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**A5-0103/2003**

25 March 2003

# ***I
# REPORT

on the proposal for a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells
(COM(2002) 319 – C5-0302/2002 – 2002/0128(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Peter Liese

Draftsman (*) : Paolo Bartolozzi, Committee on Legal Affairs and the Internal Market

(*) Enhanced cooperation between committees

CODE1AM

## *Symbols for procedures*

| | |
|---|---|
| * | Consultation procedure<br>*majority of the votes cast* |
| **I | Cooperation procedure (first reading)<br>*majority of the votes cast* |
| **II | Cooperation procedure (second reading)<br>*majority of the votes cast, to approve the common position*<br>*majority of Parliament's component Members, to reject or amend the common position* |
| *** | Assent procedure<br>*majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty* |
| ***I | Codecision procedure (first reading)<br>*majority of the votes cast* |
| ***II | Codecision procedure (second reading)<br>*majority of the votes cast, to approve the common position*<br>*majority of Parliament's component Members, to reject or amend the common position* |
| ***III | Codecision procedure (third reading)<br>*majority of the votes cast, to approve the joint text* |

(The type of procedure depends on the legal basis proposed by the Commission)

## *Amendments to a legislative text*

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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(*) Enhanced cooperation between committees

## PROCEDURAL PAGE

By letter of 20 June 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 152(4) of the EC Treaty, the proposal for a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (COM(2002) 319 – 2002/0128 (COD)).

At the sitting of 1 July 2002 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Budgets, the Committee on Legal Affairs and the Internal Market and the Committee on Budgetary Control for their opinions (C5-0302/2002).

At the sitting of 30 January 2003 the President of Parliament announced that the Committee on Legal Affairs and the Internal Market, which had been asked for its opinion, would be involved in drawing up the report, under the Enhanced cooperation between committees.

The Committee on the Environment, Public Health and Consumer Policy had appointed Peter Liese rapporteur at its meeting of 2 October 2002.

The committee considered the Commission proposal and draft report at its meetings of 19 February, 19 and 25 March 2003.

At the latter meeting it adopted the draft legislative resolution by 31 votes to 17, with 0 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Mauro Nobilia, Alexander de Roo and Guido Sacconi, vice-chairmen; Peter Liese, rapporteur; Emmanouil Bakopoulos (for Mihail Papayannakis), Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Philip Bushill-Matthews (for Martin Callanan), Dorette Corbey, Chris Davies, Avril Doyle, Jillian Evans (for Patricia McKenna), Anne Ferreira, Christel Fiebiger (for Pernille Frahm), Karl-Heinz Florenz, Robert Goodwill, Françoise Grossetête, Hedwig Keppelhoff-Wiechert (for Marialiese Flemming), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Pietro-Paolo Mennea (for Giuseppe Nisticò), Jorge Moreira da Silva, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Neil Parish, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Horst Schnellhardt, Renate Sommer, María Sornosa Martínez, Catherine Stihler, Robert William Sturdy (for Peder Wachtmeister), Nicole Thomas-Mauro, Antonios Trakatellis, Kathleen Van Brempt.

The opinions of the Committee on Budgets and the Committee on Legal Affairs and the Internal Market are attached; the Committee on Budgetary Control decided on 10 September 2002 not to deliver an opinion.

The report was tabled on 25 March 2003.

## DRAFT LEGISLATIVE RESOLUTION

**European Parliament legislative resolution on the proposal for a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells (COM(2002) 319 – C5-0302/2002 – 2002/0128(COD))**

**(Codecision procedure: first reading)**

*The European Parliament*,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 319[1]),

– having regard to Article 251(2) and Article 152(4) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0302/2002),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Budgets and the Committee on Legal Affairs and the Internal Market)) (A5-0103/2003),

1. Approves the Commission proposal as amended;

2. Asks to the matter to be referred to it again, should the Commission intend to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

| Text proposed by the Commission | Amendments by Parliament |
|---|---|
| Amendment 1 | |
| Recital -1 (new) | |
| | ***(-1) The human body is inviolable and inalienable. The human body cannot be the subject of property rights.*** |
| *Justification* | |
| *Is important to point out first of all the inalienable character of the human body and its parts.* | |

[1] OJ C 227 E, 24.9.2002, p.505.

Amendment 2

Recital 1

| | |
|---|---|
| (1) ***The extensive therapeutic use of human tissues and cells for application in the human body demands that their quality and safety be ensured in order to prevent the transmission of diseases.*** | (1) ***The transplantation of cells and tissues is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases and for economic development, albeit that the potential in this area is occasionally assessed too enthusiastically. The aim of this Directive is to further the optimal use of the opportunities to promote human health and economic development without unacceptable risks for donors and recipients. The quality and safety of these substances must be ensured, particularly in order to prevent the transmission of diseases. It is equally important that fundamental ethical principles be observed.*** |

*Justification*

*Recital 1 of the Commission proposal begins with the words 'The extensive therapeutic use of human tissues and cells for application in the human body demands that ...'. This wording appears to be extremely negative as the use of human cells and tissues is primarily an opportunity. A more positive wording should therefore be chosen to open the Directive, one which emphasises the opportunities but also refers to the problems.*

Amendment 3

Recital 1a (new)

| | |
|---|---|
| | ***(1a) The public health implications of human tissues and cells are all more important because they concern the treatment of patients with serious diseases and are often the treatment of last resort. It must be possible to ensure that patients have equal access to such treatment on the basis of objective medical criteria.*** |

*Justification*

*The principle of equal access to the treatment possibilities afforded by tissue and cell donations should be stated as one of the main objectives of this Directive.*

Amendment 4

Recital 2a (new)

***(2a) The need to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'. These campaigns would be designed to help European citizens decide to become donors during their lifetime and let their families or legal representatives know their wishes.***

*Justification*

*The surveys conducted by national associations for tissue, cell and organ donations show that a large majority of citizens would agree to have certain parts of their bodies removed after their death in order to save human lives. The same surveys reveal that more often than not European citizens are unaware that they can decide to become donors during their lifetime. This makes it more difficult for the family, relatives or legal representatives to take a decision when the person concerned has died.*

Amendment 5

Recital 3a (new)

***(3a) As cell and tissue therapy is a field in which an intensive worldwide exchange of information is taking place, it is desirable to have worldwide standards. The Commission must therefore endeavour to promote the highest possible level of protection for patients through the WHO. The Commission should report annually on the progress made in this respect.***

