*European Economic and Social Committee*

**INT/205**
**Amendment specific RTD programmes - Strengthening the European research area**

Brussels, 29 October 2003

# OPINION

of the European Economic and Social Committee

on the

**Proposal for a Council Decision amending Decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)**

COM(2003) 390 final - 2003/0151 (CNS)

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On 25 July 2003 the Council decided to consult the European Economic and Social Committee, under Article 166 of the Treaty establishing the European Community, on the

> *Proposal for a Council Decision amending Decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)*
> (COM(2003) 390 final - 2002/0151 (CNS)).

The Bureau of the European Economic and Social Committee instructed the Section for the Single Market, Production and Consumption to prepare the Committee's work on the subject.

In view of the urgent nature of the work, the Committee decided at its 403rd plenary session of 29 and 30 October 2003 (meeting of 29 October) to appoint **Mr Wolf** as rapporteur-general and adopted the following opinion by 71 votes to 26 with eight abstentions:

## 1. Introduction and point of departure

The Commission proposal deals with the limits that are to apply, under the sixth EU R&D framework programme, to research into the medical and biological potential of human stem cells procured from "supernumerary" (frozen) human embryos.

1.1 Life sciences and medicine are key aspects of the sixth framework programme of the European Community for research, technological development and demonstration activities. The first point of the specific programme covering this thematic area is the application of "*life sciences, genomics and biotechnology for health*", including " *somatic gene and cell therapies* (*in particular stem cell therapies)*" and "*immunotherapies.*" The sixth framework programme adopted by the Council and the Parliament provides the legal basis for the Commission proposal.

1.2 Community funding of stem cell research using human somatic stem cells and embryonic stem cells from supernumerary human embryos is provided for under research priority (i) *Advanced genomics and its applications for health* in the section *Application of knowledge and technologies in the field of genomics and biotechnology for health.* For example, in this section: "*Research will focus on:…. development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies"*.[1]

1.3 The specific programme adopted by Council on 30 September 2002 allows the funding of research activities involving the use of human embryos and human embryonic stem cells except in three areas:

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1 OJ L 294, 29.10.2002, p. 10.

– research activity aiming at human cloning for reproductive purposes (reproductive cloning);
– research activity intended to modify the genetic heritage of human beings which could make such changes heritable (germline gene therapy)[2];
– research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer (commonly referred to as therapeutic cloning).

1.4 At the Council meeting of 30 September 2002, the Council and the Commission agreed, however, that "*detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells shall be established by 31 December 2003.*" Until that time, the Commission will not propose to fund such research, with the exception of proposals for projects that involve the use of banked or isolated human embryonic stem cells in culture.

1.5 The Commission's purpose in submitting the present *Proposal for a Council Decision amending Decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)* is thus to establish the implementing provisions mentioned in point 1.4.

1.6 The Commission's proposal was drawn up in the light of an interinstitutional seminar on bioethics that took place on 24 April 2003. This seminar provided an opportunity for a discussion and sharing of views between experts (scientific, legal, and in ethics) and representatives of the European Parliament, the Council, the Commission, the Member States and the accession and candidate countries. However, the proposed guidelines also draw on the principles laid down by the European Group on Ethics, and in particular this group's opinion no. 15 on *Ethical aspects of human stem cell research and use*[3].

1.6.1 This group was guided by the following principles:

– *the principle of respect for human dignity;*
– *the principle of human autonomy which entails the giving of informed consent, respect for privacy and the protection of personal data;*
– *the principle of justice and of beneficence (especially with regard the improvement and protection of health);*
– *the principle of freedom of research (which must be balanced against other fundamental rights) and;*
– *the principle of proportionality (the research activity must be vital to the objective to be achieved and there must be no more appropriate alternative methods available).*

2 Research relating to cancer treatment of the gonads can be financed.

3 http://europa.eu.int/comm/european_group_ethics/index_en.htm

1.7 The Commission proposal thus addresses a field of research which combines both high expectations for medical applications and profound ethical questions. It concerns especially the procurement of new embryonic stem cells from human supernumerary embryos. In order to properly address both these scientific expectations and the ethical concerns, the Commission is proposing to fund such research only under strict and restrictive conditions.

