Survey on the

National Regulations in the European Union regarding

Research on Human Embryos

by

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INTRODUCTION

The European Group on Ethics in Science and New Technologies (EGE) is an independent multicultural and multi-disciplinary body composed of twelve experts representing a variety of viewpoints and disciplines.

The EGE has been set up by decision of the European Commission of December 1997 to advise the European institutions on the ethical aspects of European regulatory activities or policies.

On 14 November 2000, the EGE issued its 15th *Opinion on Ethical Aspects of Human Stem Cell Research and Use*. This Opinion contains a survey on national regulations in the European Union regarding research on embryos.

Since November 2000, there have been many advances in stem cell research. As a result, legal changes have occurred within the member States of the European Union or are still in discussion. The present document is updating and deepening the previous survey included in Opinion 15.

Brigitte Gratton

DEFINITIONS

The terminology used in the various legislations differs. Therefore, in the core text of this document, the above terms are defined as follows:

- **Non-therapeutic research on embryo**: research that is not done for the direct benefit of the individual embryo concerned and is likely to harm it and to lead to its destruction.

- **Therapeutic research on embryo**: intended to be in the interests of the embryo, which is going to be transferred in a woman's womb.

AUSTRIA

A - The legal situation

The Reproductive Medicine Act of 4 June 1992 defines the conditions to be respected in using gametes and embryos for medically assisted procreation. The 1992 Act also covers research on embryos.

1. Definition of the embryo

The Reproductive Medicine Act 1992 does not properly define the term embryo. Instead, the expression "cells capable of development" is used. Article 1 (3) of the Reproductive Medicine Act 1992 defines "cells capable of development" as "fertilised eggs" and "cells developed from fertilised eggs".

2. Research on embryos

a – Therapeutic research

Pursuant to the Reproductive Medicine Act 1992, therapeutic research on *in vitro* embryos, *in vivo* embryos and foetuses may be performed for no other purpose than medically assisted reproduction.

b – Non-therapeutic research

Research on embryos for non-therapeutic purposes is forbidden. The donation of eggs or embryos either to another couple or for research purposes is not permitted by the Reproductive Medicine Act 1992.

Moreover, the Austrian law requires that a minimum of surplus embryos be created. Indeed, Article 10 states that "when combining eggs and sperm outside a woman's body, the number of eggs fertilised may not be more than is required, in the light of current medical knowledge and experience, within one cycle for the purposes of ensuring reasonable, medically assisted reproduction with good prospects of success".

Thus, the spirit of the Reproductive Medicine Act 1992 is that there should not be any surplus embryos. However, this is not possible from a practical point of view, and therefore the 1992 Act provides that surplus embryos can be stored for one year, and after this period, they must be destroyed.

3. Research on human embryonic stem cells

The Reproductive Medicine Act 1992 does not explicitly cover research on human embryonic stem cells, therefore the legal situation is unclear. Human embryonic stem cell research is going to be discussed in the course of the amendment of the Reproductive Medicine Act 1992 (planned for 2003).

Following the interpretation of the Austrian Ministry of Justice, the Reproductive Medicine Act 1992 prohibits research on human embryonic stem cells. This prohibition covers both the harvesting of stem cells from embryos and research on imported embryonic stem cell lines. Indeed, both situations presuppose the destruction of embryos, which is against the spirit of the 1992 Act.

Others (scientists and professors of law members of the Bioethics Commission) consider that actions that are not explicitly prohibited by the 1992 Act are allowed.

4. Creation of embryos solely for research purposes

Article 9 (1) of the Reproductive Medicine Act 1992 provides that "viable cells may not be used for purposes other than medically assisted reproduction. They may be examined and treated only so far as this is required, in the light of current medical knowledge and experience, for the purposes of inducing a pregnancy. The same applies to semen and eggs, which are intended for use in medically assisted reproduction".

The principle of the law is that *in vitro* fertilisation is only acceptable for reproductive purposes. Thus an embryo can be created for the purpose of inducing a pregnancy, but absolutely not for research purposes.

5. Human cloning

There is no explicit regulation regarding human cloning.

In 2003, the Reproductive Medicine Act 1992 will be amended in order to forbid reproductive cloning.

As regards therapeutic cloning, there are two different interpretations of the Austrian legal position:

- Following the interpretation of the Austrian Ministry of Justice, the production of viable cells *via* cell nuclear transfer is forbidden, because viable cells can only be used for procreating children and not for any other use (Article 9 of the Reproductive Medicine Act 1992).
- Following the interpretation of one of the most important legal scholars in Austria, the ban of cell nuclear transfer is not to be found in the law, because in 1992, when the Reproductive Medicine Act was drafted and the term "viable cells" defined, these new technologies were unknown. Therefore, it is unclear whether the organisms obtained by cell nuclear transfer are

covered by the Reproductive Medicine Act 1992 or not, and further legislation should be enacted.

6. Council of Europe's Convention on Human Rights and Biomedicine

Until now, Austria has not signed the Convention on Human Rights and Biomedicine, because it is considered too permissive regarding embryo research.

B - Position of the relevant national ethics instances

The Austrian Bioethics Commission was established at the Federal Chancellery in June 2001.

No opinion on research on embryos, on human embryonic stem cells, or on human cloning has yet been given.

The only related opinion already issued by the Austrian Bioethics Commission is an opinion regarding the financing of human stem cells research within the 6th European research programme framework: *Finanzierung von Stammzellenforschung im Rahmen des 6. Rahmenprogrammes der EU für Forshung, technologische Entwicklung und Demonstration (2002-2006): Beratungen der Bioethik-Kommission abgeschlossen (8 May 2002)*. In this opinion, a majority of eleven members voted in favour of research on human embryonic stem cells under strict conditions, when a minority of eight were against it and considered that European funds should not be spent on such research.

C / Links

Bioethics Commission: www.bka.gv.at/bka/bioethik/

Parliament (Federal Chancellery): www.bka.gv.at

BELGIUM

A - The legal situation

1. Current situation

There is presently no specific regulation concerning human embryo research. The only piece of law related to embryos is a Royal Decree of 1999, which determines the conditions to be complied with by *in vitro* fertilisation centres. No embryo can be created outside these agreed centres.

Thus, the current practice is as follows: researchers carrying out research projects involving human embryos must perform the research within an agreed *in vitro* fertilisation centre, and obtain approval for their research protocol from the ethical committee of their institution (university, institution, etc…). Provided that these conditions are fulfilled, research projects involving the embryos may be carried out. But otherwise, there are no legal limitations to embryo research and cloning.

2. Law proposal regarding research on *in vitro* embryos

Senators Philippe Monfils and Philippe Mahoux put forward a law proposal regarding research on *in vitro* embryos. The proposal covers research on embryos, stem cell research and therapy, and human cloning. On 10 June 2002, the proposal and its amendments were discussed before the Bioethics Commission of the Belgian Senate and the proposal was approved. However, the proposal still has to be scrutinised and voted by the second chamber of the Belgian Parliament. Final approval will not take place before October 2002, as the Parliament is waiting for the opinion of the Belgian National Consultative Bioethics Committee before voting the legislation.

The substance of the Monfils and Mahoux proposal is as follows.

a - Research on embryos

Article 3 of the proposal allows research on *in vitro* embryos provided that the research project satisfies the following six conditions:

- it is for therapeutic purposes or for the advancement of the understanding of infertility, sterility, organ or tissue transplants, congenital or genetic diseases or cancer;
- it must be based on the most recent scientific knowledge;
- it must be carried out in a registered laboratory affiliated to a university reproductive medicine programme;

- it is carried out using embryos up to 14 days old, excluding any cryoconservation period;
- it must be carried out under the supervision of a specialist doctor and by qualified persons;
- it will only be authorised if an alternative method of research would not be as effective.

Article 5 of the proposal provides for limitations into research on *in vitro* embryos. It prohibits implanting human embryos in animals and re-implanting embryos that have undergone research, except where the research benefits the embryo (therapeutic research) or where the research does not affect the embryo (observational research). It also forbids the commercial use of embryos and research with eugenic purposes. However, the proposal does not forbid germinal therapy. The authors of the proposal made a distinction between germinal therapy with eugenic purposes (forbidden by Article 5) and germinal therapy with therapeutic purposes for the embryo itself and its descendants. This position contravenes Article 13 of the Convention on Human rights and Biomedicine, which forbids germinal therapy[2].

Following Article 8 of the proposal, the "concerned persons" (i.e. the couple for which embryos are created and the donors of gametes) must give their free and informed consent for the use of the embryos for research purposes.

Research on *in vitro* embryos would be controlled at both the local and federal level. Article 9 of the proposal provides for the setting up of a federal commission in charge of monitoring embryo research. Report on the advancement of the research project must be communicated yearly to the federal commission, and failure to do so will be punished by a fine.

b - Research on human embryonic stem cells

The legal framework provided for embryo research by the proposal would allow research on human embryonic stem cells. One of the reasons for the enactment of such a piece of law is to encourage human embryonic stem cell research.

c - Creation of embryos solely for research purposes

Article 4 of the proposal prohibits the creation of embryos solely for research purposes, except where the objectives of the research project cannot be achieved by research on surplus embryos.

[2] Article 13 of the Convention on Human Rights and Biomedicine provides that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants".

d - Human cloning

The proposal prohibits reproductive cloning[3] and authorises *a contrario* therapeutic cloning.

The proposal does not allow explicitly therapeutic cloning and does not go into details regarding the authorised methods to be used to create embryos solely for research purposes. However, in their comments on the law proposal, the authors explain that the prohibition of reproductive cloning does not include therapeutic cloning for research purposes aiming at therapeutic applications.

The creation (Article 4) and the re-implantation (Article 5) of embryos outside the limitations set up by the law, and the production of human clones (Article 6) constitute criminal offences punishable by a fine and up to five years of imprisonment.

3. Council of Europe's Convention on Human Rights and Biomedicine

Belgium has neither signed the Convention on Human Rights and Biomedicine nor its Additional Protocol on the Prohibition of Cloning Human Beings.

If this proposal is adopted, Belgium will have to make reservations in respect of Article 13 and Article 18 of the Convention on Human Rights and Biomedicine before signature and ratification.

B - Position of the relevant national ethics instances

The Belgium National Bioethics Committee was created on 15 January 1993 with the task of informing and of delivering opinions to the public, the Belgian Government and the Belgian parliament.

1. Position on embryo research

The Belgium National Consultative Bioethics Committee has not published any opinion on research on embryos or on human embryonic stem cells. However, in its *Opinion n. 2 on the Convention on Human Rights and Biomedicine* dated 27 July 1997, the Committee mentioned Article 18 of the Convention that is dealing with embryo research. Opinions within the Committee could not reach a common position, especially as regards Article 18 (2) that prohibits the creation of embryos for research purposes. While some members believe that the creation of human embryos for research purposes would serve patients' interests, others consider that it would contravene human dignity.

[3] See the conclusion of the Belgium National Consultative Committee, which contains three proposals: a definitive prohibition of reproductive cloning, a prohibition by law for the time being, or a moratorium. The proposal follows the first solution.

2. Position on human cloning

In its *Opinion n. 10 on Human Reproductive Cloning* dated 14 June 1999, the Belgium National Consultative Bioethics Committee considered the legal, philosophical and ethical issues raised by cloning techniques. It concluded that reproductive cloning should be excluded for the time being. However, while some members believe that the law should definitively prohibit reproductive cloning, others considered that a moratorium would be sufficient. This Opinion prompted the drafting of the previously mentioned law proposal regarding research on *in vitro* embryos.

No opinion on therapeutic cloning has been released yet. However, the Committee will deal with the subject in its Opinion on the law proposal on research on *in vitro* embryos, to be released in September 2002.

C - Links

Belgium National Consultative Bioethics Committee: www.health.fgov.be/bioeth

Parliament: www.parlement.be ; www.lachambre.be ; www.senat.be

DENMARK

A - The legal situation

In Denmark, two pieces of law apply as regards embryo research and human embryonic stem cell research: the 1997 Act on Medically Assisted Reproduction (no.460) and the 1992 Act on the Scientific Ethical Committees and the Handling of Biomedical Research Projects (no. 503).

1. Definition of the embryo

The 1997 Act on Medically Assisted Reproduction does not define properly the embryo. Instead, the terms « fertilised ova », « fertilised eggs » or «pre-embryos » are generally used.

