
DRAFT STATUTORY INSTRUMENTS

2015 No.

**The Human Fertilisation and Embryology
(Mitochondrial Donation) Regulations 2015**

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)(1) 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)(2) 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—

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

- (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
 - (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.