Is devolved regulation a two stage rocket to public acceptance of the use of embryos in research? The issue of the human-animal hybrid embryo in the UK.

Nicolle Zeegers, 8 juni, 2011

1. Introduction

The meaning of human dignity as a human right is dual, not to say totally ambiguous.[1] Because of this duality, national law makers refer to this principle in legitimating the legislation concerning human embryo research and at the same time bend the principle in whatever shape is suitable in the circumstances of their specific culture or economic policy. While acknowledging this, advocates of clear principles in the field of this research, such as Van Beers (2009) tend to regard the hierarchical model of lawmaking as possible rescuer of human dignity as a restrictive principle, a principle to be used in its meaning of humanity as a collectively shared value in the name of which the use of human embryos in research should be bound to clear limits. The French *Lois de Bioethique* (2004) in this respect is set as an example to countries such as the United Kingdom and the Netherlands.

Whereas political scientists such as Moe (1994) and Kanzancigil (1998) attribute the vanishing of politics from policy making to governance as mode of public decision making, Van Beers lays the blame more specifically at the devolved form of regulation that was chosen for the decision making concerning research with human embryos in the latter countries. In this paper I will introduce a case study concerning the UK policy making regarding human embryo research that seems to substantiate her claim.

However, countries' choices of regulatory design - hierarchical rules or more horizontal arrangements of co-regulation – are, different from what Van Beers seems to believe, only of secondary importance. As the current process of amending the *Lois de Bioethique* shows, also the French legislator – in its role of hierarchical ruler - is about to widen the possibilities for the use of human embryos for research. Of primary importance is the existence of an international policy-network with a common interest in stem cell

[1] Human dignity at least has two meanings, firstly, the humanity of human beings as a collectively shared idea of humanity, and secondly, the individual self-determination of the human being.

and other research in which human embryos are created or used.[2] In this policy-network, scientists, ethicists and lawyers experienced in this field of research work together with members of parliament and maybe pharmaceutical industrialists in a concerted effort directed at the increase of possibilities for biomedical experiments with the early human embryo.

2. The issue of the human-animal hybrid embryo in the UK

The UK is one of the few countries in which the creation of human embryos for research is allowed.3 UK government's goal is to stay at the forefront of biomedical technological innovation. Legislation that provides scientists room for experimentation with human embryos is conditional for attaining this goal. However, such experimentation tends to provoke public and political debate that, although in some countries small in scale, is fierce and passionate because of the moral grounds it stems from. The history of litigation concerning the *1990 Human Fertilization and Embryology Act* (1990 HFE Act*)* provides examples of such fierce and passionate debate, one of which will be addressed below. However, the focus of this paper is not litigation but the process of legislation, more precisely stated: the analysis concerns the process leading to the new 2008 HFE Act and is specifically focused at the debate whether the creation of human animal hybrid embryos should be made possible. This debate has been fought out in two arena's, firstly, the arena of the HFE Authority and, secondly, the legislative arena. The existence of the first arena, the fact that in addition to the legislative arena another arena for deliberating the formulation of rules has been created, according to Levitt each time anew paves the way, for new techniques for Assisted Reproduction, in the sense of making them legally possible. The analysis in this paper will confirm that the devolved form of regulation in the case of human animal hybrid embryos has functioned as a device for securing public acceptance.

[2] A policy network is a set of resource-dependent organizations in which each of the groups that make up the policy network needs something (resources NZ) that the others have in order to fulfill its own objectives. These resources are exchanged in a process of bargaining (Rhodes, 1988).

[3] In countries as China, Japan and South Korea the creation of embryos by "somatic cell nuclear transfer" is allowed and the creation of human-animal embryos not specifically prohibited.

The HFE Authority

The 1990 HFE Act and the HFE Authority are central to the regulatory framework concerning the artificial creation of embryos. With the HFE Act, the case-to-case decision making concerning the creation of human embryos has been delegated to the HFE Authority. This HFE Authority is responsible for licensing the use of embryos in research within the boundaries of the Act, which in the UK case includes the creation of embryos for scientific purposes. The 1990 HFE Act contains provisions stating, firstly, that the Secretary of State has to appoint the members of the Authority and , secondly, that the composition is bound to rules concerning the disciplinary background of the members. 4 These rules make clear that, although the point of establishing the HFE Authority was to include medical-scientific experts on a continuous base in the governmental decision making concerning the use of embryos in research, at the same time the government wanted to build in some guarantees to assure the independence of the Authority from the medical-scientific view. After all, the decisions of this Authority are legally binding.