2. Research on embryos

Chapter 7 (sections 25-28) of the 1997 Act on Medically Assisted Reproduction entitled "Prohibition against research and experiments" stipulates the conditions for research on embryos (both therapeutic and non-therapeutic research).

Section 25 (1) states that research on embryos, more precisely "biomedical experiments on fertilised human ova and on gametes that are intended to be used for fertilisation" can be undertaken only in the following cases:

- if the research seeks to improve *in vitro* fertilisation techniques in order to induce pregnancy;
- if the research seeks to improve preimplantation diagnosis techniques.

Additionally, the following conditions must be complied with:

- fertilised eggs can only be kept in vitro up to 14 days excluding any period of cryopreservation (Section 26);
- fertilised eggs used in research projects complying with Section 25 may be transferred into the womb only if the fertilised ovum is genetically unmodified and if the experts believe that the research has not caused any damage to the development potential of the embryo (Section 27 (1));
- research projects have been approved by the Science Ethical Committee System[4] that will assess whether the purposes of the research projects fall within the scope of Section 25 (Section 27 (2));

[4] The Committee System is made up of seven regional committees and the Central Scientific Ethical Committee. The task of regional committees is to assess biomedical research projects.

Research projects involving embryos and research projects involving imported human embryonic stem cells fall within the scope of the 1992 Act on the Scientific Ethical Committees and the Handling of Biomedical Research Projects. The Central Scientific Ethical Committee must approve all these projects.

3. Research on human embryonic stem cells

There is no specific legislation on stem cell research in Denmark.

Because of the 1997 Act on Medically Assisted Reproduction, the harvesting of stem cells from embryos cannot take place in Denmark. However, the 1997 Act does not cover research using imported human embryonic stem cell lines, thus such research is not legally prohibited in Denmark and can be carried out. Although this interpretation of the law has some opponents, it was recently confirmed in a statement of the Danish Ministry of the Interior.

4. Creation of embryos solely for research purposes

Section 25 (2) of the 1997 Act on Medically Assisted Reproduction provides that the "collection and fertilisation of ova for the purpose of conducting other experiments than the ones mentioned above in subsection (1) shall not be allowed". Therefore, the creation of human embryos for research purposes is only allowed for research projects intending to improve *in vitro* fertilisation or preimplantation diagnosis techniques, but not for other types of experiments, such as stem cell research.

5. Human cloning

a – Reproductive cloning

Experiments aiming at producing "genetically identical human individuals" are forbidden by Section 28 of the 1997 Act on Medically Assisted Reproduction. Thus the Danish legislation does not permit research into reproductive cloning.

Moreover, Section 4 of the 1997 Act forbids the simultaneous or subsequent implant of "identical unfertilised or fertilised ova into one or several women for the purpose of procreation". The provision covers both embryo splitting and somatic cell nuclear transfer. Additionally, Section 2 is also presumed to include a ban on reproductive cloning when stating that "medically assisted procreation shall not take place unless it is performed for fertilising a genetically unchanged (unmodified) ovum with a genetically unchanged (unmodified) sperm cell". Thus the 1997 Act specifically bans reproductive cloning.

The task of the Central Scientific Ethical Committee is to coordinate the work of the regional committees and to assess research projects involving embryos or embryonic stem cells.

b – Therapeutic cloning

Therapeutic cloning is not dealt with by the Danish legislation.

Research into therapeutic cloning does not comply with Section 25 of the 1997 Act on Medically Assisted Reproduction (research on embryos can only be undertaken for improving *in vitro* fertilisation or preimplantation techniques) and seems therefore to be prohibited.

Finally, research involving the fusion of genetically different embryos or parts of embryos, the production of hybrids, or the development of human individuals in a species-extraneous uterus is also forbidden.

A person infringing a provision of the 1997 Act on Medically Assisted Reproduction is liable to a fine or imprisonment.

6. Council of Europe's Convention on Human Rights and Biomedicine

Denmark signed the Convention on Human Rights and Biomedicine on 4 April 1997, and ratified it on 10 August 1999. The Convention entered into force in Denmark on 1 December 1999.

Denmark signed the Additional Protocol to the Convention on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

B - Position of the relevant national ethics instances

The Danish Council of Ethics was established by the Danish Council Act 1988 and set up by the Ministry of Health. The Council has an advisory function for the health authorities, and according to the legislation, it must give recommendations to the Ministry of Health on the establishment of rules and provisions in statutes on fertilised eggs, embryos, genetic experiments on sex cells and other issues.

In January 2001, the Danish Council of Ethics issued a statement on therapeutic cloning.

1. Position on human embryonic stem cell research and cloning

In this statement, a majority of the Danish Council of Ethics estimated that, in principle, human embryonic stem cells could be used as long as substantial benefits are available for treating diseases.

A majority of the Danish Council of Ethics estimated that there was no urgent need at the moment to allow human embryonic stem cells to be produced for research, either by cell nuclear transfer or by *in vitro* fertilisation technique. Research into embryonic stem cells should be confined to surplus embryos. Therapeutic cloning is not recommended for the time being.

2. Position on reproductive cloning

The Danish Council of Ethics unanimously rejected reproductive cloning because it would violate human dignity, because it could have adverse consequences for the cloned person and because permitting research on reproductive cloning would reflect a disregard for the respect due to the moral status of embryos.

C - Links

Council of Ethics: www.etiskraad.dk

Ministry of Health: www.sum.dk/uk/ukmenu.htm

Parliament: www.folketinget.dk

Research Agency: www.forsk.dk/eng/index.htm

FINLAND

A - The legal situation

Since 1 November 1999, embryo research is regulated in Finland by the Medical Research Act issued in Helsinki on 9 April 1999[5]. This piece of law covers medical research carried out on persons, human embryos and foetuses. It is completed by the Medical Research Decree[6], which also entered into force on 1 November 1999 and gives the preconditions of institutions applying for permission to carry out embryo research.

1. Definition of the embryo and foetus

Section 2 of the Medical Research Act 1999 defines an "embryo" as "a living group of cells resulting from fertilisation not implanted in a woman's body", and a "foetus" as "a living embryo implanted in a woman's body". Thus the term "embryo" covers only *in vitro* embryos, while the term "foetus" includes both *in vivo* embryos and foetuses.

2. Research on embryos

a - Research on *in vitro* embryos

No distinction between therapeutic and non-therapeutic research as such is made regarding research on *in vitro* embryos. In the Medical Research Act 1999, medical research is defined as the "research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of disease in general" (Section 2).

Research on "embryos" can be carried out in Finland on surplus embryos up to 14 days after fecondation, providing that a licence from the required authority is granted.

Section 11 of the Medical Research Act 1999 provides that "research on embryos outside a woman's body may be carried out only by agencies that have been granted the appropriate licence by the National Authority for Medicolegal Affairs. The conditions for the granting of the licence shall be laid down by Decree.[7] Medical research shall be permitted on embryos only if

[5] Statute n. 488/1999.

[6] N. 986/1999.

[7] Section 4 of the Medical Research Decree of 29 October 1999 set up the "conditions governing institutions that are carrying out research involving embryos". The institutions must have the appropriate research facilities, equipment and staff needed to carry out the research proposal.

no more than 14 days have passed from their formation. The time during which an embryo is kept frozen shall not count for the purposes of calculating this time limit".

Such research cannot be "undertaken without the written consent of the persons who donated the gametes" (Section 12). If this consent is withdrawn later on, the research using the concerned gametes must be stopped.

Finally, the Medical Research Act 1999 sets up some restrictions on research on "embryos":

- embryos used for research cannot be implanted in a human body or be kept alive for more than 14 days from their formation, not including the time during which they have been kept frozen (Section 13 on restrictions on research on embryos);
- research may use embryos that have been stored for up to 15 years, but after that period the embryos must be destroyed (Section 13);
- research on embryos and gametes for the purpose of modifying their hereditary properties are prohibited, unless the research is for the purpose of curing or preventing a serious hereditary disease (Section 15 on prohibited research).

b. Research on *in vivo* embryos and foetuses

Research on "foetus"[8] is allowed under specific conditions:

- The written consent of the pregnant woman is required;
- The research involving the pregnant women is only possible if it would not be possible to obtain the same scientific results by using other research subjects; and
- *Either* the research is likely to benefit directly the health of the woman or the "foetus", *or* the research is likely to benefit the health of people related to the woman or the foetus.

3. Research on human embryonic stem cells

There are no specific additional regulations on human embryonic stem cell research in Finland. Thus, as research on embryos for non-therapeutic purposes is permitted by the Medical Research Act 1999 under certain conditions (licence, consent, etc…), research on human embryonic stem cells is implicitly possible subject to the same conditions.

4. Creation of embryos solely for research purposes

The production of "embryos" exclusively for the purpose of research is forbidden by Section 13 of the Medical Research Act 1999. However, the current issue is whether an embryo created by cell-nuclear-transfer is actually covered by the Medical Research Act 1999, as Section 2 defines an embryo as "a living group of cells resulting from fertilisation".

[8] Reminder: under the Medical Research Act 1999, the term "foetus"means "a living embryo implanted in a woman's body" and thus covers both *in vivo* embryos and foetuses.

5. Human cloning

Section 26 on unlawful intervention on the genome provides that any person conducting research with the aim of cloning human beings shall be liable to a fine or imprisonment for a period not exceeding two years. Thus, reproductive cloning constitutes a criminal offence in Finland on the ground of unlawful intervention on the genome.

6. Council of Europe's Convention on Human Rights and Biomedicine

Finland signed the Convention on Human Rights and Biomedicine on 4 April 1997. The ratification of the Convention awaits the adoption of the Human Fertilisation Act (currently in preparation). A Government Bill on Human Fertilisation Treatments was handed over to the Finish Parliament on 5 June 2002.

Finland also signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

B - Position of the relevant national ethics instances

1. National ethics committees

Finland has four major national ethics committees concerning biomedicine and research:

- the Board for Gene Technology, which was set up to ensure a safe and ethically acceptable use of gene technology and which mainly deals with issues raised by genetically modified organisms;
- The National Advisory Board for Biotechnology, which also deals with the ethical issues in biotechnology;
- The National Advisory Board on Health Care Ethics, which is an expert committee concerned with ethical issues related to health care and patients' status;
- The National Research Ethics Council of Finland, set up to resolve issues of research ethics.

Finland also has several regional and institutional ethics committees on research on humans as required by the Medical Research Act 1999.

None of these committees has issued an opinion on embryo research or on embryonic stem cell research so far. But as Finland is part of the Nordic Committee on Bioethics with Denmark, Iceland, Norway and Sweden, the *Opinion on Human Stem Cell Research* from the Nordic Committee on Bioethics based on the workshop "Ethical issues in human stem cell research" (10 & 11 October 2000) prevails.

2. Nordic Committee on Bioethics

In 1996, the Nordic Committee on Bioethics was formed out of the Nordic Committee on Ethics, which was set up in 1989 by the Nordic Council of Ministers to co-operate in the fields of biotechnology and Bioethics within the Nordic region.

a - Position on embryo research

The Nordic Committee has not issued an opinion on embryo research as such. However, in its *Opinion on Human Stem Cell Research,* it is assumed that research on surplus *in vitro* embryos until day 14 of the embryonic development is allowed for a majority of the Nordic Committee's members (except Norway).

b - Position on the creation of embryos solely for research purposes

The Nordic Committee on Bioethics considers that creation of human embryos solely for research purposes is not necessary at the present stage.

c - Position on human embryonic stem cell research

The majority of the members of the Nordic Committee on Bioethics are of the opinion that embryonic stem cell research may be carried out if the following conditions are complied with:

- the stem cells used are derived from human spare embryos produced for *in vitro* fertilisation but no longer needed;
- the embryos can be used until day 14 of their embryonic development;
- informed and free consent has to have been obtained from the donating couple;
- the research proposal must be of high quality and accepted by an independent ethics committee.

d - Position on human cloning

The Nordic Committee on Bioethics recognises the potential advantages of therapeutic cloning in connection with stem cells. However, because the therapeutic perspectives of this technique seem very remote and because "slippery slope" possibilities to reproductive cloning may be seen, the Nordic Committee feels that therapeutic cloning should be forbidden at this stage of embryonic stem cell research.

