

# HUMAN FERTILISATION AND EMBRYOLOGY ACT 2008

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## EXPLANATORY NOTES

### COMMENTARY ON SECTIONS

#### **Part 1: Amendments of Human Fertilisation and Embryology Act 1990**

#### ***Section 4: Prohibitions in connection with genetic material not of human origin***

31. This section inserts new section 4A into the 1990 Act to provide that certain types of embryo, which contain both human and animal DNA, are subject to regulation under the 1990 Act. These are defined as “human admixed embryos” and include:
- Cytoplasmic hybrids (Cybrids): embryos created by techniques used in cloning, using human gametes or cells and animal eggs. The embryos would be mostly human except for the presence of animal mitochondria (see the notes on section 3 for more information on mitochondria) (section 4A(6)(a));
  - Human-animal hybrid embryos: any other embryo created using a human egg and the sperm of an animal, or an animal egg and a human sperm or by combining a pro-nucleus of an animal with a human pro-nucleus (section 4A(6)(b));
  - Human transgenic embryos: embryos created by the introduction of animal DNA into one or more cells of the embryo (section 4A(6)(c));
  - Human-animal chimeras: human embryos, altered by the addition of one or more cells from an animal (section 4A(6)(d))
  - Any embryo which does not fall within any of the categories already mentioned and which contains both human nuclear or mitochondrial DNA and nuclear or mitochondrial DNA of an animal, but where the animal DNA is not predominant (section 4A(6)(e)).
32. Section 4A(2) prohibits mixing human gametes with the gametes of an animal and creating, keeping or using a human admixed embryo without a licence.
33. Section 4A(3) provides that any human admixed embryo created under licence cannot be kept after the earliest of either:
- the appearance of the primitive streak (an indicator for the start of a process by which the cells of the embryo begin to separate into three distinct cells types which will go on to form different types of tissue); or
  - 14 days from the day on which the process of creating the human admixed embryo began.

This is consistent with the time limits for keeping human embryos *in vitro* for research purposes.

*These notes refer to the Human Fertilisation and Embryology Act  
2008 (c.22) which received Royal Assent on 13 November 2008*

34. New section 4A(5) contains a regulation-making power that enables the circumstances in which a human admixed embryo can be kept or used to be restricted. This power could be used, for example, if it became necessary to shorten the 14-day time limit, for which human admixed embryos may be kept in some circumstances. This mirrors an existing power in relation to human embryos in section 3(3)(c) of the 1990 Act. This regulation-making power is subject to the affirmative procedures.
35. Further provisions about the licensing of activities involving human admixed embryos are made in sections 11, 12, 13, and 15, paragraphs 5 and 6 of Schedule 2 and paragraph 13 of Schedule 3.
36. New section 4A(11)(a) provides a regulation-making power to amend (but not repeal) the definitions of a human admixed embryo under paragraphs (a) to (e) of subsection (6). Section 4A(11)(b) provides a regulation-making power to amend the definition of the terms “embryo”, “eggs” or “gametes” for the purpose of section 4A. Both these powers can only be exercised if it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine. Both powers are subject to the affirmative resolution procedure.