*Justification*

*Efforts should be made to ensure safety in the area of cell and tissue therapy. This should involve a clear and binding duty on the Commission.*
*The reference to the ICH has been removed, since it has been argued in various quarters that this body is not the right place for international standards in this area.*
*To ensure that this demand is acted on, the Commission must be obliged to report on its activities in this respect.*

Amendment 6

Recital 5a (new)

***(5a) The use of organs to some extent raises the same issues as the use of tissues and cells, though there are serious differences, and the two subjects should therefore not be covered by one directive. The regulation of organ transplants, however, is equally as important as the regulation of the quality and safety of cells and tissues. The Commission should therefore submit a proposal on that subject by mid-2003.***

*Justification*

*Some Members have proposed that organs should be included within the scope of the directive. This could unnecessarily complicate the adoption of the proposal for a directive and does not take into account the distinction that must be made between organs and tissues. Nevertheless, the regulation of organ transplantation in the European Union cannot be delayed because, for example, in some applicant countries, internet trade in organs is obviously taking place, which is a violation of the charter of fundamental rights. There is therefore an urgent need for legislative action in this area, should the Commission announce that it is not in a position to submit a proposal on organs in the next few months, then a motion must be tabled for the vote in plenary to incorporate organs within the scope of this directive. The exclusion of organs is acceptable but only if allogeneic bone marrow and peripheral blood stem cell transplantation are also excluded. The principles applying on these two types of procedure (i.e. organ transplantation and haemopoietic stem cell transplantation) are so similar that they should either be both "in" or "out" of the scope, otherwise the scope is not consistent.*

Amendment 7

Recital 6

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| (6) This Directive ***does not cover*** research using human tissues and cells, such as when used for purposes other than application to the human body***, i.e.*** in vitro research or in animal models. ***Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.*** | (6) This Directive ***also covers*** research using human tissues and cells such as when used for purposes other than application to the human body, ***e.g.*** in vitro research or in animal models, ***as far as donation and procurement are concerned.*** |

*Justification*

*Tissues and cells which are not to be used for human transplantation but, for example, for research, must also be covered by the Directive as donors must be protected in that instance and basic principles such as informed consent must be respected. However, in instances where the donation is for research it may not be necessary to fulfil the same requirements concerning testing, processing, storage and distribution.*

Amendment 8
Recital 7

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| (7) ***This*** Directive ***does not interfere with*** decisions ***made by Member States*** concerning the ***use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health and guarantee respect for fundamental rights. Moreover, this Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual'***. | (7) ***The*** Directive ***explicitly recognises the right of Member States to take*** decisions concerning the ***banning of donation, experimentation, processing, storage, distribution and use of any other kind of particular cells or human tissues or of cells of a particular origin. If any Member State takes such a decision the ban may also be extended to imports of cells or tissues of such kinds. Member States also have the right to ban products originating from particular cells, to ban particular tissues or cells having a particular origin and to ban their importation. For ethical reasons, and for reasons connected with the high risks of a medical nature connected with human cloning, Member States must also explicitly ban the use of tissues and cells from cloned human*** |

***embryos and of hybrids derived from germ cells or totipotent cells of human and animal origin***.

*Justification*

*The use of cells and tissues derived from cloned human embryos and human and animal hybrids cannot be permitted for ethical reasons, and for reasons connected with the extremely high medical risks involved.*

*Parliament and the Council of Europe have also repeatedly expressed their opposition to any form of human cloning. On this issue see:*

*(a) in the case of Parliament, its resolutions of 16 March 1989 on the ethical and legal problems of genetic engineering and 'in vivo' and 'in vitro' artificial insemination; 28 October 1993 on the cloning of human embryos; 20 September 1996 and 12 March 1997 on cloning; 15 January 1998 on human cloning; 30 March 2000 and 7 September 2000 on human cloning; European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, and*

*(b) in the case of the Council of Europe, the Convention for the protection of human rights and the dignity of the human person with regard to the application of biology and medicine; the Convention on Human Rights and Biomedicine and the annexed protocol, prohibiting the cloning of human beings; and Recommendation 1046 of the Council of Europe Parliamentary Assembly on the use of human embryos and foetuses in scientific research.*

*On the other points, the amendment reflects progress in the debate in the Council of Ministers and highlights the application of the subsidiarity principle. It is normal practice for Member States to be able to set more stringent standards than those laid down by Community directives, in accordance with Article 152 of the Treaty.*

Amendment 9
Recital 7a (new)

***(7a) There is no consensus within the European Union as to whether, and in what circumstances, embryonic stem cells may be processed. The processing of stem cells, and in particular the creation of stem cells in cases in which the embryo from which they originate has to be destroyed, is scientifically and ethically controversial and illegal in many Member States.***

***However, the processing of adult stem cells and of stem cells from the umbilical***

***cord is legal and ethically non-controversial in all the Member States.***

***Such alternative solutions to the use of embryonic stem cells should be specifically promoted by the European Union and by the Member States. Obstacles to the processing of adult stem cells and stem cells from the umbilical cord must be removed.***

*Justification*

*The amendment essentially corresponds to an amendment adopted by the European Parliament as part of the Nisticò report on the proposal for a European Parliament and Council directive setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC. The amendment was rejected by the Commission and the Council, on the grounds that such a provision should not appear in the Directive on blood, but in that relating to tissues and cells. Hence it appears here in its natural place.*

Amendment 10

Recital 9a (new)

***(9a) All the Member States should use cell-typing techniques that are as accurate as possible, in particular for bone marrow donations, in order to ensure the self-sufficiency of national donor registers.***

*Justification*

*Regrettably, some national bone marrow donation registers, although well managed, do not use the most accurate cell-typing possible. Molecular biology techniques should be the common standard in all the Member States thus facilitating the verification of compatibility between potential donors and patients.*

Amendment 11

Recital 12

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| (12) As a matter of principle, tissue and cell transplantation programmes should be founded on the philosophy of voluntary and | (12) As a matter of principle, tissue and cell transplantation programmes should be founded on the philosophy of voluntary and |

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| unpaid donation, anonymity of both donor and recipient, ***benevolence*** of the donor and ***encouragement of the absence of profit by establishments involved in tissue and cell transplantation services.*** | unpaid donation anonymity of both donor and recipient, ***altruism*** of the donor and ***solidarity between donor and recipient.***<br>***Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell transplant services and the related research development.*** |