2. **Gist the Commission proposal**

The gist of the Commission proposal is set out in its annex which is reproduced verbatim here:

*"In order to be funded by the Community, research projects involving the procurement of stem cells from human embryos must also meet the following conditions:*

*(a) prior to the start of research activities, participants must obtain ethical advice at local or national level in the countries where the research will be carried out;*

*(b) the human embryos used for the procurement of stem cells must have been created before 27 June 2002 as a result of medically-assisted in vitro fertilisation designed to induce pregnancy, and were no longer to be used for that purpose;*

*(c) the project must serve particularly important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans;*

*(d) all other alternative methods (including existing or adult stem cell lines) must have been examined and demonstrated not to be sufficient for the purposes of the research in question;*

*(e) the free, express, written and informed consent of the donor(s) should be provided in accordance with national legislation prior to the start of the research activities;*

*(f) no monetary compensation or other benefit in kind must be granted or promised for the donation;*

*(g) the protection of personal data, including the genetic data, of the donor(s) must be ensured;*

*(h) where appropriate, the participants in research projects must follow quality and safety standards on donation, procurement and storage in accordance to the state of the art, in order to ensure in particular the traceability of these stem cells.*

*The scientific evaluation and the ethical review organised by the Commission of the research proposals shall include verification of these conditions. The conditions set out in point (c) and (d) shall be assessed during the scientific evaluation.*

*The opinions of the European Group on Ethics in Science and New Technologies, and in particular those relating to research involving the use of human embryonic stem cells will be taken into account.*

*The participants in research projects should use their best efforts to make the newly derived human embryonic stem cell lines available to the scientific community on a non-profit making basis for research purposes.*

*A list of research projects involving the use of all types of human embryonic stem cells funded under the sixth framework programme will be published yearly by the Commission".*

3. **The Committee's comments I**:
**Medical and scientific aspects and the EU research programme**

3.1 In a number of opinions, the Committee has expressed its wholehearted support for the successful structuring of the European research area as a key step towards attaining the Lisbon objectives, incorporating and developing the potential of European research, and preventing the migration of cutting-edge European research and top-level European researchers. To that end, it is vital to give European research the opportunities it needs to achieve excellence in global competition.

3.2 In its opinion on the sixth framework programme, the Committee strongly endorsed all the thematic actions proposed therein, including the research priorities under discussion here. A key element of these priorities is research into, and using, stem cells.

3.3 Stem cells are progenitor cells of other, more specialised cells; from them, various types of specialised cells can develop (multipotency). Haematopoietic stem cells have been known for a long time (and used in therapy for leukaemia and other types of cancer).

3.4 Knowledge is now available, however, about tissue-specific stem cells for many tissues. These are referred to in the Commission report as somatic stem cells, which are generally also known as adult stem cells.

3.5 Stem cells are able to generate different cell types to match the surrounding tissue ("plasticity") although many of the particulars surrounding the extent to which they have this facility remain unknown. It has been proven, for instance, that, in the right tissues, haematopoietic stem cells have developed into liver cells, muscle cells and nerve cells. This development potential is one reason why priority is given to the use of stem cells in cell therapy procedures. Research in this field is being conducted worldwide.

3.6 The earliest stage of a stem cell in the development of the organism is the fertilised ovum. The cells continue to divide, becoming "blastocysts" between the fourth and the seventh day of development. A blastocyst contains two cell groups, the outer specialised cell layer (trophoblast) and the internal cell mass (embryoblast). This embryoblast consists of pluripotent stem cells (embryonic stem cells [ES cells]), which are progenitor cells for all later development stages of the organism.

3.7 For some time, embryonic stem cells of animals – particularly mice – have been studied in development biology and cell biology. In contrast to more specialised (tissue-specific) stem cells, they are able to reproduce identically through many cell division cycles and can be maintained in culture (cell lines) – something not normally possible (or possible only with difficulty and for a short time) in the case of tissue-specific stem cells.

3.8 Embryonic stem cells can be generated only from blastocysts, i.e. from early embryos from the fourth to the seventh day of their development.

