STATUTORY INSTRUMENTS

2015 No. 572

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015

Made - - - -	*4th March 2015*
Coming into force - -	*29th October 2015*

These Regulations are made by the Secretary of State in exercise of the powers conferred by sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(1) and (3A) of the Human Fertilisation and Embryology Act 1990(**1**).

A draft of this instrument has been approved by resolution of each House of Parliament pursuant to section 45(4) of that Act.

PART 1

Introductory Provisions

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015 and shall come into force on 29th October 2015.

Interpretation

2.—(1) In these Regulations "the Act" means the Human Fertilisation and Embryology Act 1990.

(2) In these Regulations "polar body nuclear DNA" means any nuclear DNA located in a polar body.

(3) In these Regulations a reference to the removal of any nuclear DNA (including polar body nuclear DNA) includes a reference to the removal of any material which is necessarily removed along with that DNA, and such material may include any associated organelles.

(4) For the purposes of these Regulations, the following are to be treated as removed from an egg—

(**1**) 1990 c. 37. Sections 3ZA(5) and (6), 31ZA(2)(a), 35A and 45(3A) were inserted by sections 3(5), 24, 26 and 30 of the Human Fertilisation and Embryology Act 2008 (c. 22) ("the 2008 Act"). Section 3ZA(6) is cited for the meaning of "prescribed".

(a) any polar body nuclear DNA which is destroyed while still located in the egg; and

(b) any material which is necessarily destroyed along with that DNA, and such material may include any associated organelles.

(5) In these Regulations a reference to the insertion of nuclear DNA includes a reference to the insertion of any material which is necessarily inserted along with that DNA, and such material may include any associated organelles.

PART 2

Permitted eggs and permitted embryos

Permitted egg

3. An egg ("egg P") is a permitted egg for the purposes of section 3(2)(b)(**2**) of the Act if—

(a) egg P results from the application of the process specified in regulation 4 to two eggs, each of which—

(i) is a permitted egg as defined in section 3ZA(2)(**3**) of the Act (not an egg which is a permitted egg by virtue of these regulations), and

(ii) was extracted from the ovaries of a different woman;

(b) that process has been applied to those eggs in the circumstances specified in regulation 5; and

(c) there have been no alterations in the nuclear or mitochondrial DNA of egg P since egg P was created by means of the application of that process.

Permitted egg: process

4.—(1) The process referred to in regulation 3(a) consists of the following two steps.

(2) In step 1—

(a) either—

(i) all the nuclear DNA of an egg ("egg A") is removed, or

(ii) all the nuclear DNA of egg A other than polar body nuclear DNA is removed; and

(b) either—

(i) all the nuclear DNA of another egg ("egg B") is removed, or

(ii) all the nuclear DNA of egg B other than polar body nuclear DNA is removed.

(3) In step 2 all the nuclear DNA of egg B which is not polar body nuclear DNA is inserted into egg A.

Permitted egg: circumstances

5. The circumstances referred to in regulation 3(b) are that—

(a) the Authority has issued a determination that—

(i) there is a particular risk that any egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and

(**2**) Section 3(2) was substituted by section 3(2) of the 2008 Act.
(**3**) Section 3ZA was inserted by section 3(5) of the 2008 Act.

(ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and

(b) egg B was extracted from the ovaries of the woman so named.

Permitted embryo

6. An embryo ("embryo P") is a permitted embryo for the purposes of section 3(2)(a) of the Act if—

(a) embryo P results from the application of the process specified in regulation 7 to two embryos, each of which—

(i) is a permitted embryo as defined in section 3ZA(4) of the Act (not an embryo which is a permitted embryo by virtue of these regulations), and

(ii) was created by the fertilisation of a permitted egg as defined in section 3ZA(2) of the Act (not an egg which was a permitted egg by virtue of these regulations) extracted from the ovaries of a different woman;

(b) that process has been applied to those embryos in the circumstances specified in regulation 8; and

(c) since embryo P was created by means of the application of that process—

(i) there have been no alterations in the nuclear or mitochondrial DNA of any cell of embryo P, and

(ii) no cell has been added to embryo P other than by the division of embryo P's own cells.

Permitted embryo: process

7.—(1) The process referred to in regulation 6(a) consists of the following two steps.

(2) In step 1—

(a) either—

(i) all the nuclear DNA of an embryo ("embryo A") is removed, or

(ii) all the nuclear DNA of embryo A other than polar body nuclear DNA is removed; and

(b) either—

(i) all the nuclear DNA of another embryo ("embryo B") is removed, or

(ii) all the nuclear DNA of embryo B other than polar body nuclear DNA is removed.

(3) In step 2 all the nuclear DNA of embryo B which is not polar body nuclear DNA is inserted into embryo A.

Permitted embryo: circumstances

8. The circumstances referred to in regulation 6(b) are that—

(a) the Authority has issued a determination that—

(i) there is a particular risk that any embryo which is created by the fertilisation of an egg extracted from the ovaries of a woman named in the determination may have mitochondrial abnormalities caused by mitochondrial DNA; and

(ii) there is a significant risk that a person with those abnormalities will have or develop serious mitochondrial disease; and

(b) embryo B was created by the fertilisation of an egg extracted from the ovaries of the woman so named.

Supplemental provision – licences

9.—(1) Any reference to a permitted egg in a licence whenever issued does not include an egg which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3 unless express provision is made in the licence to that effect.

(2) Any reference to a permitted embryo in a licence whenever issued does not include an embryo which is a permitted embryo for the purposes of section 3(2) of the Act by virtue of regulation 6 unless express provision is made in the licence to that effect.

PART 3

Related modifications and amendments

Modification of certain enactments for cases where mitochondrial donation has occurred

10. Regulations 11 to 18 (which make modifications to the Act and the Human Fertilisation and Embryology Act 2008) have effect in relation to cases where—

(a) an egg has been created which is a permitted egg for the purposes of section 3(2) of the Act by virtue of regulation 3, or

(b) an embryo has been created which is a permitted embryo for those purposes by virtue of regulation 6.

Modification of section 31ZA of the Act

11. In a case where this regulation has effect, section 31ZA of the Act(**4**) applies as if—

(a) for the heading there were substituted "Request for information as to genetic parentage or mitochondrial donors etc";

(b) in subsection (1) at the end there were inserted "or (2A)";

(c) after subsection (2) there were inserted—

"(2A) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person is the applicant's mitochondrial donor, and if it does show that, giving the applicant the following information contained in the register—

(a) the screening tests carried out on the mitochondrial donor and information on that donor's personal and family medical history,

(b) matters contained in any description of the mitochondrial donor as a person which that donor has provided, and

(c) any additional matter which the mitochondrial donor has provided with the intention that it be made available to a person who requests information under this section,

but not giving any information which may identify the mitochondrial donor or any person who was or may have been born in consequence of treatment services using genetic material from the applicant's mitochondrial donor, by itself or in combination

(**4**) Section 31ZA was inserted by section 24 of the 2008 Act.