In order to get the approval of the HFE Authority, researchers who wish to use embryos in their research must submit a research protocol that makes clear that the research is "necessary or desirable" for one or more of the purposes of the HFE Act.5 In addition to being convinced on the latter point the Authority cannot issue a license unless it is satisfied that the creation and/or use of embryos is necessary for the research.6

However, the boundaries of the HFE Act are sometimes contested, not only in the public debate but also legally. While the Act settled some issues concerning the moral

[4] The 1990 HFE Act ontains the following provisions concerning the composition of the Authority: The Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research. Persons belonging to these categories are disqualified from being appointed as chairman or deputy chairman in order to ensure that the overall direction of the authority is independent of the medical-scientific view. See Lee and Morgan, *Human Fertilisation and Embryology. Regulating the Reproductive Revolution*, (London, Blackstone Press Limited, 2001), 102-03.

[5] Desirable is assessed in terms of the contribution to scientific knowledge or human health that can be expected from the research. Necessary means that creating such embryos (instead of using other sources of stem cells) is necessary for the research.

[6] Some of the rules in this Act are straightforward prohibitions, for example the prohibition on the development of an embryo in vitro beyond 14 days. Human Fertilisation and Embryology Act 1990, schedule 2, para. 3 (2) and (6); R Lee and D Morgan, *Human Fertilisation and Embryology. Regulating the Reproductive Revolution*, (London, Blackstone Press Limited, 2001), 120.

boundaries of the use of human embryos in research, other questions about the moral status of the early human embryo were left unanswered. In addition, from each new scientific development new moral dilemmas may arise that were not accounted for in the legal definitions that were chosen for in the original act. The creation of human-animal hybrid embryos became an issue, for example, at the moment that scientists announced that such creation to their knowledge was about to become technically feasible and they believed this creation would offer new possibilities for the cure of diseases.7

Because of the continuous development of technical possibilities a recurrent question the HFE Authority has to deal with is whether the form of embryo that would result from the procedure described in the research protocol submitted by scientists, would fit into the legal category of a human embryo in the HFE Act. Only if this is the case, the research would fall under the remit of the Authority. Because of this, the HFE Authority, in addition to deciding whether or not to license a specific research, in some cases also has to take a decision about the interpretation of parts of the Act. The latter kind of decision making bears resemblance to the work of courts and in this respect the issue of the creation of the human-animal hybrid embryo had its precedent in the Quintavalle case in 2003.

In the Quintavalle case (2003) the question was whether the embryo created by *Cell Nuclear Replacement* was covered by the 1990 *HFE* Act. The HFE Authority had licensed research in which embryos would be created by *Cell Nuclear Replacement*. However, the definition of the human embryo in the 1990 *HFE* Act contained an element with the characterization "where fertilization is complete". 8 The court case revolved around the question whether this definition would exclude the human embryo that results from Cell Nuclear Replacement from falling under the 1990 HFE Act.9 The appellant, representing the pressure group *Pro Life Alliance*, claimed it did because the 1990 HFE

[7] With the Human Reproductive Cloning Act 2001, the placement of a human embryo other than by fertilization in the womb of a woman became an offence.
[8] *R (Quintavalle) v the Secretary of State of Health* [2003] UKHL 13.
[9] Cell nuclear replacement (CNR) is a technique in which researchers take a cell (such as a skin cell) from an adult and extract the genetic information (the nucleus) from the cell. They then transfer that genetic information into an egg from which the genetic information has been removed, activating the egg so that it starts to divide.

Act only referred to embryos that were created by a completed process of fertilization.[10] This challenge was successful in the High Court but was overturned by the Court of Appeal, whose judgment was approved by the House of Lords taking a purposive approach to the interpretation of Law.[11] With their successful challenge in the High Court the Pro Life Alliance paradoxically created a situation in which human cloning was temporarily not regulated.[12] As the Government subsequently rushed through legislation in order to repair this caveat, this situation only lasted for a short time.[13]

The question whether the creation of human-animal hybrid embryos should be allowed must be seen as the next "legal boundary conflict" that occurred with respect to the 1990 HFE Act. This time the debate revolved around the categories of "having a full human genome" and "being alive". The definitions of these categories appeared to be contested even among scientific experts.