3.8.1 Blastocyst production is a routine procedure in reproduction medicine: *in vitro* fertilisation (IVF). It has long been in use, for instance, in the breeding of farm animals.

3.8.2 The first human conceived by IVF was born in 1978. This procedure was initially highly controversial but it has now been introduced in all developed countries.

3.8.3 In most countries, *in vitro* fertilisation is subject to regulation and restriction under the law and/or professional rules of conduct. In certain cases, it can enable otherwise infertile couples to have children of their own and is thus a beneficial procedure for the parties involved.

3.8.4 This procedure involves, initially, developing several embryos (e.g. six), of which three, for instance, are implanted into the womb at the first attempt, while the other "supernumerary"[4] embryos are frozen and put into storage for a number of years for possible future use. Many of them can be kept implantable during that time.

3.8.5 Depending on the "parental project" – and what is possible medically – supernumerary embryos of this kind are bound to be produced that have no prospect of ever being lodged, implanted or nidated (a pre-condition for the development of human life).

3.9 Human embryonic stem cells (HES) were successfully procured and established as cell lines in culture in 1998. Since then, many research teams have generated HES lines.

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4 In Germany, there are only a limited number of "genuine" supernumerary embryos, as, generally speaking, those "supernumerary" ova procured as a result of hormone treatment for the woman/prospective mother but not used for the initial implantation are, following sperm penetration, frozen at the so-called "pre-nucleus stage", i.e. before the emergence of a common cell nucleus. In German linguistic usage, these are not yet termed embryos. However, in individual cases, embryos designed for first implantation are, for various reasons, not implanted, and are subsequently frozen.

3.10 Research into and using HES has grown apace since then, for three main reasons:

3.10.1 In human medicine, therapeutic stem cell applications, which are currently performed only in haematology and oncology (and to date using only tissue-specific stem cells), may be used to treat many serious, common illnesses. If successful, the expected therapeutic, human and indeed economic benefits involved would be enormous.

3.10.2 For that to happen, fundamental issues still need to be resolved in the field of stem cell biology.

3.10.3 Many of these fundamental issues relating to stem cell biology can be resolved using animal ES cells.

3.10.4 But a number of issues crucial to therapeutic applications in the treatment of human illnesses can only be resolved using human stem cells.

3.10.5 Many issues crucial to therapeutic applications in the treatment of human illnesses can also be resolved using tissue-specific stem cells (adult stem cells).

3.10.6 At current levels of knowledge, however, some key issues can only be resolved using HES cells.

## 4. **The Committee's comments II**: **Ethical and legal aspects**

4.1 Blastocysts are four- to seven-day-old embryos made up of some 200 cells that have reached a differentiation stage (trophoblast and embryoblast). They normally do not survive withdrawal of ES cells. The procurement of HES cells thus involves the destruction of human embryos that are a few days old.

4.2 These embryos are not yet foetuses[5], but small balls of approximately 200 cells. As described in scientific literature, HES lines have been generated from embryos that were developed for IVF but were not ultimately used to induce a pregnancy (known as "supernumerary" embryos).

4.3 Supernumerary embryos such as these are placed in cold storage in dedicated facilities across Europe and, if they no longer the subject of a "parental project", are later destroyed in line with national rules.

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5 The term foetus denotes an embryo from around the twelfth week of gestation until birth.

4.4 The question is, however, whether it should be permissible to kill such supernumerary embryos procured through IVF[6] (which, after all, have no potential for life) in order to procure stem cell lines.

4.5 The ethical aspects of this procedure are thus tied to the key issue of whether and under what conditions it may be justifiable to use potential human life for an extrinsic purpose – even in cases where, as with supernumerary embryos, the subject involved is in any case doomed to certain death.[7]

4.6 These issues have been widely discussed in all countries in which HES lines have been procured – and in many in which they have not – with widely varying results. The legal provisions that have been adopted show broad agreement on the substantive principles involved (a "core consensus") but differ widely on key points of detail. This is true both at global level and between the Member States of the European Community.