*Justification*

*It should be clarified that the goal is not to completely keep out the private sector, but a strong involvement of the public sector must be encouraged by the Member States.*

Amendment 12

Recital 12 a (new)

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|---|---|
| | ***(12a) It is not the aim of the Directive to keep commercial establishments at a distance from work on cells and tissue. Commercial establishments may also be accredited as cell and tissue banks provided they comply with the standards.*** |

*Justification*

*The Commission proposal is occasionally interpreted as meaning that only public establishments can be accredited as cell and tissue banks. This is not the Commission's intention and a clarification is therefore needed.*

Amendment 13

Recital 13

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|---|---|
| (13) The procurement of human tissues and cells must fully respect the Charter of Fundamental Rights of the European Union, and ***take fully into account the principles of the*** Convention on Human | (13) The procurement of human tissues and cells must fully respect the Charter of Fundamental Rights of the European Union, and the Convention on Human Rights and Biomedicine of the Council of |

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|---|---|
| Rights and Biomedicine of the Council of Europe, ***in particular in relation to donor consent.*** | Europe, ***including the protocols thereto. However, both the Charter of Fundamental Rights and the Council of Europe Convention lay down minimum requirements only, beyond which both the European Union as a whole and the individual Member States may go in their legislation. Neither text makes express provision for harmonisation but lays down minimum standards***. |

*Justification*

*The Commission proposal makes a linguistic distinction between the Charter of Fundamental Rights and the Convention of the Council of Europe. The Council of Europe Convention and its protocols contain numerous important provisions which, in your rapporteur's view, must be fully respected. The phrase 'in particular in relation to donor consent' could be misleading as other provisions of the Convention and the Protocols are highly relevant to the issue concerned and must be respected. As the Council of Europe Convention is often misinterpreted as harmonisation, it should be made clear that only minimum standards are involved and both the EU as a whole and the individual Member States can go beyond those standards.*

Amendment 14

Recital 13a (new)

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| | ***(13a) As far as compliance with legal rules protecting human dignity is concerned, the Commission and the Member States should try to create a code of conduct, if possible at United Nations level. International legislation in this sector should comply at least with the following principles:***<br>***- a ban on making the human body or its parts a source of financial gain,***<br>***- the principle of informed consent,***<br>***- a ban on producing human embryos with the same genetic data as another human being.*** |

*Justification*

*The European Union and its Member States should lead the way at international level in promoting legislative principles governing this type of research and practice by ensuring respect for life and human dignity.*

Amendment 15

Recital 17a (new)

***(17a) Member States should redouble their efforts in the fight against the illegal trafficking of tissues, human cells and parts of the human body in general.***

*Justification*

*Even though the scope of the directive does not cover human organs, for which the rapporteur is requesting a specific directive, it appears appropriate to include a reference to the fight against trafficking in all 'parts of the human body in general'.*

Amendment 16

Recital 19

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|---|---|
| (19) An adequate system to ensure the traceability of tissues and cells of human origin should be established; traceability should be enforced through accurate substance, donor, recipient, tissue bank, and laboratory identification procedures as well as record maintenance and an appropriate labelling system. | (19) An adequate system to ensure the traceability of tissues and cells of human origin should be established ***and steps taken to satisfy the requirements of health quality and safety; in this context, and in particular in the case of gamete donations, the lifting of donor anonymity may be authorised;*** traceability should be enforced through accurate substance, donor, recipient, tissue bank, and laboratory identification procedures as well as record maintenance and an appropriate labelling system. |

*Justification*

*During the discussion in committee, many members raised the difficulty of reconciling in practice observance of the principle of anonymity and the need to ensure traceability of tissue and cell donations from procurement to implantation. The lifting of anonymity may be envisaged in exceptional circumstances, in the case of gamete (egg, sperm) donations in order to satisfy the requirements of health and safety.*

Amendment 17

Recital 20

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|---|---|
| (20) In order to increase the effective implementation of the provisions adopted under this Directive, it is appropriate to provide for penalties to be applied by Member States. | (20) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to**:**<br>**-** provide for penalties to be applied by Member States.<br>***- establish clear and evolutionary rules facilitating the revision of the scope of application of the directive in the light of the rapid advance in biotechnology knowledge and practice in the sphere of human tissues and cells.*** |

*Justification*

*Self-explanatory.*

Amendment 18

Article 1

| | |
|---|---|
| This Directive lays down standards of quality and safety of human tissues and cells used for ***application to the human body***, in order to ensure a high level of protection of human health | This Directive lays down***, with due regard to fundamental ethical principles,*** standards of quality and safety of human, tissues and cells used for ***human applications***, in order to ensure a high level of protection of human health |

*Justification*

*All human action must observe fundamental ethical principles. Consequently, this also applies to the donation, procurement, testing, processing, storage and distribution of human organs, tissues and cells. The phrase "for application to the human body" is not clear as it could be interpreted as meaning only the external application of tissues or cells to the human body. The term, "for human applications" is a more precise phrase that would also include clinical (in vivo) research, which comes under the scope of the proposed Directive.*

Amendment 19

Article 2, paragraph 1

| | |
|---|---|
| 1. The provisions of this Directive shall apply to the donation, procurement, ***and testing*** of human tissues and cells ***for application to the human body***. The provisions of this Directive shall also apply to the processing, preservation, storage and distribution of human tissues and cells when they are to be used for human transplantation. | 1. The provisions of this Directive shall apply to the donation and procurement of human tissues and cells. The provisions of this Directive shall also apply to the ***testing,*** processing, preservation, storage and distribution of human tissues and cells when they are to be used for human transplantation. |
| In the case of industrially manufactured products derived from tissues and cells**,** this Directive applies only to donation, procurement and testing. | In the case of industrially manufactured products ***or final products*** derived from tissues and cells ***that are each subject to a mandatory market approval,*** this Directive applies only to donation, procurement and testing. |

*Justification*

*Tissues and cells which are not to be used for human transplantation but, for example, for research, must also be covered by the Directive as donors must be protected in that instance and basic principles such as informed consent must be respected. However, in instances where the donation is for research it may not be necessary to fulfil the same requirements concerning testing, processing, storage and distribution.*

*The second part of the amendment is intended to make a clearer distinction between the DG SANCO directive and the future directive coming from DG Enterprise.*

Amendment 20

Article 2, paragraph 1a (new)