3. The arena of decision making by the HFE Authority

In the arena of the HFE Authority the debate concerning the issue of the creation of human-animal hybrid embryos started to develop from the moment two committees of the HFE Authority were asked by the Government's Department of Health whether this form of embryo according to them was covered by the HFE Act (1990) and therefore would fall under the remit of the HFE Authority.[14] These committees were the Scientific and Clinical Advances Group (SCAG) and the Ethics and Law Committee (ELC).[15] The department asked this question as part of the review of the 1990 HFE Act that was announced on 21 January 2005. The committees were asked to focus at the role

[10] The appellant pointed out that in s. 1 of the Act an embryo regulated by the Act is defined as "a live human embryo where fertilization is complete" and that CNR does not involve a process of fertilization.
[11] The House of Lords rejected the argument of the appellant: "The crucial point … is that this was an Act passed for the protection of live human embryos created outside the human body. The essential thrust of section 1(1) (a) was directed to such embryos, not to the manner of their creation, which Parliament (entirely understandable on the then current state of scientific knowledge) took for granted".
[12] According to commentators the reason why the Pro Life alliance did this was to unmask government as cheating the public in order to have the UK stay at the fore front of stem cell research. For this information I thank Joost Baarssen who as a student analyzed the debate about this Quintavalle Case.
[13] Human Reproductive Cloning Act, 4 December, 2001.
[14] The proposal to use animal eggs instead of human eggs originates from the shortage of human eggs that is the result from the fact that eggs donating is a physically demanding process for women that even can be harmful. The embryo that would result from this combination of human cells and animal eggs later in the debate was called "cytoplasmic hybrid embryo".
[15] The Scientific and Clinical Advances Group is a group of scientific experts that advises the Authority on questions concerning new scientific and clinical developments.

that mitochondrial DNA plays in the development of the embryos and whether embryos containing human DNA and both human and animal mitochondrial DNA would be human.16 In spring 2006 the SCAG and the ELC agreed that the hybrids should be regarded as an "embryo" for the purposes of the 1990 Act and that the creation, keeping or use of such an embryo in principle could be regarded as necessary or desirable. From this the ELC concluded that the license committee of the HFE Authority "would have the discretion to authorize these activities in the case of application".

However, in November 2006 the government proposed to issue a ban on the creation of the human-animal hybrids. At this point in time the HFE Authority actually had received two applications from scientific teams to carry out research using human cells and animal eggs to produce stem cells.17 Journalists reported about the planned research of these applicants, which would include fusing human cells with rabbit cells, using alarming headlines about "Frankenbunnies". In addition, a public consultation was held that met with the expression of public unease. This was reason for the government to make the statement in its White Paper that the creation of hybrid and chimera embryos should not be allowed".18 Apparently, the combination of human and animal material in the creation of an embryo was considered a bridge too far.[19]

The government proposal to put a ban on the creation of hybrid embryos made the Authority less sure that an authorization of this research would survive legal scrutiny. Therefore it asked for legal advice about the question whether this research was covered by the legal meaning of embryos under the 1990 HFE Act. In addition, the Horizontal Scanning Expert Panel (HHSEP) was asked a number of questions to inform the lawyer's

[16] The creation of "human-animal hybrids" until the two cell stage had already been practiced in the "hamster test", a well established and explicitly endorsed test in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm.

[17] The scientists responsible for the applications wanted to produce stem cells using human cells and animal eggs. Because the mitochondria from the donor egg are still present, the resulting embryo would contain nuclear DNA from the human cell and mitochondrial DNA from the animal egg. This means that the resulting embryo would contain a small amount of animal DNA from the mitochondria present in the animal egg (according to the applicants less than 1%). The applicators for a license were Dr. Lyle Armstrong, Institute of Human Genetics, University of New Castle and Dr. Stephen Minger, Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Diseases, Kings College London.

[18] UK Government, Review of the Human Fertilization and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos, White Paper, Cm 6989, 2006.

[19] The Government in the same white paper proposed to include in the amended Act power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos in vitro may in future be allowed under license for research purposes only.

opinion.[20] The respondents from this panel agreed that the hybrid embryo would contain a complete human genome. However, no consensus could be found on whether a hybrid embryo would be capable of implantation and therefore the question whether this embryo could be categorized as alive was not decided on by this panel.