4.7 Member States' differing stances on this issue to some extent also reflect the differing viewpoints of the general public and various social groups within the individual countries. As a result, individual Member States have adopted a variety of legal provisions through democratic channels that reflect the majority view in the countries concerned.

4.8 These provisions also reflect differences of opinion as to the moment in the development of a human embryo at which individual human life begins.

4.8.1 Views vary widely:

- Some believe that human life begins at the fusion of ovum and sperm (or their cell nuclei).
- Others take the view that life does not begin until the embryo is lodged/implanted/nidated[8&9] in the womb.
- For others, life does not begin until the gastrulation phase[10] (formation of the "primitive streak" that emerges between the twelfth and fifteenth day of an embryo's development).

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6 Thus, the Commission proposal under discussion here is concerned only with the procurement of stem cell lines from supernumerary embryos generated from IVF, not therefore from cloning (somatic cell nuclear transfer – SCNT) or from induced cell division that has recently been under discussion (parthenogenesis)

7 Society generally takes a positive view of this issue in the case of organ donations from adults killed in accidents.

8 Hence some commentators (see, for instance, *Jahrbuch für Wissenschaft und Ethik 7* (2002) ,Walter de Gruyter Berlin - New York) also use the term "pre-embryos" to denote embryos existing before nidation (or in other cases before gastrulation).

9 Hence there is no ban on contraception that prevents nidation (e.g. intrauterine coils).

10 Ulrich Steinvorth, *Jahrbuch für Wissenschaft und Ethik 7*, 2002, p. 165, Walter de Gruyter Verlag. The main argument for this view is that a possible multiple-birth pregnancy cannot be ruled out until after this stage.

– Still others consider that a relatively long evolutionary process is involved, making it impossible to fix an exact time. An arbitrary decision is thus needed, for instance, from the twelfth week[11] after the embryo lodges in the womb (i.e. at the transition from embryo to foetus).

## 5. The Committee's comments III: Europolitical aspects and international practice

5.1 Given the range of views within civil society outlined above and Member States' differing legal positions on the matter, it is clearly necessary – and also makes political sense – for the Commission to adopt a moderate and, if anything, restrictive middle course in its proposals for EU rules on this sensitive issue that is nonetheless also of vital importance in the light of the opportunities it affords.

5.2 This includes the Commission's proposal not to adopt Community laws binding on the Member States in this area, but instead to establish the potential research framework, i.e. to lay down the limits within which the Commission can support research projects using human stem cells (within the purview of the sixth framework programme).

5.3 The ethical and legal aspects of stem cell research were last discussed in depth at European level at the Commission's invitation in spring 2003; the present Commission proposal is the result.

5.4 The Committee respects the views of those, including some of its own members, who reject, on ethical grounds, any procurement of human stem cell lines from supernumerary embryos generated in the course of in vitro fertilisation, and thus also reject the Commission proposal.

5.5 Looking at the overall picture, however, the Committee nonetheless considers that the Commission proposal (reproduced in point 2 above) offers a balanced, well-thought-out approach that weighs up ethical principles against the potential prospect of treating diseases - although this inevitably, and regrettably also, places considerable restrictions on research possibilities and opportunities.

5.6 The Committee trusts that the proposed rules are compatible with the Charter of Fundamental Rights of the European Union, not least since the cases mentioned in Article II - 3(2) (b), (c) and (d) of the charter are explicitly excluded in the Commission's proposal and the earlier Council decision (see point 1.4).

5.7 This also applies therefore to all the individual provisions set out in the Commission proposal – from (a) to (h). The proposal focuses on the procurement of new stem cell lines from human embryos – a matter of some contention in the Council deliberations – and lays down criteria

11 In some Member States, this time period also plays a key role in abortion legislation.

(points (a) to (h)) and procedures (the second to the fifth paragraph) to that end. Turning to the individual points:

a. The Committee welcomes the mandatory consultation of an ethics commission[12]. This is in line with normal international practice. The fact that this allows account to be taken of the legislation or rules applying in the individual Member States is also important.