***1a. This Directive shall also apply to:***

***a) haematopoietic peripheral blood, placenta and bone marrow stem cells;***

***b) reproductive cells (eggs, sperm);***

***c) foetal tissues and cells, adult and embryonic stem cells.***

*Justification*

*No human tissue or cell should be exempt from the application of minimum quality and safety standards as laid down by this Directive. This principle does not override measures taken under national legislation authorising or prohibiting the use of particular types of human cells, for example embryonic stem cells or foetal cells and tissues.*

Amendment 21

Article 2, paragraph 2, point b)

| | |
|---|---|
| ***b) autologous cells to be used for the manufacturing of medicinal products;*** | ***Deleted*** |

*Justification*

*1. The retrieval of the umbilical cord blood of newborn babies is becoming increasingly important. More and more parents of newborn children wish to have their child's umbilical cord blood retrieved and stored so that it can perhaps be used for therapeutic purposes in the event of a subsequent illness affecting the child (autologous use) or a sibling (allogeneic intra-family use).*

*2. On principle, the quality and safety standards for umbilical cord blood must correspond with the standards applicable to human tissues and cells in general.*

*3. As it stands, Article 2(2)(b) of the draft directive excludes autologous cells which are to be used for the manufacturing of medicinal products from the scope of the directive. Given that umbilical cord blood is a source of stem cells, this exclusion is not justified. Umbilical cord blood for autologous or intra-family allogeneic use also needs to be included in the scope of the directive.*

*4. This can be justified as follows:*

*(1) The increasing importance of retrieval of umbilical cord blood in Germany and in other European and non-European countries makes clear legal provisions necessary. The groups involved need legal certainty in this area.*

*(2) The legal treatment of the retrieval of umbilical cord blood already varies to an extraordinary degree within Germany. For example, one Land considers that manufacturing authorisation under the law governing medicinal products is not required for the retrieval of umbilical cord blood, whilst other Länder do consider it necessary. It is also unclear whether umbilical cord blood is a raw material, an active substance or a medicinal product. The discrepancies become still wider if all the EU Member States are considered. Legal certainty and transparency require clear, uniform rules for umbilical cord blood.*

*(3) On the whole, the draft directive provides an appropriate framework for the special case of the retrieval of umbilical cord blood. However, a series of specific aspects need to be taken into account, in particular:*

*(aa) In the case of the retrieval of umbilical cord blood, there is no donor within the definition given in Article 3(c). The blood is retrieved from an organ which is separate from both the mother's and the child's body, but not from the human body;*

*(bb) In legal terms, the owner and person entitled to dispose of umbilical cord blood is the newborn child, on whose behalf the parents are entitled to act.*

Amendment 22

Article 2, paragraph 2, point c)

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|---|---|
| c) blood and blood components as defined by ***[Directive of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC.]***; | c) blood and blood components, as defined by ***Directive 2002/98/EC***; |

*Justification*

*Self-explanatory.*

Amendment 23

Article 3, point a)

| | |
|---|---|
| a) '*Cells*' shall mean individual cells or a collection of cells when not bound by any form of connective tissue. | a) '*Cells*' shall mean individual cells or a collection of cells***, of human origin,*** when not bound by any form of connective tissue. |

*Justification*

*Clarification of the wording in accordance with the proposal of the Economic and Social Committee.*

Amendment 24

Article 3, point b)

| | |
|---|---|
| b) ***'Tissue' shall mean all constituent parts of the human body formed by cells.*** | b) '***Tissue' shall mean an aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of an organism, including surgical residues and the placenta but excluding organs, blood and blood products. Hair, nails and body waste products are also excluded.*** |

*Justification*

*The definition in the Commission proposal is inadequate and even incorrect. The above definition clearly describes what tissue is. It is based on that in the Merriam-Webster Medical Dictionary. It also indicates which human tissues do not fall within the scope of this Directive.*

Amendment 25

Article 3, point c)

| | |
|---|---|
| c) '*Donor'* shall mean a living or deceased individual, including *non-natus,* who is the source of cells or tissues. | c) '*Donor'* shall mean a living or deceased individual, including *non-natus,* who is the source of cells or tissues. ***In this context, the term 'individual' is used synonymously with*** |

| | |
|---|---|
| | ***the term 'human being'.*** |

*Justification*

*It is variously argued that certain groups of human beings are not individuals (e.g. newborn babies or mentally handicapped people). It must be made clear that the EU cannot endorse such a distinction between human beings and individuals under any circumstances.*

Amendment 26

Article 3, point f)

| | |
|---|---|
| f) '*Processing'* shall mean all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells for ***transplantation.*** | f) '*Processing'* shall mean all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells for ***use in human beings.*** |

*Justification*

*It is important to make it clear that in the context of this Directive 'processing' is restricted to obtaining finished products for grafting, where 'processing' in the wider sense could also cover the manufacture of drugs or tissue engineering.*

Amendment 27

Article 3, point qa) (new)

| | |
|---|---|
| | ***qa) 'Human embryo' includes any organism that is derived by fertilisation, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.*** |

*Justification*

*The amendment offers a definition of 'human embryo'.*

Amendment 28

Article 4, paragraph 2

| | |
|---|---|
| 2. This Directive ***shall not prevent a Member State from maintaining or introducing*** more stringent protective measures that comply with the provisions of the Treaty. | 2. This Directive ***expressly recognises the right of Member States to maintain or introduce*** more stringent protective measures that comply with the provisions of the Treaty. |

*Justification*

*The wording of this amendment puts greater stress on application of the principle of subsidiarity. It is normal for the Member States to be able to apply stricter measures than are laid down by Community directives.*

Amendment 29

Article 4, paragraph 2a (new)

| | |
|---|---|
| | ***2a. This Directive expressly recognises the right of Member States to prohibit the donation, procurement, testing, experimentation, processing, storage, and distribution of tissues and cells of a certain origin. A Member State that enacts such a ban can extend that ban to the import of such cells or tissues. Member States are also entitled to ban products derived from certain cells, certain tissues or cells of a certain origin, and the import thereof.*** |

*Justification*

*The amendment reflects progress in the debate in the Council of Ministers and highlights the application of the subsidiarity principle. It is normal practice for Member States to be able to set more stringent standards than those laid down by Community directives, in accordance with Article 152 of the Treaty.*

Amendment 30

Article 4, paragraph 2b (new)

***2b. Member States shall at least prohibit the following activities:***
***- research on human cloning for reproductive purposes,***
***- research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei.***