Subsequently, this indecisiveness was incorporated as follows in the legal advice to the HFE Authority: "if (…) it cannot be shown definitively that the embryo does not have the normal potential to develop, it is most likely that the court would find that this constitutes a live human embryo for the purposes of the Act". The reasoning in this advice was that the courts are likely to see the embryo in a way that ensures that this type of research falls under the scope of regulation rather than not. Here the legal adviser is referring to the purposive approach to statutory interpretation used by the House of Lords in the Quintavalle case in 2003 in order to interpret the 1990 Act.

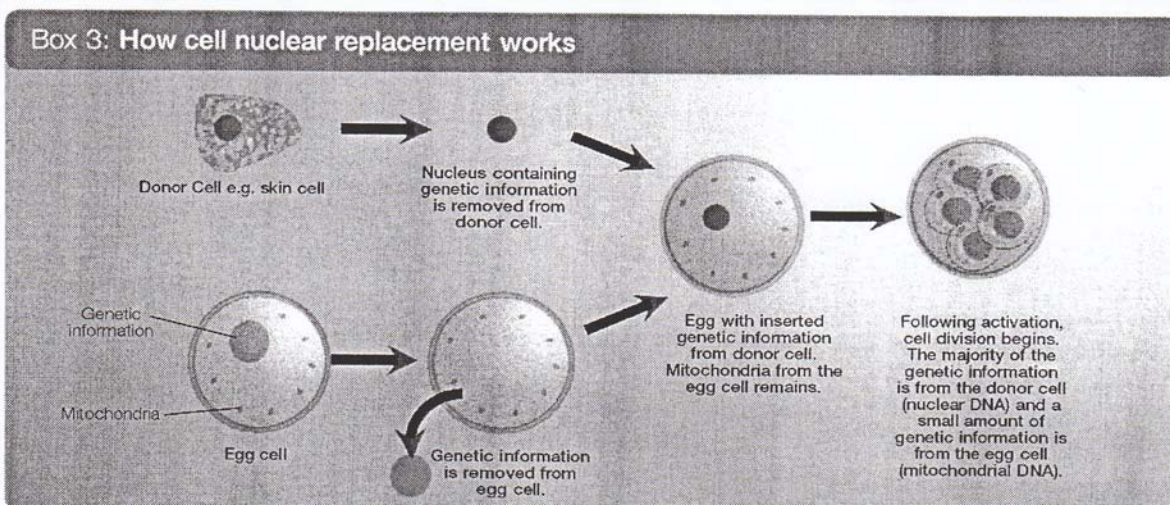
On 11 January 2007, the Authority did rule that, under current regulation, the research would fall under their remit, but at the same time postponed the actual decision about the applications. The Authority thought it to be wise to first have a full and proper public debate and consultation about the question whether, in principle, licenses for these sorts of research could be granted.21

4. The public consultation held by the Authority

The public consultation ran from 26 April to 20 July 2007 and consisted of, firstly, a consultation of the public in general, meant to gain insights into their views on the subject of human animal hybrid research and, secondly, a scientific consultation, intended to describe the scientific context of this research. Crucial for the first part was the consultation document in which the public was informed on what human animal hybrid research is about. [22] Two types of human-animal hybrid embryos that were distinguished in this document regarded the creation of human embryos out of animal eggs: the "true

[20] The Horizontal Scanning Expert Panel is a worldwide panel of experts that includes experts in stem cell technology from universities in the UK, Australia and Japan, specialists in assisted reproductive technologies from the US and Belgium and leading academics in cloning techniques, developmental genetics and cryopreservation.
[21] See www.hfea.gov.uk (last accessed on 6 May 2009).
[22] HFE Authority, Hybrids and Chimeras, April 2007.

hybrid" and the "cytoplasmic hybrid".23 These two types were presented as if they were almost opposites of each other. The document indicated that "true hybrid", created by mixing human and animal gametes are what people think of when they think of hybrids: "…they imagine the half-human, half-animal monsters, like the minotaur that are associated with myths and legends". 24 To the contrary the *cytoplasmic hybrid embryos* that would be created in stem cell research are to be created by inserting the nucleus of human cells into enucleated animal eggs. The cell nuclear replacement with a human nucleus in those eggs would work as presented in the following drawing:



Source: HFE Authority, April, 2007, p. 8.

