Dear Kate

**Draft Human Tissue and Embryos Bill: provisions on inter-species embryos**

Thank you for letter of 24 May asking for an indication of the amendments the Government would propose to make to the draft Bill to bring it in line with the Government’s policy position on inter-species embryos as stated in the introduction to the Bill command paper.

I should first stress that we see it as highly important to have clarity as to what is meant by ‘hybrids’ and ‘chimeras’ in the context of the remit of the draft Bill. This is necessary, amongst other things, to ensure that entities that come within the Home Office’s licensing remit, for example the ‘Down’s mouse’, are not inadvertently caught by human embryology legislation and that it captures only those appropriate to a regulator of human embryos.

We therefore describe at clause 17 of the draft Bill which types of inter-species embryos (hybrids and chimeras) we believe should come within the remit of the Bill. The clause will introduce a new section 4A to the Human Fertilisation and Embryology Act:

- **section 4A(5)(a)** – an embryo created by using human gametes and the gametes of an animal (ie ‘true hybrids’)
- **section 4A(5)(b)** - an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell (ie ‘cybrids’)
- **section 4A(5)(c)** - a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal (ie ‘human-animal transgenic embryos’)
- **section 4A(5)(d)** - a human embryo that has been altered by the introduction of one of more animal cells (ie ‘human-animal chimeras’)

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section 4A(5)(e) – any other embryo that contains both –
(i) any haploid set of human chromosomes, and
(ii) any haploid set of animal chromosomes or any other sequence of
nuclear or mitochondrial DNA of an animal

(i.e any other embryo that is at least ‘half’ human).

As indicated in the introduction to the draft Bill command paper, the Government has taken account of the report and recommendations of the Commons Science and Technology Committee and has accepted the principle that legislation should provide for certain inter-species embryos to be created for research purposes. The approach we propose is for the Bill to provide that the creation and use of the types of inter-species embryos listed at the proposed new section 4A(5)(b) to (d) may be authorised by research licence, without the need for secondary legislation (regulations) to this effect.

The re-drafting of the clauses will have to include addressing associated provisions such as consent to the use of the embryos and their storage, licence conditions and directions.

I should also point out that section 4(A)(5)(e) is intended to provide the flexibility for the Bill to cover new types of inter-species embryos that emerge without the need for primary legislation to amend the definition. Our proposed approach is that neither embryos under section 4(A)(5)(e) nor ‘true’ hybrids under section 4(A)(5)(a) would be allowed unless affirmative regulations under the proposed new paragraph 3(3) of Schedule 2 to the 1990 Act (introduced by paragraph 6 of Schedule 2 to the draft Bill) provided for their creation to be authorised by research licence in the light of evidence of the need for it.

An exception to this is the mixing of human sperm with a hamster’s egg for the purpose of testing the fertility or normality of the sperm up to the two-cell stage. This is allowed under the Human Fertilisation and Embryology Act and is the position the draft Bill maintains.

As the committee will be aware, an alternative approach to allowing on the face of the Bill the creation and use of inter-species embryos to be authorised by research licence would be for regulations under the new paragraph 3(3) of Schedule 2 to provide for it.

We are asking Departmental lawyers and Parliamentary counsel to produce revised draft clauses for the approach we have in mind, which we will provide to the committee as soon as they are available.

As indicated in the draft Bill command paper, we very much welcome the committee’s views. For example, whether the description of inter-species embryos at clause 17 captures the right type of entities appropriately; whether the proposed balance between allowing their creation on the face of the Bill or through regulations is right; and whether the Bill contains sufficient flexibility and future-proofing powers. We would appreciate any suggestions for any alternative approaches they may wish to recommend.