b. The procurement of new stem cell lines is limited to human embryos created for IVF treatment before the start of the sixth R&D framework programme but which will no longer be considered for use in inducing a pregnancy, and are thus deemed supernumerary. This arrangement reflects the legislative consensus in those countries in which the procurement of HES lines and/or the use of existing lines is regulated by law. Having a cut-off date prevents the improbable, but nonetheless conceivable scenario whereby human embryos are procured specifically for research purposes. (Under the rules adopted for sixth R&D framework programme, reliable steps must be taken to rule out such a scenario and the practice is permitted under certain conditions only in Great Britain.)

c. There is agreement in international law that projects to be supported must serve particularly important research aims.

d. It is also standard international practice to demonstrate in advance that alternative methods for achieving the research objectives in question (for instance animal experiments or tests using tissue-specific human [adult] stem cells) have been fully explored. That can of course be done only in the light of currently available knowledge and should not delay pending decisions unduly.

e. The requirement to secure donors' *informed consent* is also in line with international norms and is, moreover, common practice in the case of organ donations.

f. The Committee welcomes the proposal to rule out any payment[13] as this broadly reflects international legal practice.

g. The requirement to protect personal data on all matters such as these is also self-evident.

h. The quality assurance and traceability requirements relate to the current legal position and knowledge of work with biological materials from patients and those involved in

12 The Committee has reservations however about whether this measure is also necessary in Member States where it is not required under national law.

13 In this case too, there is an analogy to organ donations.

experiments. These requirements are also important for the establishment of stem cell banks mentioned in point 5.8.3 below.

5.8 The paragraphs after point (h), hereinafter referred to as paragraphs 2 to 5, deal with procedures for safeguarding those criteria and look at some of the reasons behind the measures.

5.8.1 **Paragraph 2** sensibly spreads the responsibility for examining the criteria under points (a) to (h). The scientific evaluation alone can determine the status of research objectives and whether these can only be attained using newly established HES lines. In contrast, points (a), (b) and (e) to (h) set out formal criteria which are to be examined on an administrative level using uniform yardsticks. Non-compliance with one of the criteria rules out support for the project concerned.

5.8.2 **Paragraph 3** refers to opinions of the European Group on Ethics in Science and New Technologies This provision may potentially help ensure that account is consistently taken of state-of-the-art knowledge in the rapidly developing field of stem cell research.

5.8.3 **Paragraph 4** lays down that newly derived HES lines are to be made available freely (and on a non-profit making basis) to the scientific community. The Committee feels it is vital in this regard that the Commission wants to "*contribute to the establishment of public stem cell banks and their networking at European level*". This point ties in with considerations of the European Science Foundation.

5.8.4 The standardisation this brings represents added European value. It is also a key prerequisite and secure foundation for ongoing research. It is in the interest of both Europe and the world and cuts the number of embryos needed to procure stem cells.

5.8.5 New HES lines procured with support under the sixth framework programme should therefore be deposited in a public stem cell bank.

5.8.6 This can also counter the restrictions placed on use as a result of the patenting of existing stem cell lines.

5.8.7 **Paragraph 5** is also welcomed; in it, the Commission commits itself to publishing the projects it supports in which HES cells are used (but not the names of the people working on those projects).

6. **The Committee's comments IV**:
**Member States with differing national laws**

6.1 Member States' legal systems vary widely. Not all Member States explicitly address stem cell research. Some countries' laws are more liberal than the Commission's proposal, others more restrictive. The development is in a state of flux.

6.2 Thus, scientific institutions in Member States with more restrictive laws may not take part in stem cell research projects that fully exploit the scope afforded under the Commission proposal (in other words where they are not restricted to stem cell lines whose use is permitted in all Member States), and cannot, therefore, apply for financial assistance in relation to such projects.

6.3 Conversely, scientific institutions in Member States with more liberal laws are not entitled to EU research funding either, unless they restrict themselves to research that meets the conditions laid down in the Commission proposal.

6.4 This situation is unsatisfactory, on the one hand, because all Member States contribute to the Community budget and thus also to the Community resources used to promote research, and, on the other, because exclusions such as these also limit the potential of the European research area by ruling out certain Member States (or rather their scientific institutions) from involvement in the networked research programme (and from a share in the support).