C - Links

Ministry of Education: www.minedu.fi

Ministry of Justice: www.om.fi

National Advisory Board on Health Care Ethics: http://pro.tsv.fi/tenk/english1.htm

National Research Ethics Council of Finland: www.minedu.fi/minedu/research/organisation/research_ethics_council/research_ethics_council.html

Nordic Committee on Bioethics: www.ncbio.org

FRANCE

A - The legal situation

1. The current situation: the Bioethics laws of 1994

In France, research on human embryos is currently governed by one of the 1994 Bioethics laws[9], the law 94-654 of 29 July 1994 regarding the "donation and use of human body parts and derivatives, medically assisted procreation and antenatal diagnosis".

a – Definition of the embryo

French law does not define the embryo. Because Article 16 of the Civil Code ensures the protection of the human being from the beginning of life, the French Constitutional Court has had to examine the provisions of the law 94-654, which is dealing with the conservation, destruction and even selection of embryos. In its decision dated 27 July 1994, the Constitutional Court stated that the constitutional principle of human dignity applies, but that the selection of embryos for pre-implantation diagnosis purposes during *in vitro* fertilisation and the destruction of embryos do not give rise to any constitutional objections, since the right to life and the principle of equality do not apply to embryos.

b - Research on *in vitro* embryos

As a general principle, research on *in vitro* embryos is forbidden. Article 152-8 of the Public Health Code provides that "any experimentation on embryos is forbidden".

However, the law 94-654 authorises studies that have a medical aim and that do not harm the concerned embryo. These studies are subject to certain conditions:

- the obtaining of written consent from the man and the woman;
- the authorisation by the Minister for Health with the approval of the National Commission for Reproductive Medicine and Biology.

The French law merely makes a distinction between research for medical purposes that does not harm the embryo and may be authorised, and other types of research, which are prohibited.

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[9] The Bioethics laws include law 94-653 of 29 July 1994 regarding the "respect of the human body" and integrated in the Civil Code; law 94-654 of 29 July 1994 regarding the "donation and use of human body parts and derivatives, medically assisted reproduction and antenatal diagnosis" and integrated in the Public Health Code; law 94-548 of 1 July 1994 regarding the "use of nominative data for research purposes in the field of health and modifying law 78-17 of 6 January 1978 on informatique, files and liberties" and integrated in the Public Health Code. In addition, there is the 1988 law regarding the protection of persons involved in biomedical research projects and the 1975 law on abortion.

But research for medical purposes does not need to be therapeutic in the sense that it does not needs to treat the embryo, as long as it does not harm it (for example, research for improving medically assisted reproduction techniques or antenatal diagnosis).

The 94-654 law provides that surplus embryos produced during *in vitro* fertilisation may be frozen and stored for a maximum of five years. After this period, the embryos cannot be used for research and must be destroyed.

c – Research on *in vivo* embryos and foetuses

Research on *in vivo* embryos and foetuses is governed by Article 209-4 of the Public Health Code regarding research involving pregnant women. Research that is expected to be of direct personal benefit to the person undergoing it (the mother) may be carried out if the informed consent of the mother is obtained and if approval from the advisory committee for the protection of persons involved in biomedical research is granted. Research without direct personal benefit may only be carried out if it presents no foreseeable serious threat to the health of the mother or to the health of the child, if it makes a useful contribution to the knowledge about pregnancy and if it cannot be carried out otherwise.

d – Research on human embryonic stem cells

There is currently no specific regulation regarding human embryonic stem cell research and use. The harvesting of stem cells from human embryos is obviously not permitted by the French legislation, as it would lead to the destruction of the embryo. However, research involving already isolated human embryonic stem cell lines is not prohibited.

Under a law dated 1 July 1998, the Ministry of Research is able to issue licences to import and export human organs, tissues and cells. A decree dated 23 February 2000 sets out the conditions for issuing such licences. Thus the importation of human embryonic stem cells has been legally possible since 2000. However, the French Ministry of Research waited until the National Assembly had agreed on the principle of research involving human embryonic stem cells. Agreement was given on 22 January 2002 when the National Assembly passed the proposal bill for the revision of the Bioethics laws. The proposal expressly allows research on human embryonic stem cells, but it will not come into effect before the second half of 2003. Consequently, in April 2002, the French government decided to allow the importation of human embryonic stem cells derived from surplus embryos only for research purposes until the proposal becomes law.

e – Creation of embryos solely for research purposes

As research on *in vitro embryos* is forbidden except if it does not harm the concerned embryo, the creation of embryos solely for research purposes is obviously prohibited. Article 152-3 of the public Health Code prohibits the creation of human embryos *in vitro* for purposes other than medically assisted reproduction, and Article 152-8 (1) of the same Code prohibits explicitly the creation of human embryos for purposes of study, research or experimentation.

f – Human cloning

French law does not explicitly ban human cloning. However, in a report dated 22 April 1997, the National Consultative Bioethics Committee concluded that this lack of an explicit prohibition could not be interpreted either as a legal *vacuum* or as implying that human cloning is authorised in France. Indeed, the creation of human embryos *in vitro* for other purposes than medically assisted reproduction (Article L 152-3) and especially for research purposes (Article L 152-8) is prohibited. Thus the creation of human clones for therapeutic purposes (therapeutic cloning), and for research purposes, which includes both research into reproductive cloning and therapeutic cloning, are not permitted.

As regards reproductive cloning, because the terms of Articles L 152-2 and L 152-3 of the Public Health Code restrict the possibilities of *in vitro* fertilisation to the context and for the purposes of medically assisted reproduction and mention only techniques that enable an embryo to be constituted by sexual reproduction, it follows that the French legislation intended to authorise only the forms of assistance to childbearing that entail the induced fusion of the gametes of a couple desiring parenthood, and not reproductive cloning[10]. Consequently, French law in its present state is deemed not to authorise human cloning, although it does not contain a specific prohibition.

2. The proposal for the revision of the 1994 Bioethics laws

The 1994 laws provide for their revision every five years. Because of delays in the legislative calendar, the proposal for the revision of the Bioethics laws was only discussed by the French National Assembly in January 2002, and adopted on 22 January 2002[11]. The proposal still needs to have its first reading before the Senate and then a second reading before both houses, with implementing decrees to follow. Therefore, the proposal is unlikely to come into force until the second half of 2003.

The main objectives of the revision proposal regarding embryo research and stem cells are to prohibit certain practices such as reproductive cloning and to allow, with limitations, others such as embryo research whose medical interest can no longer be underestimated.

a – Research on embryos and on human embryonic stem cells

Chapter IV of the proposal on « research on embryos and embryonic and foetal stem cells » provides new conditions for research on embryos and embryonic stem cells. Following Article 19 of the proposal, research on human embryos and human embryonic stem cells is allowed on condition that it is carried out for medical purposes only and that there is no alternative method regarding the state of the art.

Only *in vitro* embryos created for medically assisted reproduction and that are no longer going to be implanted in a woman's uterus can be used in research projects. The donating couple

[10] See the report of the National Advisory Ethics Committee dated 22 April 1997.

[11] National Assembly: text n. 763; Senate: text n. 189.

must give its informed consent in writing and after a three-month period of reflection. Article 18 suppresses the five-year period for cryoconservation, thus there is no limitation period for cryoconservation any more.

Finally, the Procreation, Embryology and Human Genetics Agency must approve the research projects. The proposal makes an important change regarding the administrative framework of medically assisted reproduction by creating this Agency to replace the current National Commission for Reproductive Medicine and Biology. The Procreation, Embryology and Human Genetics Agency is controlled by both the Ministry of research and the Ministry of Health and responsible for monitoring research in reproduction, biology and genetics.

Carrying out research on embryos without authorisation or outside the limitations set up by the law is punishable by a fine of 100 000 Euros and seven years of imprisonment (Article 21).

b - Creation of embryos solely for research purposes

The creation of human embryos for research is still forbidden by Article 19 of the proposal. Consequently, therapeutic cloning is deemed to be banned as well[12].

c - Human cloning

Article 15 of the revision proposal prohibits reproductive cloning. It states that it is forbidden to make any intervention for the purpose of giving birth to a child or for the purpose of developing an embryo that does not come directly from the gametes of a man and a woman.

Infringement of Article 15 constitutes a criminal offence. The person committing such an offence is liable to 20 years of imprisonment (Article 21).

3. Reports linked to the revision of the 1994 Bioethics laws

The prospective revision of the laws gave rise to the publication of several official reports. The following ones are more specifically concerned with research on human embryos and on human embryonic stem cells:

- a 1998 parliamentary report on cloning, cell therapy and the therapeutic use of embryonic stem cells presented by Alain Claeys (Member of Parliament) and Claude Huriet (Senator) (French National Assembly document n. 2198 and Senate's document n. 238).

[12] In its first draft of the proposal, the French Government of Lionel Jospin had intended to allow therapeutic cloning, when the president Jacques Chirac stated he was against it. Finally, the Government decided not to go ahead with legislation allowing therapeutic cloning on the advice of the Council of State (Opinion on the proposal to the Government dated June 2001). Therapeutic cloning was also rejected by the Special Commission charged by the Parliament to examine the proposal. On the contrary, the National Consultative Bioethics Committee favoured therapeutic cloning by a short majority in its Opinion dated 7 February 2001.

- a 1999 Council of State report. This report, drawn up at the Government's request, also stresses the need to re-examine the ban on embryo research.
- A 2002 parliamentary report on the law proposal n. 3166 regarding bioethics, presented by Bernard Charles and Alain Claeys for the Special Commission (National Assembly document n. 3528).

4. Council of Europe's Convention on Human Rights and Biomedicine

France signed the Convention on Human Rights and Biomedicine on 4 April 1997, but has not yet ratified it.

France signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

B - Position of the relevant national ethics instances

The French National Consultative Bioethics Committee was established by a decree from the President of the French Republic on 23 February 1983. The Committee is an independent body linked to the Ministers for Research and for Health.

The position of the National Consultative Bioethics Committee will mainly be summarised from its latest *Opinion n. 067 dated 18 January 2001 on the preliminary draft revision of the laws on Bioethics*[13].

1. Position on research on human embryos and embryonic stem cells

The National Consultative Bioethics Committee considers that, where the parents do not want to pursue theirs parental project and do not want to donate their embryos to other couples, the use of surplus embryos for research purposes is ethically acceptable and should be allowed by law.

The Committee favours opening up limited and regulated possibilities of research on spare embryos, especially as regards isolating human embryonic stem cells, because of their promising therapeutic prospects.

2. Position on the creation of embryos solely for research purposes

The Committee considers that the production of human embryos by *in vitro* fertilisation for research purposes should remain prohibited.

[13] Not the adopted proposal. However, the adopted one mainly follows the advice given by the Committee, except on therapeutic cloning.

Regarding the creation of embryos by cell nuclear transfer, however, opinions differ. A majority of the Committee is in favour of a controlled authorisation to engage in therapeutic cloning because of the promising therapeutic possibilities it offers.

3. Position on reproductive cloning

The Committee is unanimously in favour of explicitly prohibiting human reproductive cloning.

C - Links

Minister for Health, Family and Disabled Persons: www.sante.gouv.fr/index.htm

Minister of Research and New Technologies: www.recherche.gouv.fr

National Assembly (Parliament): www.assemblee-nat.fr

National Consultative Bioethics Committee: www.ccne-ethique.fr

Senate (Parliament): www.senat.fr

State's Council: www.conseil-etat.fr

GERMANY

A - The legal situation

The legal aspects of research on embryos and of the harvesting of human embryonic stem cells from embryos are regulated by the Embryo Protection Act of 13 December 1990, which was enacted to prevent the misuse of artificial fertilisation and of *in vitro* embryos. The 1990 Act covers the embryo *in vitro* up to its nidation in the uterus of a woman.

1. Definition of the embryo

In Article 8 (1) of the Embryo Protection Act 1990, an embryo is defined as a « single fertilised human egg cell capable of development, from the time of nuclear fusion onwards, and further any totipotent cell derived from an embryo which is capable, given the further necessary conditions, of dividing and developing into an individual ».

This means that a fertilised and viable human ovum is considered as an embryo from the time of nuclear fusion. The same applies to every totipotent cell taken from an embryo, which is capable of division and development into an individual. During the first 24 hours after nuclear fusion, a human ovum is deemed viable unless it is established before this period of time has elapsed that the human ovum concerned is not capable of developing further that one cell stage.