*Justification*

*The European Union like the Member States should regulate and focus research efforts on techniques that do not undermine respect for life and human dignity and should prohibit any technique involving the use of human beings as a material, even at the embryo stage.*

Amendment 31

Article 4, paragraph 4a (new)

***4a. Should the Member States not prohibit the use of germ cells and embryonic and foetal stem cells obtained and stored in accordance with the standards laid down in this Directive, they shall regulate such use by means of appropriate legislation.***

*Justification*

*It is essential that the Member States specifically regulate the use of cells of an ethically 'sensitive' origin.*

Amendment 32

Article 7, paragraph 2

| | |
|---|---|
| 2. Tissue banks shall maintain an official record on the origin and destination of the | 2. Tissue banks shall maintain an official record on the origin and destination of the |

| | |
|---|---|
| tissues and cells processed for application in the human body. ***An annual report of these activities shall be submitted to the competent authority***. | tissues and cells processed for application in the human body. ***A publicly accessible record should also be maintained on the distribution of tissues and cells with a view to ensuring optimal use and equal access.*** |

*Justification*

*Self-explanatory.*

Amendment 33

Article 8, paragraph 4, point (c)

| | |
|---|---|
| (c) examine any documents relating to the subject of the inspection. | (c) examine any documents relating to the subject of the inspection. ***The Commission assists Member States when cooperating on the preparation of guidance concerning the training and qualification of officials involved in inspections and control measures in order to reach a consistent level of competence and performance.*** |

*Justification*

*Guidance is required for Member States concerning the appropriate training and qualification of officials. Without such guidance, Article 8.4 will be difficult to apply consistently between Member States.*

Amendment 34

Article 9, paragraph 1

| | |
|---|---|
| 1. Member States shall take all necessary measures to ensure that all imports of human tissues or cells from third countries are approved by the competent authority. All tissues and cells that are exported to third countries shall comply with the requirements | 1. Member States shall take all necessary measures to ensure that all imports of human tissues or cells from third countries are approved by the competent authority ***and comply with the requirements of the Directive.*** All tissues and cells that are exported to third countries shall comply with |

| | |
|---|---|
| of this Directive. | the requirements of this Directive***, though adjustments may be made in regard to the purely technical requirements set out in Annexes I to II and IV to VII if the legislation of the third country expressly provides for other legal arrangements which guarantee the safety of patients in those third countries and provide at least the same level of protection as the Directive.***<br><br>***Particularly in cases where the patient's condition means that any delay is unacceptable, the Member State authorities shall lay down the procedure in advance in order to avoid lengthy bureaucratic processes.*** |

*Justification*

*The situation in third countries (e.g. the emergence of other diseases in the population of the third country) may call for different technical rules. The essential requirements must, however, be met in every case.*

*The sentence which has been added at the end is designed to respond in particular to the concerns expressed by the World Marrow Donor Association. Bureaucratic procedures must not endanger patients' lives.*

Amendment 35

Article 9, paragraph 2

| | |
|---|---|
| 2. The import/export of human tissues and cells for transplantation shall be undertaken only through accredited tissue banks. | 2. The import/export of human tissues and cells for transplantation shall be undertaken only through accredited tissue banks ***explicitly authorised for this activity in accordance with Article 6 (3). The tissue banks shall ensure that human tissues and cells imported from third countries***<br>***a) are imported in accordance with paragraph 3 and comply with quality and safety standards, equivalent to those laid down in this Directive,***<br>***b) have been donated, procured and exported in accordance with the law of the third country and*** |

| | |
|---|---|
| | ***c) can be traced from the donor to the recipient and vice versa in accordance with the procedures referred to in Article 10 (2).*** |

*Justification*

*There is no reason why in the case of human tissues and cells imported from third countries, the only relevant factor to be taken into account by the competent authorities should be the safety and quality of human tissues and cells. Those authorised to import tissues and cells should ensure that human tissues and cells have been acquired legally in the third country, may be exported under the laws of that country and can be traced from the donor to the recipient.*

Amendment 36
Article 9, paragraph 3

| | |
|---|---|
| 3. The competent authority shall approve imports of human tissues and cells from third countries only when equivalent standards of quality and safety to the ones laid down in this Directive are ensured. | 3. The competent authority shall approve imports of human tissues and cells from third countries only when equivalent standards of quality and safety to the ones laid down in this Directive***, and likewise respect for fundamental ethical principles,*** are ensured. |

*Justification*

*Like compliance with quality and safety standards, it must be ensured that, where human tissues and cells imported from third countries are concerned, the ethical principles governing the field (including the free, informed consent of donors, or unpaid donation) are followed, in order to protect human dignity.*

Amendment 37

Article 9, paragraph 4

| | |
|---|---|
| 4. The procedures for verifying the equivalent standards of quality ***and*** safety in accordance with paragraph 3 shall be established by the Commission in accordance with the procedure referred to in Article 30(2). | 4. The procedures for verifying the equivalent standards of quality***, safety and respect for fundamental ethical principles*** in accordance with paragraph 3 shall be established by the Commission in accordance with the procedure referred to in Article 30(2). |

*Justification*

*Like compliance with quality and safety standards, it must be ensured that, where human tissues and cells imported from third countries are concerned, the ethical principles governing the field (including the free, informed consent of donors, or unpaid donation) are followed, in order to protect human dignity.*

Amendment 38

Article 10, paragraph 1

| | |
|---|---|
| 1. Member States shall ensure that tissue establishments take all necessary measures to ensure that all tissues and cells procured, processed, stored and distributed on their territory can be traced from the donor to recipient and vice versa. | 1. Member States shall ensure that tissue establishments take all necessary measures to ensure that all tissues and cells procured, processed, stored and distributed on their territory can be traced from the donor to recipient and vice versa. ***This traceability also applies to all relevant data relating to products and materials coming into contact with these tissues and cells.*** |

*Justification*

*Traceability involves a wider range of factors (for example cells used for cell cultures) which are better defined by this additional clause.*

Amendment 39

Article 10, paragraph 1a (new)

| | |
|---|---|
| | ***1a. In order to guarantee full and effective traceability of human tissues and cells, Member State may authorise the lifting of donor anonymity in particular in the case of gamete donations.*** |

*Justification*

*In practice it is sometimes difficult to reconcile completely the requirements of health safety and bioethics when it comes to ensuring full traceability from the donor to the recipient and vice versa. To this end, it is necessary to have a derogation to the fundamental principle of*