In addition the document indicated that the "cytoplasmic hybrid embryos" would contain 1% animal DNA at maximum, whereas the "true hybrids" would have an equal amount of DNA from the two species from which the eggs and the sperm are obtained.´[25]

In the opinion poll, that was part of the consultation, respondents were asked whether they would agree with the creation of the "cytoplasmic hybrid embryos". A

[23] The third type that fell within the category of "hybrids" is the transgenic human embryo: forms of human embryo that have animal genes inserted into them during early development. The creation of these embryos has not been practiced yet, but the creation of transgenic animal embryos has.
[24] HFE Authority, supra, n 22, 9.
[25] The document concedes that although a true hybrid embryos might possibly be created in the laboratory "any attempt to create a living hybrid from two closely related species would be extremely unlikely to even produce a viable pregnancy".

percentage of 48% of the respondents disagreed with such creation while over a third of the people agreed.26 Taking the public unease into account that had led to this consultation this result was easy for the advocates of human animal hybrid embryos. Apparently, the document's information concerning how different the "cytoplasmic hybrid embryo" was from the "true hybrid" has had its effect, considering the low percentage of respondents objecting the creation of the latter form of embryo.

The HFE Authority quoted this result in the statement on its decision regarding hybrid embryos, published on 5 September 2007: "public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and it is likely to lead to scientific or medical advancements". The subsequent claim was that these respondents would withdraw their objection in case "the research would be tightly regulated", a claim they derived from the "public dialogue work" that also has been part of the consultation.27 The Authority combined this conclusion of the public consultation as well as the scientific contribution with the legal advice above and concluded that "cytoplasmic hybrid embryos" as specific form of hybrid research, could be permitted. 28

So, at this point, the scientists involved in the consultation by the Authority had found common ground with the lay respondents of the public opinion, at leas 48 % of them. The compromise seemed to lay in the acceptance of the creation of "cytoplasmic hybrid embryos" at the expense of the rejection of the creation of "true hybrids".

5. The arena of the (pre) legislative process of amending the 1990 HFE Act

Not everybody could agree with the compromise that seemed to lay behind the decision of the Authority on 10 September 2007. Already at the beginning of the year, 10 January, a lobby of scientists and members of parliament, strongly supportive of human animal hybrid research, had made itself public with a letter that was sent to the members of the

[26] In July 2007 a sample of 2073 residents of the UK was interviewed.

[27] This public dialogue work consisted in: meetings and workshops in which various public perceptions, motivations and attitudes to the creation of human-animal embryos were explored. HFE Authority, Hybrids and Chimeras, April 2007.

[28] About other kinds of human hybrid and human chimera research the statement says that "not only did the scientific community not wish to perform such research at present but also (…) the prospect was so distant that they could not envisage what forms this research would take in future" (HFE A statement, 5 September 2007).

Authority, shortly before they would make a decision.29 This letter has been published in The Times as well.[30] The lobby was led by Liberal Democrat MP Evan Harris, member of the Select Committee Science and Technology and explicitly supported by a conservative member as well as a the Labour ex-chair of this committee.31 The letter in the Times in addition to these persons was signed by scientists involved in stem cell research, such as Stephen Minger, Lyle Armstrong and Ian Wilmut as well as social scientists, legal academics, medical ethicists and leaders of organizations of medical professional organizations and organizations of bio industry and bio science.

The Select committee is charged with monitoring the work and activities of the Office of Science and Innovation, which is part of the Department of Trade and Industry, and as such this Committee also made an inquiry in the government proposals for the new legislation for the use of embryos for research. In April 2007 the Committee reported, in reaction to government's proposal to ban the creation of human-animal chimera or hybrid embryos that scientific aims such as the pursuit of knowledge about the genetic basis of disease and the direction of stem cells into future cell-based therapy would make the creation of such embryos necessary. 32

The Government in its draft bill met the Select Committee only halfway by proposing to include the creation of "cytoplasmic hybrids" in the categories of embryo that could be authorized by a research license but to exclude the creation of "true hybrids" from authorization, which would put a ban on the creation of the latter form.33