2. Research on embryos

a - Non-therapeutic research on embryos

The Embryo Protection Act 1990 forbids any embryo research, which is not for the benefit of the concerned embryo. Non-therapeutic research on embryos and on individual totipotent cells is therefore prohibited.

Article 2 (1) of the Act stipulates that it is a criminal offence to dispose of "a human embryo created outside the body or taken from a woman before completion of its nidation in the uterus or to give away, acquire or use it for purposes other than its maintenance". To undertake the "further development of a human embryo outside the body for a purpose other than to give rise to a pregnancy" constitutes a criminal offence as well.

Infringement of the law is sanctioned by imprisonment for up to 3 years or a fine (Article 2).

b - Therapeutic research on embryos

An experiment on an embryo is permitted only when it serves the purpose of preserving the embryo concerned. Such research for therapeutic purposes may require consideration by a multidisciplinary local Ethics Committee that has an advisory function and give recommendations on a case by case basis. The legal framework applying is the Embryo Protection Act 1990 as well. Therapeutic research is lawful on *in vitro* and *in vivo* embryos and on foetuses as long as it serves the purpose of preserving its own life.

It is a criminal offence to use human gametes with artificially modified genetic information for creating *in vitro* embryos for the purpose of procreation (penalty: up to 5 years' imprisonment).

3. Research on human embryonic stem cells

The German legislation does not allow the production of stem cells from fertilised eggs. Article 1 (2) (c) of the Embryo Protection Act 1990 provides that it is an offence to *"*separate and use totipotent cells of an embryo for research and diagnosis*"*. Therefore the harvesting of embryonic human stem cells from an embryo is unlawful.

However, embryonic stem cells research is not completely barred in Germany, as since 30 January 2002, research on imported human embryonic stem cells is authorised. Indeed, last January, a majority of the German Bundestag opted in favour of a motion that would allow research on imported human embryonic stem cells under strict conditions and only on already existing stem cell lines.

4. Importation of human embryonic stem cells

a – Situation as before 30 January 2002

The importation of totipotent stem cells for research purposes was covered by the Embryo Protection Act 1990. Indeed, under the terms of Article (1) (8), totipotent cells are equivalent to embryos. The acquisition and use of embryos for a purpose other than preserving their life is prohibited by Article (2) (1) of the Embryo Protection Act 1990. Thus the importation, which is covered by the term "acquisition", of totipotent stem cells for use in embryonic stem cell research was therefore prohibited in Germany.

The situation regarding the importation of pluripotent embryonic stem cells was different. Indeed, although pluripotent embryonic stem cells are derived from embryos or totipotent cells, they are neither embryos nor totipotent cells, since they can no longer develop into human beings. Thus, the importation of pluripotent stem cells was not specifically prohibited by the Embryo Protection Act 1990.

b – Current situation

Since the decision of the German Bundestag on 30 January 2002, the importation of human embryonic stem cells from already existing stem cell lines is allowed under strict conditions. Both totipotent and multipotent stem cells are covered by this decision.

The conditions for importation are the following ones:

- only already existing stem cell lines produced from surplus embryos created for reproduction are used;
- the informed consent of the donor couple was freely obtained;
- the aims of the research are worthy;
- research applications are assessed by a high-level ethics committee;
- there is a licensing authority to administer the system.

5. Creation of embryos solely for research purposes

The creation of human embryos for research purposes is forbidden by the Embryo Protection Act 1990 Article 2 (1) provides that it is an offence to "any person undertaking the artificial fertilisation of a human egg for a purpose other than to lead to the pregnancy of the woman from whom the egg cell originates (…) will be liable to imprisonment for up to three years or a monetary fine".

6. Human cloning

The Embryo Protection Act 1990 prohibits both therapeutic and reproductive human cloning. Article 6 (1) of the Embryo Protection Act provides that "any person artificially causing a human embryo with the same genetic information as another embryo, foetus, human or cadaver to be created will be punished by imprisonment for up to five years or with a fine". It is deemed that the 'causing a human embryo' includes the creation of embryos by cell nuclear transfer, although the definition of article 8 of the Act assumes that the creation of embryo is by means of the fusion of the cell nuclei of egg and sperm cells (Cf. The Federal Government Report on Cloning dated 26 August 1998). However, an amendment may be added to the Embryo Protection Act 1990 that would result in the specific prohibition of therapeutic cloning.

7. Council of Europe's Convention on Human Rights and Biomedicine

Germany has not signed the Convention on Human Rights and Biomedicine because it found it too permissive regarding embryo protection.

B - Position of the relevant national ethics instances

1. German National Ethics Committee

The Federal Chancellor Gerhard Schröder created the German National Ethics Council in May 2001. The Council primarily focused on the importation of human embryonic stem cells, which was largely debated in Germany at that time. In December 2001, the Council issued its first *Opinion on the import of human embryonic stem cells*.

The majority of the members were for the provisional import of human embryonic stem cells for a limited period only and subject to strict conditions as follow:

- the stem cells must be issued from surplus embryos;
- the couple whose embryo was used to derive stem cells had to have given an informed consent;
- the relevant stem cell line has to have been derived independently form the research project in Germany and before the project was requested;
- the details of the imported stem cell line have to have been recorded at a central public registration office;
- the research project must have a medical aim and its results should not be obtainable in a comparable way with other human cells;
- the scientific quality of the project must be verified by expert review;
- an ethics committee must approve the project;
- the results of the project must be published;
- the import should be permitted for an initial period of three years.

All these conditions should apply equally to state-funded and private research, and they should be satisfied prior to importation.

The Bundestag mainly followed these conditions, and added that only human embryonic stem cells from already isolated embryonic stem cell lines could be imported.

2. Other instances

a - The Central Ethics Commission of the German Medical Association

The Central Ethics Commission of the German Medical Association issued a *Statement on Stem Cell Research* on 23 November 2001. The majority of the Central Ethics Commission is of the opinion that surplus embryos from *in vitro* fertilisation could be used for research and stem cell research purposes (1 dissenting vote). The import of pluripotent of pluripotent stem cells should not be obstructed (4 dissenting votes). However, the creation of human embryos solely for research purposes and reproductive cloning is not ethically justifiable.

b - The German Research Organisation

The German Research Organisation, which is the central public funding organisation for academic research in Germany, called for standardisation and co-operation in human embryonic stem cell research in May 2001. It specifically stated that it considers reproductive and therapeutic cloning as neither scientifically nor ethically responsible.

c - The Study Commission on Law and Ethics in Modern Medicine

The German Bundestag set up this commission on 24 March 2000. It issued a report on stem cell research as well as a supplement focussing on importation problems, entitled *Research in imported human embryonic stem cells*.

C - Links

Bundestag: www.bundestag.de

Central Ethics Commission of the German Medical Association: www.aerzteblatt.de

National Ethics Council: www.nationalerethikrat.de

GREECE

A - The legal situation

Greece does not have any legislation regarding research on embryos or on human embryonic stem cells. However, since Greece ratified the Council of Europe's Convention on Human Rights and Biomedicine and since research on embryos is carried out in Greece, the Greek Government had to establish a protective framework for the embryo. This framework did not have to be a piece of law, as long as it was binding for the scientists carrying out experiments involving embryos. Thus, in 1998, the Greek Central Council for Health, which regulates medically assisted reproduction and also deals with embryo research, issued guidelines on medically assisted reproduction.

1. Research on embryos and on human embryonic stem cells

As regards research on embryos, these guidelines provide as follows:

- research on embryos is authorised only during the first 14 days from fertilisation (excluding any period of storage);
- the consent of the parents is required;
- the approval of the relevant ethics committee must be obtained;
- the left over embryos should be stored and not immediately destroyed;
- the embryos cannot be stored for more than one year, and must be destroyed after that period;
- the informed and written consent of the parents before *in vitro* fertilisation should be obtained.

2. Human cloning

There is no national legislation dealing with human reproductive cloning or with therapeutic cloning. However, it seems that cloning would be unlawful under the Greek Constitution and the general legislation.

Furthermore, the guidelines issued by the Greek Central Council for Health specifically excludes reproductive cloning.

Finally, since the Additional Protocol on the Prohibition of Cloning Human Beings entered into force on 1 March 2001, human cloning is prohibited in Greece.

3. Council of Europe's Convention on Human Rights and Biomedicine

Greece signed the Convention on Human Rights and Biomedicine on 4 April 1997, and ratified it on 6 October 1998. The Convention entered into force in Greece on 1 December 1999.

Greece signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998 and ratified it on 22 December 1998. The Additional Protocol entered into force in Greece on 1 March 2001.

B - Position of the relevant national ethics instances

The National Bioethics Commission, established by law 2667/1998, is an independent advisory body of experts, which shall be subject to the Primeminister. The Commission is expected to be aware about the possible applications of biological sciences. Its mission is to explore their ethical, social and legal impact.

On 21 December 2001, the National Bioethics Commission issued a recommendation "On the use of stem cells in biomedicine and clinical medicine". Until now, however, no legislation has been adopted.

In principle, scientific committees of the hospitals where embryo research is carried out should oversee the research done in their hospitals.

C - LINKS

Ministry of Health and Welfare: www.ypyp.gr

Parliament: www.parliament.gr

National Bioethics Commission: www.bioethics.gr

IRELAND

A - The legal situation

1. Definition of the embryo

The Irish law does not properly define the embryo. Instead of embryo, the Irish Constitution used the term "unborn", which is not defined either.

2. Research on embryos

There is no legislation dealing with research on embryos in Ireland. However, Article 40 (3) (3) of the Section on Fundamental Rights of the Irish Constitution 1937 (as amended in 1983) provides that "the State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right."

Thus, in the Irish constitutional context where protection of the life of the "unborn" prevails, research on embryos is implicitly[14] forbidden. This implicit prohibition applies for both non-therapeutic and therapeutic research on embryos, although the situation is unclear regarding therapeutic research.

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[14] Implicitly, because it is unclear whether the term "unborn" in Article 40 (3) (3) designates not only the *in vivo* embryo but also the *in vitro* embryo, as the term "unborn" has not been legally interpreted. There are two possible interpretations, as follows:
(1) If Article 40 (3) (3) applies from the moment of fertilisation and for both *in vivo* and *in vitro* embryos, the State would have to defend the right to life of the *in vitro* embryo as well. As a result, both embryo and human embryonic stem cell research should be held unconstitutional.
(2) On the contrary, if "unborn" designates the embryo in the womb, then Article 40 (3) (3) would apply from implantation in the womb, and research on *in vitro* embryos could be held lawful.
But in the Irish constitutional context where protection of the life of the unborn prevails, the common interpretation is the first one (1). This is reinforced by the Twenty-fifth Amendment of the Constitution (Protection of Human Life in Pregnancy) Bill 2001, which proposes to add a subsection to Article 40 (3) of the Irish Constitution providing protection to the life of the "unborn in the womb" in accordance with the Protection of Human Life in Pregnancy Act 2002. Indeed, the addition of a subsection providing protection for the "unborn" specifically in the womb, even though this refers to the issue of abortion, suggests that the term "unborn" alone may designate *in vitro* embryos (out of the womb) as much as *in vivo* embryos.

In the same perspective, the creation of embryos solely for research purposes is deemed to be unconstitutional.

3. Research on human embryonic stem cells

There is no legislation dealing with stem cells research in Ireland. However, a Commission on Assisted Human Reproduction was established by the Department of Health and Children on 25 February 2000 in order to "prepare a report on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and legal factors to be taken into account in determining public policy in this area" (Department of Health and Children). This report is expected for late 2002 or early 2003 and will provide a basis for an informed public debate and then policy proposals. This report should address the issue of human embryonic stem cells research.

4. Human cloning

Ireland does not have a specific legislation covering human cloning.

By acknowledging "the right to life of the unborn", Article 40 (3) (3) of the Irish Constitution implicitly forbids research on embryos, but does not cover human cloning. Thus, there is currently no legal prohibition of human cloning in Ireland.

However, the Medical Council Guidelines, which regulate medical activities and medical research would not permit the reproductive cloning of human beings.

5. Council of Europe's Convention on Human Rights and Biomedicine

Ireland has not signed the Convention on Human Rights and Biomedicine.

B - Position of the relevant national ethics instances

The Royal Irish Academy at the request of the Department of Enterprise, Trade and Employment recently established the Irish Council for Bioethics. It has not given any opinion yet.