*anonymity solely in the case of gamete donations.*

Amendment 40

Article 10, paragraph 4a (new)

***4a. The data required to ensure full traceability in accordance with this Article shall be kept for at least thirty years.***

*Justification*

*The principle of traceability should be defined in terms of time. The wording is similar to that in Directive 2002/98/EC establishing quality and safety standards for human blood and blood components.*

Amendment 41

Article 12, paragraph 1

| | |
|---|---|
| 1. Member States shall ***encourage*** voluntary and unpaid donations of tissues and cells ***with a view to ensuring that they are in so far as possible provided from such donation.*** | 1. Member States shall ***ensure*** voluntary and unpaid donations of tissues and cells. ***Donation of human tissues and cells must be done out of the donor's free will without payment except compensation. Detailed rules shall be laid down by the Member States. The Member States report to the Commission every two years after the adoption of the directive how they fulfil this requirement.*** |

*Justification*

*All amendments that have been tabled ask for more strict wording concerning voluntary and unpaid donation. The regulation of the details of compensation shall anyhow be left to the member states. Member states may decide if they reimburse tickets for travel or a flat rate, if they allow small gifts or refreshments and if they offer the donor to take time off work. It might be useful to define different compensations for different type of cells and tissues. To avoid an exaggerated interpretation of the word "compensation", member states have to report to the European Commission how they fulfil the requirements.*

Amendment 42
Article 12, paragraph 1 a (new)

***1a. Member States shall provide the public with information about the circumstances in which donated tissues and cells are used, with particular reference to the benefits for public health and to the requirements that tissue banks comply with standards of quality, safety and respect for fundamental ethical principles.***

*Justification*

*Appropriate information about the benefits of donation, on the one hand, and the respectability of tissue banks, on the other, may encourage the propensity to donate on the part of the public.*

Amendment 43

Article 12, paragraph 3

| | |
|---|---|
| 3. Member States shall ***encourage*** that ***the procurement of*** tissues and cells ***is carried out on a non-profit basis***. | 3. Member States shall ***ensure*** that ***there is no trading in unmodified*** tissues and cells.<br><br>***When human tissues are used as the basis for obtaining, through engineering, products that require sophisticated medical techniques, such activities may be permitted for bodies and organisations operating on a profit basis.*** |

*Justification*

*The Commission's wording is unclear. The decisive factor is that the demand made in the Charter of Fundamental Rights, that parts of the human body as such may not be commercialised, is complied with. However, other activities involving cells and tissue should also be possible for commercial establishments, particularly cell modification and work with modified cells.*

*In some Member States, work with cells and tissue does take place on a business footing. There are no indications to date that this results in health hazards or that commercial establishments comply less with ethical standards than public ones. The decisive factors are the standards and the controls and not the question of who runs an establishment. If commercial establishments comply with the standards, their activity is to be welcomed as they promote innovation.*

*As a matter of principle, the operation of tissue banks should be restricted to public health bodies or other non-profit-making organisations. However, in the event that tissue engineering cannot take place other than in an industrial context, a derogation from the non-profit principle may be permitted.*

Amendment 44

Article 12, paragraph 3a (new)

***3a. Where commercial establishments are active in the cell and tissue sector, Member States shall ensure that, in the event of termination of business or bankruptcy, the cells and tissues held by them are transferred to other establishments in the cell and tissue sector.***

*Justification*

*Given that the directive does not rule out the operation of tissue banks by private institutions run as commercial businesses, rules should also be laid down determining how the material stored there is to be dealt with in the event of termination of business or bankruptcy.*

Amendment 45

Article 12, paragraph 3b (new)

***3b. Member States shall encourage the donation of umbilical cord blood for the public but may allow the parents the option of having their children's umbilical cord blood stored provided the standards laid down in this Directive are observed.***

*Justification*

*Stem cells from umbilical cord blood are a promising source of cell therapy. At present umbilical cord blood is usually still discarded after the birth. Sometimes, however, the blood is also stored by commercial businesses for the child concerned or its siblings. It should be ensured in any case that sufficient umbilical cord blood is available for heterologous transplantations and that the promising research in this field is also carried forward.*

Amendment 46
Article 12, paragraph 3c (new)

***3c. The removal of tissues from foetuses originating from the voluntary interruption of pregnancy shall not be permitted.***

***In the event of spontaneous interruption of pregnancy, any removal of foetal tissue shall require proof of the specific, free and informed consent of the parents.***

*Justification*

*Parliament's resolution of 16 March 1989 on the ethical and legal problems of genetic engineering opposes the use for this purpose of foetuses from the voluntary interruption of pregnancy.*

Amendment 47

Article 13 paragraph 1

| | |
|---|---|
| 1. The procurement of human tissues or cells shall be carried out only after all mandatory consent requirements in force in the Member State are met. | 1. The procurement of human tissues or cells shall be carried out only after all mandatory consent requirements in force in the Member State are met. ***In this context, Member States must take account of at least the following requirements:*** |
| | ***Living donors:*** |
| | ***Before any procurement of tissues or cells, the donor shall have given his/her prior informed and express consent in writing or, in exceptional cases precisely defined in law,*** |

***orally in the presence of witnesses. Until the moment the donated tissues or cells are actually utilised, the donor shall have the right to withdraw his/her consent without having to face any negative consequences. In the case of persons who cannot legally give consent themselves, the provisions of Article 13a shall apply.***

***In the case of the retrieval of umbilical cord blood, the consent of the mother or the legal representative of the child must be obtained.***

***Deceased donors:***
***In the case of procurement of tissues and cells from deceased persons, the donor must not have expressly refused her/his consent during lifetime. In the absence of any declaration of the donor during lifetime, tissues or cells shall only be procured if the relative of the deceased donor has given prior and express consent in writing or, in exceptional cases precisely defined in law, orally in the presence of witnesses. Member States are free to decide on more stringent requirements.***

*Justification*

*It must be clarified that the consent can only be withdrawn until the tissues and cells are actually utilised and second, in the case of deceased donors, it has to be clarified that the consent of the relatives is only necessary if the donor didn't make any declaration during his/her lifetime.*

Amendment 48

Article 13a (new)

***Article 13a***

***Protection of persons who are not in a position to give their voluntary informed consent***

***Cells and tissues may not be retrieved for the purpose of allogeneic donation from***

***persons who are not in a position to give informed legal consent. Exceptionally, in cases clearly defined by the legislation of the Member States, regenerative tissue and regenerative cells may be retrieved if,***

