

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

**SCIENTIFIC & CLINICAL ADVISORY GROUP
AND ETHICS AND LAW COMMITTEE**

DEFINITION/REGULATION OF AN EMBRYO

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| Committee | SCAG/ELC |
| Meeting Date | 15 December 2004 |
| Agenda Item | 10 |
| Paper Number | SCAG/ELC (12/04)02 |
| Paper Title | Definition/Regulation of an Embryo |
| Author | Katy Berry (Policy Officer) |
| For Information, discussion or decision? | Discussion & decision |
| Resource Implications | None |
| Recommendation to the Committee | To agree on the advice to give top DH on regulation of embryos. |

Background

1. In advising DH on issues to be addressed through the forthcoming review of the 1990 Act, the Authority has raised the need to take a fresh look at the definition of an embryo. The aim is to ensure that embryos created through a variety of means, other than by fertilisation, can be subject to regulation under the Act.

2. Discussions in SCAG and ELC so far have focussed on attempts to draft a scientific definition that meets our objective, and we have probably taken that discussion as far we can. Rather than arriving at a single definition of an embryo, the best way of assisting DH would be for the Authority to set out clearly what, in its view, revised legislation should seek to achieve and to provide examples of the types of embryo we would want to see covered. The precise definition can then be considered by the Parliamentary draftsman.

3. This paper brings together the key themes from earlier discussions and seeks agreement on advice to the Department. This will be incorporated into a

wider paper on Review of the Act issues for consideration by the Authority in February.

Current legislation

4. At present there are two pieces of primary legislation that regulate the use of embryos *in vitro*.

- 1) The Human Fertilisation and Embryo Act 1990
- 2) The Human Reproductive Cloning Act 2001

The Human Fertilisation and Embryo Act 1990 states that:

*1.—(1) In this Act, except where otherwise stated—
(a) embryo means a live human embryo where fertilisation is complete, and
(b) references to an embryo include an egg in the process of fertilisation,
and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.*

The Human Reproductive Cloning Act states that:

(1) A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.

5. The Human Reproductive Cloning Act, therefore, covers embryos created other than by fertilisation. The wording of this Act suggests that 'embryos' that were not created by fertilisation are still considered embryos. This provision thereby introduces a broad scope of types of organism that are considered as embryos for the purpose of the legislation.

6. Any embryo that was created other than by fertilisation and is placed in a woman is therefore covered by primary legislation, and doing this would constitute a criminal offence. An embryo created by ways other than fertilisation that is not placed in a woman may still be considered an embryo by the HFE Act 1990. This was clarified by a decision made by the House of Lords with respect to embryos created through CNR. In short, the Lords decided that 'embryo', in the meaning of the 1990 Act, is everything scientists hold to be an embryo.

The case of Regina v. Secretary of State for Health (March 2003) was dismissed by the House of Lords. The issues in this appeal were whether live human embryos created by cell nuclear replacement (CNR) fall outside the scope of the HFE Act 1990 and whether licensing the creation of such embryos is prohibited by 3(3) d of the Act. The High Court ruled that creation of embryos in this way fell outside the remit of the Act and was not prohibited by section 3(3) d¹. The case was then taken to the Court of Appeal which agreed with the judge on the second point but reversed the ruling on the fact that the creation of embryos in this way fell outside of the scope of the Act. Both points were re-argued before the House of Lords.

The decision made by the House of Lords clarified that it was the intention of the 1990 Act to cover all human embryos created *in vitro* irrespective of how the embryos were produced. At the time the legislation was drafted it was not known that it would be possible to create embryos in this way so there was no provision made for it in the definition.

Recommendations to the Department of Health about regulating embryos

7. Any new drafting should ensure that the current legislative approach is maintained. There is already primary legislation that ensures that embryos created by techniques other than fertilisation are not placed into a woman; the Review of the Act would need to ensure that creation of or research on all types of embryo is regulated by the HFEA.
8. The legislative approach used should not be overly restrictive because it is important that embryo research is carried out. However, because of the public concern surrounding this type of research it is necessary that the HFEA is regulating the work in this field. The legislation should therefore allow useful and ethically responsible research to be carried out in embryos under HFEA licence.
9. Any legislation should be wide enough to ensure that embryos created by ways other than by fertilisation are covered by the Act without being so broad that it brings under the remit of the Act things that should not be covered by the Act, for example it would be recommended that embryos created by cell nuclear replacement are covered but gametes should not be.

Issues that have been identified in the discussions so far

10. Making reference to the **potentiality** of an embryo in a definition can raise difficulties for example, by saying something equivalent to 'an entity that has the potential to become a human being'. This causes difficulties because this could

only be known by allowing the embryo to develop *in vitro* beyond the 14 day stage or to even implant it into a woman to observe whether it can develop to term (which would breach the Human Reproductive Cloning Act).

11. Making reference to the **activities** which led to the embryos creation can be too limiting, since there might be new, unforeseen ways of creating embryos which would then be excluded by legislation.

12. Making reference to the **human genome** in order to define human embryos is problematic when one considers chimeras and whether the HFEA should not be involved in their creation. Also, many non-human organisms (including plants) share much 'human' DNA, so a definition that is based on the presence of some or any number of human genes might unintentionally include organisms clearly outside of the HFEA's remit.

13. There are difficult issues raised when **parthenote** embryos are considered. Mouse embryos created by parthenogenesis have been shown to develop to adulthood. It is also possible to create human parthenote embryos by the process of parthenogenesis both intentionally and spontaneously. Because parthenote embryos might be used in further research it is desirable that these embryos are covered by legislation. The problem that this raises is that currently a licence is not required to carry out research on oocytes. If the definition was drafted such that parthenotes were covered, it would mean that a licence might be needed to carry out research on oocytes, in case an oocyte spontaneously becomes an embryo.

Types of embryos that may need to be covered

14. It is essential to ensure that all types of embryos, including those that are created by ways other than by fertilisation, are covered by the Act. The Act will need to cover any embryo created *in vitro* by fertilisation or by any other means, regardless of whether it will be placed back into a woman.

15. A list of currently predicted or available techniques that can be used to create embryos is below. Obviously, no comprehensive list of types of embryos that may need to be regulated could be produced because of the pace at which scientific developments occur in this field.

- Cell nuclear replacement.
- Ooplasmic transfer (egg cytoplasm transfer)
- Interspecies cell nuclear replacement
- Parthenogenesis
- Fertilised egg nuclear replacement
- Human-human chimera

- Adult stem cell dedifferentiation
- Embryonic stem cell differentiation
- Embryos created using artificial gametes

Decision

16. Members are invited to

- Discuss and agree the approach suggested in this paper and
- Agree advice to the DH on what issues need to be addressed through a section in any Bill that defines the remit of the HFEA in regulating the use of 'embryos'