C - Links

Department of Health and Children: www.doh.ie
Government: www.gov.ie
Health Research board: www.hrb.ie
Irish Council for Bioethics: www.ria.ie

ITALY

A - The legal situation

1. Research on embryos

There is currently no specific legislation governing research on embryos and on human embryonic stem cells in Italy[15].

2. Importation of embryos

An Order issued by the Minister of Health on 25 July 2001 bans the importation and the exportation of human gametes and embryos until 31 December 2001. This period has been extended until 30 June 2002 by a further order dated 18 December 2001, which applies also to another previous order banning the commercialisation of human gametes and embryos.

3. Human cloning

An order issued by the Minister of Health on 5 March 1997 bans all forms of cloning, both human and animal for a period extending until 31 December 2000. This order has been extended three times up to 30 June 2002.

However, the Court of Verona in a 1999 decision stipulated that a mere order, without legal basis, could not prevent scientific research. Therefore, it seems that research into human cloning could take place without infringing the law.

4. Council of Europe's Convention on Human Rights and Biomedicine

Italy signed the Convention on Human Rights and Biomedicine on 4 April 1997, but has not yet ratified it.

Italy signed the additional protocol on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

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[15] There is, however, a law proposal on *in vitro* fertilisation that has been approved by one chamber of the Italian Parliament and is currently (i.e. as in June 2002) discussed before the second chamber. But the proposal covers only medically assisted reproduction, and not research on embryos. It forbids reproductive cloning, which constitutes a criminal offence punishable by 20 years of imprisonment.

B - Position of the relevant national ethics instances

1. The National Bioethics Committee

The Italian National Bioethics Committee was set up following the approval of the resolution n. 6-00038 dated 5 July 1988. Since its creation, in connection with this publication, it has issued: - a *Report on the Identity and Status of the Human Embryo* (22 June 1996); - a *Report on Cloning* (17 October 1997); - an *Opinion on the Convention on Human rights and Biomedicine* (21 February 1997) ; - an *Opinion on the Preliminary Draft Protocol on the Protection of the Human Embryo and Foetus of the Bioethics Committee of the Council of Europe* (31 March 2000); and an *Opinion on the Therapeutic Use of Stem Cells* (27 October 2000).

From all these publications, the position of the National Bioethics Committee can be summarised as follows:

a - Position on stem cell research

The Italian National Bioethics Committee considered that it is possible to use tissues from aborted embryos / foetuses (*Report on the Identity and Status of the Human Embryo*) and that it is ethically legitimate to derive stem cells from the cells of spontaneously aborted foetuses or those produced by voluntary interruption of pregnancy, provided that there is no relation between the abortion and the derivation of stem cells (*Opinion on the Therapeutic Use of Stem Cells*).

Furthermore, in its *Opinion on the Therapeutic Use of Stem Cells*, part of the Committee considered that it is ethically acceptable to derive human embryonic stem cells for therapeutic purposes from embryos that were created during infertility treatments but were no longer suitable for implantation. Consent by the donating woman or couple should be obtained, and research projects should be rigorously assessed by an ethical committee as regards the suitability of the concerned embryo for implantation, the donation consent procedure and the therapeutic purposes of the experimentation. Other members of the National Bioethics Committee were however against using supernumerary or spare embryos for stem cell research in any case.

b - Position on the creation of embryos solely for research purposes and on therapeutic cloning

The National Bioethics Committee opposed the creation of human embryos for the sole purpose of research and considered therapeutic cloning to be morally unacceptable (*Opinion on the Convention on Human Rights and Biomedicine*, *Report on Cloning*, and *Opinion on the Therapeutic Use of Stem Cells*). However, according to some members, “the experimental results of somatic nuclear replacement may suggest that this new line of research could produce therapeutic results of great impact for the beings without any alternative such as to suggest evaluating the ethical aspects of future applications on a case by case basis” (*Opinion on the Therapeutic Use of Stem Cells*).

c - Position on reproductive cloning

The National Bioethics Committee is opposed to reproductive cloning.

2. Report by the Committee formed by the Italian Minister of Health on the use of stem cells for therapeutic purposes

On 28 December 2000, a committee formed by the Italian Minister of Health and presided over by Professor Dulbecco published a report on the use of stem cells for therapeutic purposes. The conclusions of the report favoured both research on supernumerary embryos and therapeutic cloning, thus opposing the position of the National Bioethics Committee on the latest point.

C - Links

Ministry of Health: http://ministerosalute.it

National Bioethics Committee: www.palazzochigi.it/bioetica/ or www.governo.it/bioetica

Parliament: www.camera.it

LUXEMBOURG

A - The legal situation

1. Research on embryos and on human embryonic stem cells

a – Current situation

Luxembourg has no legislation dealing with embryo research, and no embryo research or stem cells research is performed in the country.

b – Law proposal

However, a law proposal on medically assisted reproduction was made in 1998 by the deputy Marc Zanussi (proposal 4567). The proposal provides that the use of surplus embryos should be possible for research having a medical purpose. The informed consent of the parents and the approval of the National Commission of Medicine and Reproductive Biology should be required. The creation of embryos for commercial, industrial or research purposes should be forbidden. But the proposal does not make the distinction between therapeutic research on embryos and non-therapeutic research having a medical purpose.

2. Human cloning

There is no legislation on human cloning in Luxembourg. However, the Health Commission of the Parliament is taking the issue of human cloning into consideration.

3. Council of Europe's Convention on Human Rights and Biomedicine

Luxembourg signed the Convention on Human Rights and Biomedicine on 4 April 1997, but has not yet ratified it.

Luxembourg signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

B - Position of the relevant national ethics instances

The National Consultative Ethics Committee for Life and Health Sciences has issued an *Opinion on the Convention on Human Rights and Biomedicine* that raises the question of embryo research.

Moreover, following a Health Minister's proposal, the Government of Luxembourg agreed on 8 February 2002 to request the formal opinion of the National Consultative Ethics Committee regarding research on *in vitro* embryos for therapeutic purposes and policy recommendations on the question. The Government of Luxembourg is therefore waiting for the report before drafting regulations on embryo research.

C - Links

Government: www.gouvernement.lu/gouv/

National Consultative Ethics Committee for Life and Health Sciences of Luxembourg:

20, Montée de la Pétrusse
L-2912 Luxembourg.

THE NETHERLANDS

A - The legal situation

Before June 2002 and the adoption of the Embryo Act, there was no legislation regarding embryo research in the Netherlands. However, the Ministry of Health asked all research protocols involving embryos to be submitted for approval by the Central Committee for Research Involving Human Subjects (CCMO). The CCMO had to use a 1995 Government Memorandum on Embryo Research when evaluating the research projects. This 1995 Memorandum precluded embryonic stem cell research except on already existing stem cell lines and the creation of embryos for non-reproductive purposes.

Research on human embryos is now covered by the Embryo Act, which was adopted by the Dutch Parliament in June 2002 and will enter into force probably before the end of 2002. This recent piece of law regulates the uses of human gametes and embryos and contains provisions governing the donation of embryos for research, including human embryonic stem cell research.

1. Definition of the embryo and foetus

Section 1 of the Embryo Act defines an embryo as « a cell or a complex of cells with the capacity to develop into a human being » and a foetus as « an embryo in the human body ».

2. Research on embryos

a - General principles regarding research involving embryos and gametes leading to the creation of embryos

All research involving embryos and gametes leading to the creation of embryos must be performed in accordance with a research protocol containing a full description of the intended research and this research protocol must be approved by the Central Committee (Section 3).

The donation of gametes (Section 5) or embryos (Section 8) is allowed by the Act with the following conditions:

- the donors are adults capable of making a reasonable assessment of their interests (Section 5 (1) for gametes and Section 8 (1) for embryos);
- the information was supplied in such a way that it is reasonably certain that it was understood (Section 6);
- a written informed consent was obtained without consideration (Section 5 (2) for gametes and Section 8 (2) for embryos).

With respect to the donation of surplus embryo for research, Section 8 (1) stipulates more specifically that:

"Adults who are capable of making a reasonable assessment of their interests in this regard may make available for the following purposes embryo which have been created outside the body for their own pregnancy, but which will no longer be used for this purpose:

(a) to induce pregnancy in another person;

(b) to culture embryonic cells for medical purposes, medical and biological research and medical and biological education;

(c) to carry out research that is permissible under this Act using those embryos."

The permissible research under the Embryo Act is the following:

b - Non-therapeutic research involving *in vitro* embryos

Division 3 of the Embryo Act regulates « research with embryos outside the human body which does not induce a pregnancy ». Following Section 10, such research is allowed on condition that the required approval by the Central Committee is obtained. This approval will be obtained only if the research can reasonably be expected to "lead in new insights in the field of medical science" and if those "insights" cannot be obtained using other methods.

Additionally, the embryos or the gametes from which they are created have to be made available for research purposes, the written informed consent of the donors must be obtained without consideration (Section 12), and a protocol has to be drafted as required in Section 3.

c - Therapeutic research involving *in vitro* embryos

Division 4 of the Embryo Act regulates « research with embryos outside the human body, which is intended to induce pregnancy ». The required approval by the Central Committee will be delivered only if the research will probably « lead to new insights with regard to research or therapeutic methods that are aimed at inducing pregnancy and the birth of a healthy child », if the expected results cannot be achieved by other less invasive methods, and if « the interests to be served by the research are proportional to the drawbacks and risks for the potential child and the woman » (Section 16).

Additionally, the written consent of the woman and her husband / life companion must be obtained after the giving of information in writing and in such a way that it is reasonably certain that the concerned persons have understood it (Section 17).

d - Therapeutic research involving foetuses

Division 5 of the Embryo Act governs "research with foetuses". Research involving a foetus is allowed only if it is in the interests of the foetus. Section 20 provides that "research using a

foetus is permitted only if it might assist in the diagnosis, prevention or treatment of serious diseases in the foetus concerned and if it cannot be postponed until after birth".

Research concerned with a foetus will be approved by the Central Committee only if the research will probably "lead to new medical insights in relation to unborn and new-born children or regarding the continuation of pregnancies to term", if other less invasive methods of research cannot be used, and if the interests of the research are "proportional to the drawbacks and risks for the foetus and the woman" (Section 19).

Full informed consent must be obtained in writing from the pregnant woman, who must be capable of making a reasonable assessment of her interests, or from her parents, legal representative, guardian, husband or life companion (Section 21).

3. Research on human embryonic stem cells

In addition to research on already existing stem cell lines, which was already allowed before June 2002, the Embryo Act makes it possible to conduct research in order to isolate new embryonic stem cell lines from existing embryos left over after in vitro fertilisation (Section 8 (1) (b)).

The Dutch legislation provides that research involving the isolation of new human embryonic stem cell lines can be carried out on surplus embryos during the 14 days following fertilisation, after consent of the donors has been obtained.

The Central Committee (CCMO) must review all research projects involving embryos and the production of new human embryonic stem cell lines. This requirement does not apply to research projects involving already existing stem cell lines.

4. Creation of embryos solely for research purposes

The Embryo Act enounces, as a general principle, the prohibition of the creation of human embryos solely for research purposes. Section 24 (a) of the Embryo Act bans the creation of human embryos « specifically for research purposes or for purposes other than the induction of a pregnancy ». Thus the creation of human embryos for the purpose of isolating new embryonic stem cell lines is forbidden.

However, this ban is not irreversible and could be lifted by Royal Decree (Section 33 (2)) within five years after the coming into force of the Act. It is therefore more accurate to talk about a moratorium.

Furthermore, the Embryo Act already contains provisions that will enter into force on the date the ban is lifted:

- Section 11 provides as follows: « Carrying out research with embryos created specifically for this purpose is prohibited. This prohibition shall not apply to research which is reasonably likely to lead to new insights in the fields of infertility, artificial reproduction techniques,

hereditary or congenital diseases or transplant medicine, and which can only be performed by making use of embryos as referred to in the first sentence ».

- Section 9 provides that adults « capable of making a reasonable assessment of their interests in this regard may make their gametes available for the creation of embryos specifically for: a. culturing embryonic cells intended for implantation in human where this can only be achieved using cells from specially created embryos; b. carrying out research using those embryos that is permissible under this Act ».

5. Human cloning

Because of this ban / moratorium, the creation of embryos by cell nuclear transfer for research purposes (therapeutic cloning) is precluded in the Netherlands for the moment.

If this ban is lifted, following Section 11 of the Act, therapeutic cloning will then be allowed in order to produce embryonic stem cells to be transplanted on condition that the same results could not be achieved by another means (for example by the transplant of adult stem cells).