***- there is no other comparable donor capable of giving informed legal consent,***

***- the recipient is a brother or sister of a donor,***

***- the donation is potentially life- saving for the recipient,***

***- the informed consent is obtained by the legal representative,***

***- the consent represents the presumed consent of the donor and can be revoked at any time without prejudice to the donor or the legal representative,***

***and***

***- the potential donor does not refuse.***

***The donor must receive information concerning the retrieval of cells and therapy in accordance with his/her ability to understand such information.***

***Cell and tissue retrieval must be designed to minimise pain, discomfort and any other foreseeable risk. Both the risk threshold and the degree of distress must be specifically defined and monitored.***

***The cell and tissue retrieval must be endorsed by an ethics commission which has expertise in the field of the disease concerned and of the patient group concerned, or which takes advice in clinical, ethical and psychosocial problems in that field. The competent authorities in the Member States may ask the ethics commission concerned to lay down criteria for such donation in advance where the cell and tissue transplant does not allow any delay. In this case it is sufficient that it can be shown without doubt that it accords with the vote of the ethics commission.***

| | |
|---|---|
| | ***The interests of the donor who is unable to give consent shall always take precedence over those of science and society.*** |
| | ***Cells and tissues may be retrieved for the purpose of autologous donation where there is reason to assume that the transplant is of direct benefit to the patient and informed consent has been obtained by the legal representative. Cells and tissues may not be retrieved from this group of people for the sole purpose of research.*** |

*Justification*

*The ethics commission should lay down criteria in advance which would have to be complied with in an emergency and which would have to be verified. A clearer distinction should also be drawn between allogeneic donation, autologous donation and donation for research purposes.*

Amendment 49

Article 14, paragraph 3

| | |
|---|---|
| 3. Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Members States on the conditions of disclosure if the donor is closely related to the recipient. | 3. Member States shall take all necessary measures to ensure that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa, without prejudice to legislation in force in Members States on the conditions of disclosure if the donor is closely related to the recipient. ***In the case of gametes in particular, Member States may waive anonymity in order to respect the right of children to know their genetic parents.*** |

*Justification*

*Experience with adopted children shows that it is very important for the development of the children to know their genetic origin. This should be taken into account in this directive. In some Member States, children even have the constitutional right to know their genetic origin.*

Amendment 50

Article 15, paragraph 4

| | |
|---|---|
| 4. The tissue banks shall ensure that the selection and acceptance of tissues and cells comply with the requirements of ***Annex VI***. They shall also ensure that all donations are tested in accordance with Annex V. | 4. The tissue banks shall ensure that the selection and acceptance of tissues and cells comply with the requirements of ***Annex IV***. They shall also ensure that all donations are tested in accordance with Annex V. ***No tissues or cells derived from human embryos shall be used for transplantation.*** |

*Justification*

*The donation and use of material derived from human embryos, including cloned human embryos or animal/human hybrid embryos, should be excluded as the use of such materials is at least for the time being too risky.*

*The cross-reference is incorrect at present.*

Amendment 51

Article 15, paragraph 6a (new)

| | |
|---|---|
| | ***6a. Cloned human embryos, and human - animal hybrid embryos produced by cloning, aggregation or any other procedure, and cells and tissues derived from them, shall be excluded as sources of material for transplant.*** |

*Justification*

*The science of cloning has many risks. The defects at the molecular and cellular level that lead to the high incidence of failures, gross abnormalities and pre- peri- and post-natal death of reproductively cloned animals (such as the recent deaths of cloned sheep),would be present in cells used for therapeutic cloning.*

Amendment 52

Chapter IV, title

| | |
|---|---|
| PROVISIONS FOR QUALITY AND SAFETY ***IN TISSUE PROCESSING*** | PROVISIONS FOR QUALITY AND SAFETY ***OF TISSUES AND CELLS IN THEIR ENTIRETY*** |

*Justification*

*The heading should refer to the entire process.*

Amendment 53

Article 16, paragraph 3, indent 5a (new)

| | |
|---|---|
| | ***- information concerning the final destination of the tissues and cells.*** |

*Justification*

*Tissue establishments should have information concerning the end use of the tissues and cells.*

Amendment 54

Article 16, paragraph 5

| | |
|---|---|
| 5. Tissue establishments shall keep ***donor records*** for a minimum of 30 years after the confirmed clinical use of the ***last*** tissue/cell. | 5. Tissue establishments shall keep ***the data required for full traceability*** for a minimum of 30 years after the confirmed clinical use of the ***respective*** tissue/cell. ***Storage may also be in electronic form.*** |

*Justification*

*The documentation should refer to all the data required to ensure full traceability.*

Amendment 55

Article 17, paragraph 1, point b)

| | |
|---|---|
| b) he / she shall have at least ***two*** years practical experience, in one or more tissue banks ***accredited in accordance with Article 6***. | b) he / she shall have at least ***three*** years practical ***and relevant*** experience, in one or more tissue banks***, which fulfil the criteria of the directive or in a directly related field such as a blood bank, industry or research and development***. |

*Justification*

*Authorisation of tissue banks in accordance with the Directive cannot be commenced until the Directive enters into force. The Commission's proposal is therefore impracticable as no-one can have two years experience in accredited tissue banks following the entry into force of the Directive if the Directive is not yet in force. For that reason the focus should be on the practical requirements of the Directive which have already been met in many tissue banks and not on formal authorisation under the Directive. Related fields should also be recognised as experience. Two years' experience would not seem sufficient given the complexity of the work. At least three years are required.*

Amendment 56

Article 19a (new)

| | |
|---|---|
| | ***19a. Once the tissues have been retrieved, the deceased donor body should be constructed so that it is as similar as possible to its original anatomical shape. Reconstruction methods should minimise any impact on normal funeral procedures.*** |

*Justification*

*The Commission includes this provision in Annex VI. Reconstruction of the cadaver is a very important issue. It should not be left to a technical annex but should appear in the Directive itself.*

Amendment 57
Article 24, paragraph 1, point da) (new)

***da) where a third party distributes tissues or cells.***

*Justification*

*This possibility is not currently provided for and subcontracting of this function often occurs in practice.*

Amendment 58

Article 25, paragraph 1

| | |
|---|---|
| 1. Member States shall ensure that public and private establishments involved in health care, and establishments authorised to manufacture medicinal products or medical devices, have access to human tissue and cells, without prejudice to the provisions in force in Member States on the use of certain tissues and cells. | 1. Member States shall ensure***, with due regard for the principle of transparency,*** that public and private establishments involved in health care, and establishments authorised to manufacture medicinal products or medical devices, have access to human tissue and cells, without prejudice to the provisions in force in Member States on the use of certain tissues and cells. |

