Acts of Parliament.

ISBN 978-0-34-826512-5

£5.78

http://www.legislation.gov.uk/id/uksi/2024/1091

9 780348 265125