6. Council of Europe's Convention on Human Rights and Biomedicine

The Netherlands signed the Convention on Human Rights and Biomedicine on 4 April 1997. It intends to ratify it. However, before ratification and because of the ban / moratorium of Section 33 (2) of the Embryo Act, the Dutch Government intends to make a provision to article 18 (2) of the Convention.

The Netherlands signed the Additional Protocol to the Convention on the Prohibition of Cloning Human Beings on the 4 May 1998, but it has not yet ratified it.

B - Position of the relevant national ethics instances

The Health Council of the Netherlands was established by the first Health Act in 1902. It is an independent pluridisciplinary instance whose task is to advise the Dutch Government on social and scientific issues related to health. The Health Act 1956, as amended in 1997, defines the Health Council's duties as follows: "… to advise the government and the parliament on the current level of knowledge with respect to public health issues…".

1. Position on embryo research and human embryonic stem cell research

In 1997, the Health Council published a first report on research and use of embryonic stem cells. This report focused on the need to take into account embryonic stem cell research while drafting legislation on embryo research. The Council concluded that the research purposes for which embryo research could be allowed should be extended to research of high medical interest and no longer limited any more to research on infertility, medically assisted procreation or genetic diseases.

On 27 June 2002, the Health Council issued a second report dealing with embryonic stem cell research: *Stem cell for tissue repair: Research on therapy using somatic and embryonic stem cells*.

In this second report, the Council concluded (among other points) that research into embryonic stem cells was important for the possible development of new forms of cell therapy and that the creation of new embryonic stem cell lines may be of major importance since the availability of the current cell lines is limited, and those lines may also be contaminated and one-sided in their genetic composition.

Thus it agrees with the Embryo Act that permits isolating new embryonic stem cell lines from spare embryos.

2. Position on therapeutic cloning

In the same report, the Council concluded that the research dealing with cell nuclear transplant was in the long term important for the research dealing with the possibility of preventing rejection, but that there were no urgent scientific reasons based cell research for lifting, in the short term, the moratorium in the Embryo Bill on cell nuclear transplant.

Therefore, it recommended « no ban (statutory or non-statutory) in advance on research into the possibility of nuclear transplants and the creation of new embryonic stem cell lines ».

Furthermore, the Council recommended the inclusion, in the Embryo Act, of research into transplants of human nuclei into animals' egg cells, and the conducting of research into the practicality of using somatic stem cells for transplantation purposes.

C - Links

Dutch Parliament: www.parlement.nl

Health Council: www.gr.nl

Minister of Health: www.minvws.nl

PORTUGAL

A - The legal situation

1. Research on embryos

There is currently no specific national legislation either on medically assisted procreation or on research involving embryos or human embryonic stem cells.

The Ministry of Health has elaborated a law proposal to regulate assisted reproduction techniques, which was approved by the Parliament in 1998. However, this proposal had encountered a veto from the President of the Portuguese Republic in 1999. As a result, there is not yet any national legislation regulating medically assisted procreation.

Consequently, the legal status of the *in vitro* embryo is not established despite two propositions on the Civil Code (regarding the establishment of paternity) and on the Penal Code.

Furthermore, since Portugal ratified the Convention on Human Rights and Biomedicine, Article 18 of the Convention applies, which means that, in the absence of a protective framework for the embryo, embryo research cannot be carried out.

2. Creation of embryos solely for research purposes

Although the Portuguese law does not deal with the creation of human embryos solely for research purposes, it is now forbidden in Portugal because of the ratification of the Convention on Human Rights and Biomedicine. Indeed, Article 18 (2) prohibits the creation of embryos for research purposes.

3. Human cloning

There are no national regulations on human cloning in Portugal. But since 1 December 2001, cloning human beings is prohibited because of the ratification of the Additional Protocol on the Prohibition of Cloning Human Beings.

4. Council of Europe's Convention on Human Rights and Biomedicine

Portugal signed the Convention on Human Rights and Biomedicine on 4 April 1997, and ratified it on 13 August 2001. The Convention entered into force on 1 December 2001.

Portugal signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998, and ratified it on 13 August 2001. The Additional Protocol entered into force on 1 December 2001.

B - Position of the relevant national ethics instances

The Portuguese National Council of Ethics for the Life Sciences published the following relevant opinions:

- *Report-Opinion 3/CNECV/93 on Medically-Assisted Reproduction*, issued on 1 February 1993;
- *Report-Opinion 15/CNECV/95 on Experimentation on the Human Embryo*, issued on 4 October 1995;
- *Opinion 21/CNECV/97 on the Ethical Implications of Cloning*, issued on 1 April 1997.

1. Position on embryo research

The Portuguese National Council of Ethics considers that research on embryos is not ethically acceptable with regard to the special status of the embryo. In its *Opinion on Experimentation on the Human Embryo* from 1995, it stipulates that "it is seriously illicit to conduct upon embryo experimentation from which it will not benefit and which, on the contrary, will lead to its destruction (since any embryo subjected to experimentation may not be implanted in the uterus)".

The National Council of Ethics founds its position on Article 24 of the Portuguese Constitution that establishes the inviolability of human life. Consequently, as « it seems impossible to deny the existence of a new human life in the embryo as from syngamy, the embryo cannot be the object of any experimentation that leads, or might lead, to its destruction. »

Although the National Council does not adopt a specific definition of the embryo and foetus, it mentions in its report that the real start of a new human life is the fertilisation of the egg by the sperm, precisely when two pronuclei (one maternal and one paternal) fusion. Therefore, experimentation could be possible, namely on the ovum after penetration by the sperm, but before the fusion of the nuclei. In its conclusions, the National Council says that « there are no objections to the utilisation, for experimental purposes, of activated oocytes (pathenotes); nor, though with some reserve, to the recourse to fertilised oocytes, so long as the fusion of the pronuclei (syngamy) has not yet taken place ».

Practically, this means that research carried out on gametes (including studies of cryopreservation, maturation and parthenogenesis using oocytes) prior to syngamy is ethically acceptable. But research carried out on the embryo following syngamy is ethically unacceptable.

Research carried out with the intention of benefiting the embryo should also be prohibited in the present state of scientific knowledge, but may in the future be ethically acceptable. This should be distinguished from experimental therapy that is acceptable so long as the general principles that regulate experimental therapy are respected.

The National Council recommends avoiding the creation of surplus embryos.

The Committee called for the elaboration of a specific regulation on medically assisted procreation and on the status of the embryo to avoid the legal limbo resulting from the absence of legislation.

2. Position on human embryonic stem cell research

The National Council of Ethics mentioned the issue of human stem cells in its 1999 annual report, but has not yet issued an opinion on the subject. In pursuance to its position on embryo research, the National Council of Ethics is likely to oppose human embryonic stem cell research.

3. Position on human cloning

In its *Opinion on the Ethical Implications of Cloning* dated 1997, the National Council of Ethics of Portugal states that "the cloning of human beings, because of the problems it raises concerning the dignity of the human person, the equilibrium of the human species and life in society, is ethically unacceptable and must be prohibited."

Focusing on the analysis of the ethical issues of cloning, the opinion of the council is mainly founded on the dignity of the human person, which precludes being used as an object or instrument for whatever purposes and on a previous opinion, which excludes "the creation of genetically identical human beings through cloning or other means" as a form of "instrumentalisation of the reproductive process". The Council considers that "the deliberate production of genetically identical human beings […] would entail an intolerable instrumentalisation of such production".

No distinction is made between reproductive and therapeutic cloning. It is worth remembering that in 1997, stem cells research and therapeutic cloning were not an issue.

C - Links

Parliament: www.parlamento.pt

Portuguese National Council of Ethics for the Life Sciences: www.cnecv.gov.pt

SPAIN

A - The legal situation

The law 35/1988 on Assisted Reproduction Techniques of 22 November 1988, the law 42/1988 on Donation and Use of Human Embryos and Foetuses or their Cells, Tissues or Organs of 28 December 1988, and two Constitutional Rulings of 1996 (STC 212/96) and of 1999 (STC 116/99) constitute the Spanish legal framework regarding research on human embryos and human embryonic stem cells.

1. Definition of the embryo

The law 35/1988 on Assisted Reproduction Techniques defines and distinguishes the pre-embryo, the embryo and the foetus. The term « pre-embryo » designates an embryo from fecondation until it is 14 days old. The term « embryo » designates an embryo aged from 15 days until three months. This period corresponds with the formation of organs. The term « foetus » is use for embryos of more than three months.

The law 35/1988 on Assisted Reproduction Techniques regulates the creation and use of « pre-embryos » of less than 15 days. The law 42/1988 on Donation and Use of Human Embryos and Foetuses or their Cells, Tissues or Organs provides the conditions for the donation of « embryos » of more than 14 days and their cells, tissues and organs.

2. Research on embryos

a - Research on "pre-embryos"

When setting conditions upon which research can be carried out on embryos of less than 15 days, the Assisted Reproduction Techniques Act distinguishes between the viable[16], non-viable, dead and aborted nature of the "pre-embryos":

- Research on **viable** *in vitro* "pre-embryos" can only be carried out for therapeutic, diagnostic or prophylactic purposes, and on condition that no change is made to the genetic non-pathologic inheritance of the embryo.
- Non-therapeutic research is permitted on **non-viable** and on **dead** "pre-embryos", excluding voluntary aborted embryos.
- All kind of research on **in vivo** or voluntary **aborted** "pre-embryos" is forbidden.

[16] Viable means "biologically" competent and non-viable means "biologically" incompetent.

Furthermore, Section 15 of the Act outlines the required conditions that all kinds of research on human "pre-embryos" must satisfy:

- the progenitors must give their informed consent in writing;
- the research cannot be done on animals;
- the pre-embryo does not develop in vitro for more than 14 days;
- the research is carried out by agreed centres and qualified teams of professionals.

b - Research on "embryos" and "foetuses"

Non-viable or dead "embryos" and "foetuses" can be used for diagnostic, therapeutic, pharmacological, clinical, surgical or non-therapeutic research purposes in the conditions defined by the law regarding the use of "pre-embryos" (free informed consent in writing of the donors, no abortion, qualified medical team).

In 1989 the constitutionality of the law 35/1988 on Assisted Reproduction Techniques was challenged by the popular party (then in the opposition) before the Constitutional Court. One of the grounds of the claim was that the Act breached the mandatory constitutional protection of human life contained in Article 15 of the Spanish Constitution by not protecting the embryo. The claim failed after the Constitutional Court ruled on 17 June 1999 that the Assisted Reproduction Techniques Act was in accordance with the Spanish Constitution.

The relevant aspects of the Constitutional Court decision regarding research on embryos are as follows:

- Article 15 of the Spanish Constitution does not recognise a fundamental right to life to unborn human beings.
- However, unborn human beings (and thus *in vivo* and *in vitro* embryos) deserve some protection under a rather constitutionally protected interest.
- *In vitro* "pre-embryos" do not deserve the same protection as *in vivo* "pre-embryos". Thus interventions such as diagnosis, therapy and prevention are only allowed on *in vitro* "pre-embryos".
- This protection is only applicable to the **viable** embryo. This means that non-viable embryos have no legal protection under the Spanish Constitution. The debate has been focused on the clarification of the meaning of non-viability. Some people considered that a non-viable embryo is an embryo which is "biologically" incompetent. Others argued that it designates an embryo which is not going to be transferred into a woman's womb and is therefore considered as "functionally" incompetent. This last definition of non-viability would have allowed the use of surplus embryos for non-therapeutic research.

However, in the 1999 Constitutional Court decision, non-viability was deemed to refer only to a biological competence, thus a surplus "pre-embryo" is viable even though it is not transferred into a woman. Non-therapeutic research can therefore only be carried out on biologically non-

viable embryos (either *in vitro* "pre-embryos" or embryos), and not on surplus "pre-embryos" that are biologically competent.

3. Research on human embryonic stem cells

There are no specific regulations on human embryonic stem cell research in Spain.

Pursuant to the Act on Assisted Reproduction Techniques, the harvesting of human embryonic stem cells can only take place on biologically non-viable "pre-embryos", as non-therapeutic research can only take place on non-viable "pre-embryos" or "embryos", and if the research cannot be done on animals. Therefore, surplus embryos cannot be used for embryonic stem cell research purposes.[17]

Furthermore, it is unclear whether Spanish law allows the importation of already isolated human embryonic stem cells for research purposes. The current Spanish Government opposes the carrying out of such research anyway.