---

[29] In this letter the members of the Authority were told that it would be wise to license the research.
[30] The Times, 10 Jan, 2007.
[31] The Select Committee Science and Technology Committee is one of 18 departmental select committees in the House of Commons charged with monitoring the work and activities of a specific Government department. The Science and Technology Committee is unusual in that it monitors the Office of Science and Innovation, which is part of the Department of Trade and Industry, rather than a department in its own right. The Select Committee Science and Technology is made up of around 10 to 15 Members of the House of Commons.
[32] Furthermore, the stem cells produced would be medically useful in drug discovery and toxicity testing. See Report Select Committee Science and Technology, Government proposals for the regulation of hybrid and chimera embryos. HC, 5 April, 2007, 61.
[33] In this draft bill, all interspecies embryos were to be explicitly excluded from the definition of an "embryo". Instead these forms of embryo were to be regulated under a new section 4A with the title Prohibitions in connection with genetic material not of human origin. The "cytoplasmic hybrids" fall under the description given in (b) of the following forms of interspecies embryo that were distinguished in this draft bill:
(a) an embryo created by using human gametes and the gametes of an animal,
(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,

The decision of the HFE Authority in September 2007 was congruent with this as the government in the draft Bill proposed to forbid the creation of "true hybrids".[34]

However, after Government presented its draft bill, parliament was at turn. The Joint Committee on the Human Tissue and Embryos (Draft) Bill was established by the two Houses of Parliament in order to consider this draft bill.35 This committee recommended including the "true hybrids" in the categories of human embryo that would be conditionally allowed. 36 The committee reasoned against the proposal of the government to distinguish between true hybrids and the other categories of human embryo that there was no "sound point of principle" to make this distinction. The Joint Committee at this point explicitly referred to ethicist Holm, who as a witness before the committee had claimed that both categories of hybrid embryos were "equally objectionable on ethical grounds".37 Once researchers have crossed the species barrier, no valid distinction is to be made between an entity that is 99% human and an entity that is 50% human According to the Joint Committee this view was supported by many others and it referred to the contributions of the All Party Parliamentary Pro-Life Group, Christian Action Research and Education and the Christian Medical Fellowship.

The Minister opposed this argument with the pragmatic argument that currently there was no call for research using "true hybrids" and as public opinion was a concern

---

(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,
(d) a human embryo that has been altered by the introduction of one or more animal cells, or
(e) any other embryo that contains both –
(i) any haploid set of human chromosomes, and
(ii) any haploid set of animal chromosomes of any other sequence of nuclear or mitochondrial DNA of an animal. See Human Tissue and Embryos (Draft) Bill, May 2007.

[34] In the introduction to the draft bill Secretary of State for Health states about the list of forms of embryo that would be conditionally allowed "This list (…) does not include 'true' hybrids created from mixing human and animal gametes. The secretary adds 'Other than as currently permitted for the purpose of testing the fertility or normality of human sperm'"This is a well established and explicitly endorsed test in which human sperm is mixed with hamster eggs to test the health and motility of the human sperm.

[35] The Joint Committee was asked to report on it to both Houses by 25 July 2007. Its membership consisted of 9 members of the House of Commons and 9 members of the House of Lords. Five of the MPs were members of the Science and Society Committee or had been a member of the former Science and Society Committee.

[36] Joint Committee on the Human Tissue and Embryos (Draft) Bill, Human Tissue and Embryos (Draft) Bill, vol. I: Report, HC (2006-07) 630-I, HL Paper 169-I; Joint Committee on the Human Tissue and Embryos (Draft) Bill, Human Tissue and Embryos (Draft) Bill, vol. II: Evidence, HC (2006-07), 630-II, HL Paper 169-II.

[37] Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol I, supra, n 36, 46.

she wanted to postpone the discussion on this point. The Joint Committee stated not to be persuaded by this argument and added to this evidence that "true hybrids" were already created in the so-called "hamster-test".38 In reaction to this Government officials sought to explain the difference between the "true hybrid" resulting from this test and any other sort of "true" hybrid, but again their explanation appeared not to persuade the Joint Committee. In its report the committee persisted that no distinction should be made.