6.5 In the Committee's view, however, this does not preclude the Council, acting by a qualified majority and having consulted the Parliament, from adopting this Commission proposal to amend Decision 2002/834/EC.

6.6 However, the Community's funding remit does not include the right to standardise or harmonise Member States' laws.

6.7 In the light of the above, the Committee recommends the following:

6.7.1 When implementing this research programme, the Commission should work to ensure that the individual projects or programme elements are structured in such a way that research institutes that would otherwise be excluded can still be involved as far as possible in some aspects or subsections of the ventures, where the activities concerned do not violate European or national law.

6.7.2 In future revisions of their national legislation, the Member States concerned should seek, as far as possible, to come into line with these proposals so that, gradually, uniform rules are established that apply to all Member States. This is good for European research and medicine, not least given the high level of international networking and cooperation that exists in this field. The Committee feels that the present proposal offers a good compromise in this regard.

7. **Summary**

7.1 This proposal comes in response to the request made by the Council to the Commission in September 2002. It addresses those points in the implementing provisions of the sixth R&D framework programme that the Council felt required regulation.

7.2 The proposal on this sensitive but, given the opportunities it affords, nonetheless vitally important issue adopts a moderate and, if anything, restrictive approach, treading a "middle way" between the different national laws that apply in the Member States. It thus represents a compromise between diverging individual viewpoints.

7.3 The proposed rules meet the challenge. They allow support to be given to key scientific research serving important medical and biological ends. They give special priority to projects fostering international coordination and cooperation. They establish clear criteria and procedures to comply with the appropriate ethical and legal factors.

7.4 The Committee respects the views of those, including some of its own members, who reject, on ethical grounds, any procurement of human stem cell lines from supernumerary embryos, and thus also reject the Commission proposal.

7.5 In the light of all the factors involved, however, the Committee recommends that, bearing in mind the detailed points made above, the Commission proposal be accepted.

7.6 The Committee again asks the Commission to ensure that, in implementing the scientific programme, the programme elements are broadly structured in such a way so as not to rule out the involvement of top-rate scientific institutions in some Member States.

7.7 It again calls on Member States to pursue the same objective in future revisions of national legislation and to seek an overarching consensus on what is, admittedly, a very difficult issue, thereby broadening the scope of the fundamental agreement that currently exists on core issues (see point 1.3 above) to encompass a future coherent set of rules accepted by all Member States.

7.8 New HES lines, which are procured with support under the sixth framework programme, should be stored in a public stem cell bank and be freely accessible to European researchers.

Brussels, 29 October 2003.

| The President of the European Economic and Social Committee | The Secretary-General of the European Economic and Social Committee |
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| **Roger Briesch** | **Patrick Venturini** |

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**N.B.**: Appendix overleaf.

**Appendix**

## REGULATIONS IN EU MEMBER STATES REGARDING HUMAN EMBRYONIC STEM CELL RESEARCH

| | AT | BE | DK | DE | ES | FI | FR * | GR | IE | IT | LU | NL | PT * | SE | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Allowing for the procurement of human embryonic stem cells from supernumerary embryos by law | | X | X | | X | X | | X | | | | X | | X | X |
| Prohibition of the procurement of embryonic stem cells from human embryos but allowing by law for the importation of human embryonic stem cell lines | | | | X | | | | | | | | | | | |
| Prohibition of the procurement of embryonic stem cells from human embryos | X | | | | | | X | | X | | | | | | |
| No specific legislation regarding human embryo research | | | | | | | | | | X | X | | X | | |
| Allowing for the creation of human embryos for stem cell procurement by law | | X | | | | | | | | | | | | | X |
| Prohibition of the creation of human embryos for research purposes and for the procurement of stem cells by law or by ratification of the Convention of the Council of Europe on Human rights and Biomedicine signed in Oviedo on 4 April 1997 | X | | X | X | X | X | X | X | X | | | X | X | | |

* FR should normally allow the procurement of human embryonic stem cells from supernumerary embryos by law very soon (Parliament 2nd lecture, planned on 10-11 December 2003).

* PT legislation is currently under preparation