4. Creation of embryos solely for research purposes

Section 20 of the Act 35/1988 prohibits the creation of human embryos for purposes other than reproduction.

Additionally, the Act prohibits the creation of chimeras or hybrids.

5. Human cloning

As the law 35/1988 prohibits the creation of human embryos for purposes other than reproduction, therapeutic cloning is not permitted.

As regards reproductive cloning, since 1995, Article 161-2 of the Spanish Penal Code prohibits cloning of human beings. Such an action would be punished by imprisonment from one to five years and suspension of professional activities for six to ten years.

6. Council of Europe's Convention on Human Rights and Biomedicine

Spain signed the Convention on Human Rights and Biomedicine on 4 April 1997 and ratified it on 1 September 1999. The Convention entered into force in Spain on 1 January 2000.

Spain signed the Additional Protocol on the Prohibition of Cloning Human beings on 12 January 1998 and ratified it on 24 January 2000. The Protocol entered into force on 1 March 2001.

[17] It is important to note that the cryopreservation of embryos is allowed by Spanish law, which means that having surplus embryos is not excluded.

Both pieces of law are now part of the Spanish legal framework dealing with research on human embryos, human embryonic stem cells and human cloning.

B - Position of the relevant national ethics instances

1. The National Commission on Human Artificial Reproduction

The National Commission on Human Artificial Reproduction was created by the law 35/1988 on Assisted Reproduction Techniques in order to supervise the correct application of this Act. It gained its full status in 1999, only after the Constitutional Court decision was released. The National Commission on Human Artificial Reproduction, which has an advisory function, is in favour of using surplus embryos from *in vitro* fertilisation and stored embryos for research purposes. The Commission is also in favour of therapeutic cloning and recommends modifying the law.

2. The Ethics Committee (Spanish Foundation for Science and Technology, Ministry of Science and Technology)

The Ministry of Science and Technology created the Ethics Committee in April 2002. It has an advisory function to the Government. By contrast with the National Commission on Human Artificial Reproduction, the Ethics Committee is opposed to the use of human embryos for research purposes.

3. The Bioethics and Law Observatory

The Opinion Group of the Bioethics and Law Observatory, based in the Scientific Park of Barcelona, was formed to study the ethical, social and legal implications of new biotechnology techniques and to make proposals for legislative action (advisory function as well).

a - Position on embryo research and on the creation of embryos solely for research purposes

In its *Declaration on Embryo Research* dated July 2000, the Group considers that research involving in vitro embryos is not objectionable and should not be limited to purely diagnostic or therapeutic purposes, but should be extended to scientific purposes. Non-therapeutic research should also be carried out in the following cases:

- on left over embryos with the consent of the donors;
- on embryos « created expressly for research into pathologies suffered by the donor couples »;
- on embryos « created from gametes donated for research purposes and not in connection with any fertility project »;
- on « somatic embryos obtained by cloning ».

Such research projects should only take place within the first 14 days of development of the embryo and should be evaluated, regulated, approved and controlled by the competent body. Embryos used for non-therapeutic research should not be transferred. Finally, the creation of gametic embryos for research purposes should only take place if the same results cannot be obtained by using animal models, surplus embryos or somatic embryos.

b - Position on human embryonic stem cell research and on therapeutic cloning

In its *Declaration on Embryonic Stem Cells* dated December 2001, the Group recommends the modification of the Spanish legislation in order to allow scientists to obtain embryonic stem cells for research purposes. The Group considers that the use of human embryonic stem cells for therapeutic and research purposes is acceptable in the following cases and provided that informed consent of the donors has been obtained:

- stem cells obtained from spare embryos donated for the purpose of scientific research;
- stem cells obtained from non-transferable *in vitro* embryos;
- stem cells obtained from frozen embryos that have exceeded the legally permitted cryopreservation period;
- stem cells obtained from embryos created by cell nuclear transfer;
- stem cells obtained from gametic embryos (i.e. created for the creation of stem cells using human gametes).

Such projects should be evaluated, regulated, approved and controlled by a competent authority. The creation of embryos from human gametes is « recommendable if it is not possible to use spare embryos donated for research purposes », or embryos that have become available for the reasons outlined above. It says that the obtaining of embryonic stem cells in these ways is justifiable « in the absence of proof that identical results can be obtained in all respects by using foetal or adult stem cells ».

4. The Spanish Committee of Experts on Cloning

In its report dated June 1999, the Spanish Committee of Experts in Cloning supports the lifting of the existing ban on therapeutic cloning. The Committee is however strictly opposed to the legalisation of human reproductive cloning.

5. The Spanish Royal Academy of Medicine

In March 2002, the Spanish Royal Academy of Medicine declared its opposition to any use of human embryos for research purposes. It said that all supernumerary embryos should be used for implantation into women. It also rejected human embryonic stem cell research because the harvesting of stem cells from an embryo entails its destruction, and the importation of human embryos for research purposes. Finally, the Academy is against both reproductive and therapeutic cloning.

C - Links

Bioethics and Law Observatory: www.ub.es/fildt/bioetica.htm

Ministry of Health: www.msc.es

Ministry of Science and Technology: www.mcyt.es

Parliament: www.congreso.es

SWEDEN

A - The legal situation

The Act (1991: 115) on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova issued on 14 March 1991 defines the conditions under which research on human embryos and human embryonic stem cells can be performed. The Health and Medical Care Act (1992: 763) applies as well.

1. Definition of the embryo

Instead of the term embryo, the 1991 Act on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova generally uses the expression "fertilised (human) ovum".

2. Research on embryos

Non-therapeutic research on surplus *in vitro* embryos is allowed until day 14, after which the embryo must be destroyed. The research projects must be carried out for the following purposes:

- to improve infertility treatments;
- to improve contraceptive methods;
- to develop the knowledge of the embryonic development and the causes of defects.

Section 2 of the 1991 Act provides that "experiments on fertilised ova for purposes of research or treatment may be performed, at most, up to and including the fourteenth day after fertilisation. Experiments may not have the purpose of developing methods for achieving potentially hereditary genetic effects".

Consent of the donors must be obtained. Section 1 of the 1991 Act on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova states that "measures under this Act involving fertilised human ova require the consent of the donors of ova and sperm cells".

Pursuant to Section 2 and Section 4 of the 1991 Act, a fertilised ovum, an ovum before fertilisation or the sperm cells used for fertilisation that have been subject of experimentation must not be implanted in a woman's womb. They must be destroyed without delay.

All research projects must be submitted to an Ethics Committee.

3. Research on human embryonic stem cells

Although the 1991 Act on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova was enacted before human embryonic stem cell research took place, it covers such a research.

As stem cell research elucidates mechanisms for cell differentiation, it was deemed to fall within the third category of authorised research projects (to develop knowledge of the embryonic development and the causes of defects) by the Ethics Committees and the Swedish Research Council. Thus the 1991 Act does not forbid stem cell research. A large number of human embryonic stem cell lines have been isolated in Sweden, which is one of the leading countries in the field of stem cell research so far.

4. Creation of embryos solely for research purposes

The production of human embryos solely for research purposes is not allowed according to the 1991 Act on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova.

5. Human cloning

The Swedish legislation has been interpreted as containing an implied prohibition to cloning human beings: "If a fertilised ovum has been the subject of experimentation for the purposes of research or treatment, it may not be implanted in a woman's body. The same applies if the ovum, before fertilisation, or the sperm cells used for fertilisation have been a subject of experimentation" (Section 4 of the 1991 Act on Measures for Purposes of Research and Treatment Involving Fertilised Human Ova).

Reproductive cloning seems to be embodied in this prohibition.

Therapeutic cloning does not fall within the scope of Section 4. Swedish law could be interpreted as implicitly forbidding therapeutic cloning because it prohibits the production of embryos solely for research purposes. But there is a legal vacuum as regards therapeutic cloning.

6. Council of Europe's Convention on Human Rights and Biomedicine

Sweden signed the Convention on Human Rights and Biomedicine on 4 April 1997, but has not yet ratified it.

Sweden signed the Additional Protocol on the Prohibition of Cloning Human Beings on 12 January 1998, but has not yet ratified it.

B - Position of the relevant national ethics instances

1. Position on human embryonic stem cell research

The Swedish Research Council issued ethical guidelines for stem cell research in December 2001. The Council considered that the use of embryos in research is ethically acceptable if there is no alternative to obtain equivalent results and if the project is judged to be necessary for the advancement of stem cell research.

Stem cells may be taken from surplus embryos created for *in vitro* fertilisation purposes. The embryos cannot be older than 14 days. The donating couples have to give their informed consent. Embryos that have been frozen for possible later use may be used for stem cell research providing that their storage is to be terminated (legal period of five years) and that the donating couple has given its informed consent.

The number of embryos used to implement the research project must be limited to the necessary number.

2. Position on the creation of embryos solely for research purposes

The guidelines do not accept the creation of human embryos from eggs and sperm solely for research purposes.

3. Position on therapeutic cloning

However, in the same guidelines the Council found that the creation of embryos by somatic cell nuclear transfer to get access to stem cells is ethically defensible, because of the prospect for major long-term advances in treating diseases. Thus, a distinction is drawn between the creation of embryos by fertilisation and the creation of embryos by cell nuclear transfer.

Consequently, as the current legislation does not allow therapeutic cloning, the Council proposes a review of the legislation.

Therapeutic cloning should be subject to the following conditions :

- A government authority should issue a licence and monitor the research activities ;
- Legislation prohibiting the implantation of embryos created by somatic cell nuclear transfer should be adopted.

As Sweden has signed the European Convention on Human Rights and Biomedicine according to which human embryos cannot be produced for research purposes, Sweden would therefore be obliged to make a reservation in respect of Article 18 (2) of the Convention before ratification in order to be able to legalise therapeutic cloning.

The Swedish Research Council judges the commercialisation of embryos and stem cells to be incompatible with ethical research and recommends that such a commercialisation should be established as a criminal offence.

C - Links

Swedish National Ethics Council: www.smer.gov.se

Swedish Research Council: www.vr.se/english/

UNITED KINGDOM

A - The legal situation

The Human Fertilisation and Embryology Act 1990 regulates the practice of assisted reproduction and embryo research. The Warnock Committee' s report on human fertilisation and embryology (dated 1985) formed the basis of this piece of law. The Act sets up a statutory body, the Human Fertilisation and Embryology Authority, which regulates the activities which are authorised under the Act.

1. Definition of the embryo

Section 1 (1) of the Human Fertilisation and Embryology Act 1990 states that the term " (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".

2. Research on embryos and creation of embryos solely for research purposes

a - General conditions

Research on either spare human embryos or human embryos created for research purposes is allowed under strict conditions and provided that the required licence has been granted by the Human Fertilisation and Embryology Act 1990. Research on embryos older than 14 days is prohibited. Embryos can be stored for a period not exceeding five years, and then must be destroyed (Section 14 (4)).

Section 3 (1) of the Human Fertilisation and Embryology Act 1990 prohibits the creation, the keeping or the use of a human embryo outside the human body without a licence, and Section 3 (3) lists the activities that a licence cannot authorise:

- keeping or using an embryo after the appearance of the primitive streak[18],
- placing an embryo in any animal,
- keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or

[18] Following Section 3 (4), "the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored".

- replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.

b - Licences for research

Schedule 2 of the Human Fertilisation and Embryology Act 1990 lists the three different types of licences that can be issued under the Act: - licences for treatments; - licences for storage of embryos and gametes; - licences for research on embryos. A licence for research may authorise the "creation of embryos in vitro", and the "keeping or using of embryos" (Schedule 2 (3) (1)).

In order for a research licence to be issued, the Fertilisation and Embryology Authority must be satisfied that firstly the use of human embryos is necessary for the purposes of the research (Section 3 (6)) and that secondly the research activity is "necessary or desirable" for one of the following purposes stated in Schedule 2 (3) (2):

- promoting advances in the treatment of infertility,
- increasing knowledge about the causes of congenital disease,
- increasing knowledge about the causes of miscarriages,
- developing more effective techniques of contraception, or
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,

or for such other purposes as may be specified in regulations.