On 13 November 2008, the 2008 HFE Bill became an Act of Parliament.39 The "true hybrids" are included in the categories of human animal forms of embryo that with this Act are conditionally allowed to be created. The name inter-species embryos, that in an earlier phase had been chosen for these categories by an amendment in the House of Lords, was in a later phase changed again into "human admixed embryo". The "human admixed embryo" as legal category refers to types of embryo which contain both human and animal DNA and among the five subcategories indicated to be conditionally allowed are the cytoplasmic hybrid embryo as well as the true hybrid embryo.40

6. Conclusion

The rule making concerning the creation of human animal hybrid embryos in the 2008 UK HFE Act clearly shows that the HFE Authority, as devolved regulator, has provided in an extra pre-legislative arena in the following sense. The Authority, consisting for at least a third (but no more than a half) of persons with a medical-scientific background, in consultation with scientific experts represented in its scientific advisory committees the SCAG and the HHSEP as well as legal advisors and ethicists decided that the research in

---

38 Joint Committee, Human Tissue and Embryos (Draft) Bill, Vol. I, n 36, 46.

39 Human Fertilisation and Embryology Act 2008 (C22).

40 Different from the (Draft) Bill the cytoplasmic hybrid in the Act is described under (a) while the true hybrid falls under the description given under (b). See Human Fertilisation and Embryology Act 2008 Section 4A(6):

(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with –
    (i) two human pronuclei, or
    (ii) one nucleus of a human gamete or of any other human cell, or
    (iii) one human gamete or other human cell.
(b) any other human embryo created by using –
    (i) human gametes and animal gametes, or
    (ii) one human pronucleus or one animal pronucleus.

the applications in principle was covered by the 1990 HFE Act and therefore would fall under its remit. Subsequently, the Authority in its public consultation reassured the part of the public at unease with the idea of combining human and animal DNA. This was done in the consultation document by stressing how different, how distanced in terms of the proportion of animal DNA, this "cytoplasmic hybrid embryo" would be from the "true hybrid embryo". Under the assumption that the creation of the latter was not at issue, almost half of the respondents of the opinion poll consented in making the creation of the cytoplasmic hybrid embryo legally possible.

However, in the legislative arena the proponents appeared to put much effort in taking the legal facilitation of the creation of human animal hybrids one step further by also conditionally allowing the creation of "true hybrids". Whereas the HFE Authority seemed to listen to some extent to moral objections of the public and acted as if these would be reason for drawing new legal boundaries, this was completely different in the legislative arena. The ethicist's argument that 'once the species barrier is crossed the proportion of animal DNA makes no difference' in this arena was hold against the advocates of a boundary in terms of the proportion of animal DNA. This resulted in a new act, the 2008 HFE Act, in which the creation of both forms of animal hybrid embryo is conditionally allowed.

This analysis of the issue of the creation of human animal hybrid embryos leaves little doubt about the question whether and how the existence of two instead of one phase of deliberation about new legal boundaries are helpful in neutralizing public resistance. In this sense the devolved form of regulation indeed has provided in a two-stage rocket to public acceptance of this new technique. However, a more hierarchical model of law making, in which the national legislature formally is the one and only forum for deliberating the legislative rules, does not necessarily make a big difference in this respect. The regulatory design maybe the lubricating oil but is not engine behind the legal facilitation each time of yet another new biomedical technique without proper political debate or public reflection about the principles of humanity involved. Instead of the regulatory design, it is the worldwide policy network built around biomedical research that is the engine behind this.

A clear indication of such policy network can be found in the letter concerning human animal hybrid embryos that was sent to the Authority in the beginning of 2007. This letter was signed by members of parliament, mostly participating in the Select Committee Science and Technology, and scientists such as Stephen Minger, Lyle Armstrong and Ian Wilmut. It reveals the strong ties that exist between the scientists directly involved in stem cell research and this Select Committee.41 Although much effort is put in involving not only national scientific experts in the consultation, for instance by engaging stem cell scientists from other countries in the Authority's Horizontal Scanning Expert Panel or asking them to witness in inquiries by parliamentary committees, this doesn't change the fact that the circle of experts in this specialized field is very small. Therefore applicants of research proposals, experts consulted by the HFE Authority and experts consulted by parliamentary committees all are participants of the same inner circle. The input of these experts in the rule making process is indispensable but however unique and scientifically sound their advice may be, they have a clear stake themselves in facilitating as much as possible innovation.

[41] Stephen Minger, Lyle Armstrong were the applicators for a license to create human animal hybrids, see n 23.