These other purposes must aim to "increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied". Consequently, although the law does not distinguish between research on embryos for therapeutic purposes and for non-therapeutic purposes, and although the latter is not forbidden in principle, it is strictly limited by the 1990 Act. Until 2001, it did not include stem cell research.

It is the Human Fertilisation and Embryology Authority that is in charge of supervising the licensing process. All applications for research licences are subjected to peer review, and the Human Fertilisation and Embryology Authority insists on the fact that it must be satisfied that the use of embryos is essential for the purpose of the research project before granting a licence.

3. Research on human embryonic stem cells and on therapeutic cloning

The Human Fertilisation and Embryology Act 1990 was completed by the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, which were passed by the House of Lords on 22 January 2001 (Statutory Instrument 2001 n. 188). They were drafted following the recommendations made by the Expert group chaired by the Chief Medical Officer in its report dated August 2000, *Stem Cell Research: medical progress with responsibility* (see above).

The 2001 Regulations make research on human embryonic stem cells and on therapeutic cloning lawful in the United Kingdom since January 2001. They amend the 1990 Act to include further purposes for which embryo research is allowed, so as to permit the use of human embryos up to 14 days old for research on the derivation and potential of human embryonic stem cells. The creation of embryos by somatic cell nuclear transfer for stem cell research is also legal under the 2001 Regulations. Section 2 (2) provides that a licence for research may be issued for the following purposes:

- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease, or
- enabling any such knowledge to be applied in developing treatments for serious disease.

These purposes have to be added to the ones listed in Schedule 2 (3) (2) of the 1990 Act. Thus the producing of stem cells from blastocyst-stage embryos, whether these were donated by *in vitro* fertilisation patients, created *in vitro* for research purposes, or produced by somatic cell nuclear transfer, can be licensed.

In November 2001, an Administrative Court Judge ruled that cloning by somatic cell nuclear transfer, whether for creating stem cells or babies, could not be regulated by the Human Fertilisation and Embryology Act 1990, since an organism created by cell nuclear transplant did not fall within the definition of an embryo contained in Section 1 (1) of the 1990 Act (i.e. an embryo is the product of fertilisation)[19].

The British Government appealed against the decision of the Administrative Court Judge in order to bring the technique of somatic cell nuclear transplant back within the scope of the Human Fertilisation and Embryology Act 1990 and to avoid the technique being ungoverned by the law. On 18 January 2002, the Court of Appeal reversed the decision and refused leave to petition to the House of Lords (highest Court in the United Kingdom), which means that the decision cannot be appealed anymore. Thus it was held that an organism created by somatic cell nuclear transfer fell within the definition of an embryo contained in Section 1 of the 1990 Act, and that therapeutic cloning was within the scope of the Act[20].

4. Human reproductive cloning

The Human Reproductive Cloning Act 2001, which was introduced to the Parliament on 21 November 2001 and came into force on 4 December 2001, prohibits reproductive cloning by rendering it a criminal offence to « place in a woman a human embryo which has been created otherwise than by fertilisation ». A person guilty of such an offence is liable to a term of imprisonment not exceeding 10 years and/or a fine.

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[19] See *R (on the application Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health*.

[20] See *R (on the application Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health (CA)*.

This piece of law was rushed before the Parliament in order to avoid a legal *vacuum* regarding reproductive cloning following the November 2001 decision and before the Court of Appeal decision as regards the capacity of the Human Fertilisation and Embryology Authority to govern reproductive cloning.

5. Council of Europe's Convention on Human Rights and Biomedicine

The United Kingdom has neither signed nor ratified the Convention on Human Rights and Biomedicine.

The United Kingdom has neither signed nor ratified the Additional Protocol on the Prohibition of Cloning Human Beings.

B - Position of the relevant national ethics instances

In the United Kingdom, there is one internationally recognised independent Bioethics committee, the Nuffield Council on Bioethics. In addition, several committees have been appointed by the British Government to report on the scientific, legal and ethical issues raised by human embryonic stem cell research and therapeutic cloning[21].

1. The Nuffield Council on Bioethics

Stem Cell Therapy: the ethical issues

The Nuffield Council on Bioethics was established by the Trustees of the Nuffield Foundation in 1991 to identify, examine and report on the ethical questions raised by recent advances in biological and medical research. The Council is an independent body, which provides advice that assists policy-making. In April 2000, the Nuffield Council on Bioethics published a discussion paper: *Stem Cell Therapy: the ethical issues*.

a – Position on human embryonic stem cell research

The Council concluded that « the removal and cultivation of stem cells from a donated embryo does not indicate a lack of respect for the embryo ». The Council considered that there were « no grounds for making a moral distinction between research into diagnostic methods or reproduction which is permitted under the UK legislation and research into potential therapies which is not permitted ». The Council therefore recommended that « research involving human embryos be permitted for the purpose of developing tissues to treat diseases from derived

[21] In the same line, the Warnock Committee was appointed in 1985 by the British Government to report on embryo research.

embryonic stem cells and that Schedule 2 of the Human Fertilisation and Embryology Act be amended accordingly ». Since then, the Act has been amended in that sense.

b – Position on the creation of embryos *in vitro* solely for research purposes

The Council considered that while there is a sufficient number of donated surplus embryos for use in research, there is no reason to allow embryos to be created solely for research purposes. However, the Council suggested that the issue be kept under review.

c – Position on therapeutic cloning

The same does not apply to therapeutic cloning or the creation of embryos by somatic cell nuclear transfer for research into the derivation of stem cells. The Council considered that the « creation of embryos using somatic cell nuclear transfer for research into the derivation of stem cells offers such significant potential medical benefits that research for such purposes should be licensed ». Thus the Council recommended that « Schedule 2 of the Human Fertilisation and Embryology Act be amended to permit research involving embryos for the additional purpose of developing tissue therapies from derived embryonic stem cells ». This recommendation has also been adopted.

2. The Human Genetics Advisory Committee

Cloning Issues in Reproduction, Science and Medicine

In June 1999, the Human Fertilisation and Embryology Authority and the Human Genetics Advisory Committee issued a report entitled *Cloning Issues in Reproduction, Science and Medicine*. The report drew a distinction between reproductive cloning and therapeutic cloning, and was clearly influenced by the potential therapeutic benefits of human embryonic stem cells. Consequently, the report recommended to the Secretary of State for Health that two new purposes be added to the original list of purposes for which research licences could be issued:

- developing methods of therapy for mitochondrial diseases, and
- developing methods of therapy for diseased or damaged tissues or organs.

Both purposes match the aims pursued by human embryonic stem cell research.

In response to this recommendation, the British Government established an Expert Group chaired by the Chief Medical Officer with the task of examining the scientific implications of somatic cell nuclear transfer in embryo research.

3. The Chief Medical Officer's Expert Group

Stem Cell Research: medical progress with responsibility

In September 1999, the British Government set up an Expert Group chaired by the Chief Medical Officer to review the potential of developments in stem cell research and cell nuclear replacement to benefit human health, and to make proposals in order to update the list of authorised activities for the granting of research licences. The results of this review were published in a report dated August 2000, *Stem Cell Research: medical progress with responsibility*, also called the Donaldson report.

This report formed the basis for the drafting of the Regulations 2001. Its principal recommendation was that "research using embryos (whether created by in vitro fertilisation or cell nuclear replacement) to increase understanding about human disease and disorders and their cell-based treatments should be permitted, subject to the controls in the Human Fertilisation and Embryology Act 1990".

4. The House of Lords Select Committee on Stem Cell Research

Report on Stem Cell Research

On 7 March 2001, the Select Committee was appointed by the House of Lords to consider and report on the issues connected with human cloning and stem cell research and on the concerns arising from the Human Fertilisation (Research Purposes) Regulations 2001. Indeed, concerns were expressed as to the unnecessary dimension of these regulations, as to their unethical aspect and as to the fact that they represented a step toward human reproductive cloning.

In the conclusions of its report on Stem Cell research published on 13 February 2002, the Select encourages research into embryonic stem cells and therapeutic cloning as regulated by the Regulations. It also endorses the legislative prohibition of human reproductive cloning contained in the Human Reproductive Cloning Act 2001, and the Department of Health proposal to establish a stem cell bank. Any stem cell line derived under a research licence should be registered in the bank, and before granting any new licence, the Human Fertilisation and Embryology Authority should ensure that there are no existing stem cell lines in the bank suitable for the proposed research project.

In addition, the Select Committee makes several recommendations to the Government such as, among others:

- undertaking of a further review of scientific developments, particularly of the progress in adult stem cell research, and of the development of a stem cell bank, in order to determine whether embryo research is still necessary;
- keeping under review of the funding of the Human Fertilisation and Embryology Authority;
- keeping under review of the outcomes of research licensed on a regular basis;

- establishing a body similar to the Gene Therapy Advisory Committee, which would oversee clinical studies involving stem cells, or extending the role of the Gene Therapy Advisory Committee to achieve the same ends;
- examining with the Human Fertilisation and Embryology Authority the drawing of guidance as to what constitutes "serious diseases" in the Human Fertilisation and Embryology 9Research Purposes) Regulations 2001;
- The Human Fertilisation and Embryology Authority should ensure that the implications arising from the "immortality"of stem cell lines are fully covered in obtaining informed consent from the donors giving embryos.

In addition, the following institutions are also linked to research involving human embryonic stem cells: the British Medical Association, the Medical Research Council, the Royal Society, and the Welcome Trust.

C - Links

HMOS ("Her Majesty's Stationery Office" for official publications by the Government): www.hmso.gov.uk

Department of Health: www.doh.gov.uk

Nuffield Council on Bioethics: www.nuffieldfoundation.org/bioethics/

Parliament (House of Lords and House of Commons): www.parliament.the-stationery-office.co.uk

ANNEX

A - Council of Europe

1. Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS no.: 164)

The Convention on Human Rights and Biomedicine opened for signature in Oviedo (Spain) on 4 April 1997 and entered into force on 1 December 1999.

With regard to embryo research, the following articles are relevant:

Article 18 – Research on embryos *in vitro*

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
2. The creation of human embryos for research purposes is prohibited.

Article 36 – Reservations

3. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.
4. Any reservation made under this article shall contain a brief statement of the relevant law.
5. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.
6. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

2. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (ETS no.: 168)

This Additional Protocol opened for signature in Paris (France) on 12 January 1998 and entered into force on 1 March 2001.

Its most relevant content is as follows:

The member States of the Council of Europe, the other States and the European Community Signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,
Noting scientific developments in the field of mammal cloning, particularly through embryo splitting and nuclear transfer;
Mindful of the progress that some cloning techniques themselves may bring to scientific knowledge and its medical application;
Considering that the cloning of human beings may become a technical possibility;
Having noted that embryo splitting may occur naturally and sometimes result in the birth of genetically identical twins;
Considering however that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine;
Considering also the serious difficulties of a medical, psychological and social nature that such a deliberate biomedical practice might imply for all the individuals involved;
Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings,
Have agreed as follows:

Article 1

1. Any intervention seeking to create a human being[22] genetically identical to another human being, whether living or dead, is prohibited.
2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.

3. Links

Council of Europe, Steering Committee on Bioethics (CDBI):
www.coe.int/T/E/Legal_affairs/Legal_co-operation/Bioethics/

Full text of the Convention on Human Rights and Biomedicine:
http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm

[22] Cf. Point 6 of the Explanatory Report to the Additional Protocol on the Prohibition of Cloning Human Beings: "in conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression "human being" for the purposes of the application of the present Protocol". The Explanatory Report is not an instrument providing an authoritative interpretation of the text of the Protocol, but it facilitates the understanding of its provisions.

Full text of the Additonal Protocol on the Prohibition of Cloning Human Beings:
http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm

B - European Group on Ethics in Science and New Technologies to the European Commission

1. Opinions

With regard to research on embryos and on human embryonic stem cells, the most relevant opinions are the following:

- *Opinion 9 on the Ethical Aspects of Cloning Techniques* (28 Mai 1997);
- *Opinion 12 on the Ethical Aspects of Research involving the Use of Human Embryo in the context of the 5th Framework* (23 November 1998);
- *Opinion 15 on the Ethical Aspects of Human Stem Cell Research and Use* (14 November 2000);
- *Opinion 16 on the Ethical Aspects of Patenting Inventions involving Human Stem Cells* (7 May 2002).

2. Links

European Group on Ethics in Science and New Technologies to the European Commission:
http://europa.eu.int/comm/european_group_ethics/index_en.htm

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