*Justification*

*The increasing use of products of human origin and the prospects for medical research in this field come up against the problem of the amount of tissues and cells available, which is still limited. Consequently, in addition to promoting donation Member States must ensure maximum accessibility and forestall any possible discrimination.*

Amendment 59

Article 25, paragraph 1a (new)

***1a. If used for unmodified transplantation, especially in case of shortage, distribution of tissues and cells must be in accordance with objective medical criteria.***

*Justification*

*Objective criteria must be applied to the use of scarce cells and tissue which are transferred to patients virtually without modification. In the case of cells which are available in large quantities and are technically modified by means of tissue engineering, the national health systems must decide on funding and access.*

Amendment 60

Article 29

| | |
|---|---|
| The adaptation of the technical requirements set out in ***Annexes I to VII*** to technical and scientific progress shall be decided by the Commission in accordance with the procedure referred to in Article 30(2). | The adaptation of the technical requirements set out in ***Annexes I, II, VI and VII*** to technical and scientific progress shall be decided by the Commission in accordance with the procedure referred to in Article 30(2).<br>***In order to modify Annexes III, IV and V, the European Commission will present a proposal to the Parliament and the Council.*** |

*Justification*

*Annexes III, IV and V contain issues which go beyond technical points and require the participation of the Parliament and the Council. They should therefore be removed from the comitology procedure.*

Amendment 61

Article 31, paragraph 1a (new)

| | |
|---|---|
| | ***1a. In revising and amending the technical annexes, the Commission shall make use of the experience of other regulatory authorities outside the EU.*** |

*Justification*

*Cell and tissue therapy is much further advanced in the United States than in the European Union. Regulatory work in this field is also further advanced in the USA (FDA). The positive results in this field should be used; the mistakes made in the USA should be used as a learning process.*

Amendment 62

Article 32a (new)

***Article 32a***

***Human organs***

***The Commission is invited to bring forward as soon as possible and in any case before July 2003 a legislative proposal addressing the transplantation of human organs, taking into account the specific nature of such transplants and the severe shortages that result in many patients going untreated.***

*Justification*

*The transplantation of human organs requires a different policy approach due to their specific nature and the severe shortages that result in many patients going untreated. The Commission should bring forward a legislative proposal before July 2003.*

Amendment 63

Annex I, Part B, point a)

| | |
|---|---|
| a) Have an organisational structure and operational procedures appropriate to the activities for which accreditation is sought, ensuring that it is able to receive, distribute, and allocate tissues and cells for transplantation on a 24 hour basis; | a) Have an organisational structure and operational procedures appropriate to the activities for which accreditation is sought, ensuring that it is able to receive, distribute, and allocate tissues and cells for transplantation on a 24 hour basis; |

| | |
|---|---|
| | ***Member States shall make exemptions to the requirement on operating on a 24 hour basis in the event that the tissue bank provides only tissues and cells for which no urgency is required.*** |

*Justification*

*This amendment provides linguistic clarification.*
*For a number of tissues, 24 hour availability is essential. For other tissues, however, a certain waiting time is acceptable. Where a cell tissue bank deals only in materials which need not be available around the clock, it would be exaggerated to prescribe 24 availability.*

Amendment 64

Annex III, part A, paragraph 7

| | |
|---|---|
| 7. The confirmed results of the analytical tests ***must be communicated, and*** clearly explained***, to the donor***. | 7. ***The donor should be informed that he has the right to receive*** the confirmed results of the analytical tests clearly explained. ***He shall be free to exercise this right or not.*** |

*Justification*

*There is a right to know but also a right not to know. A donor who for personal reasons does not wish to be informed of the results of certain tests should not be informed.*

Amendment 65

Annex III, part A, paragraph 8a (new)

| | |
|---|---|
| | ***8a. Allogeneic germ cell donors shall be informed about possible legal implications and consequences of their donation.*** |

*Justification*

*Under the laws of some Member States, germ cell donors qualify as the legal parents of the*

*child and also have to be disclosed to the child. Germ cell donors should thereof be informed about any legal and financial implications their donation may have.*

Amendment 66

Annex III, part B, paragraph 2

| | |
|---|---|
| The confirmed results of the donor's evaluation must be communicated, and clearly explained, to the donor's relatives ***when these results have relevance for their health or for public health.*** | The confirmed results of the donor's evaluation must be communicated, and clearly explained, to the donor's relatives ***in accordance with the legislation in the Member States.*** |

*Justification*

*The rules in the Member States are very different. The Commission's proposal infringes, in certain circumstances, the principle of confidentiality and medical secrecy.*

Amendment 67

Annex III, Part B a (new)

| | |
|---|---|
| | ***Ba. Umbilical cord blood and placenta*** |
| | ***When umbilical cord blood and placenta are retrieved, the woman or parents concerned must be provided with general information on the use of the cells and tissue. In the event of commercial storage of umbilical cord blood, the woman and the couple must be informed that many of the possible new treatments are at a very experimental stage.*** |

*Justification*

*It is not yet possible to predict what opportunities will be available for the use of umbilical cord blood in a few years' time. Consequently, the information can only be general and cannot describe specific use.*

Amendment 68

Annex IV, Section 2, point 2.2a (new)

| | |
|---|---|
| | ***2.2a CLONED HUMAN EMBRYOS AND ANIMAL – HUMAN HYBRID EMBRYOS*** |
| | ***Cloned human embryos, and human - animal hybrid embryos produced by cloning, aggregation or any other procedure, and cells and tissues derived from them, shall be excluded as sources of material for transplant.*** |

*Justification*

*The science of cloning has many risks. The defects at the molecular and cellular level that lead to the high incidence of failures, gross abnormalities and pre- peri- and post-natal death of reproductively cloned animals (such as the recent deaths of cloned sheep),would be present in cells used for therapeutic cloning.*

Amendment 69

Annex V, title

| | |
|---|---|
| LABORATORY TESTS REQUIRED FOR DONORS | LABORATORY TESTS REQUIRED FOR DONORS ***AND STEM CELLS*** |

*Justification*

*Annex V should lay down test requirements also for stem cells. See justification for amendment 73.*

Amendment 70

Annex V, paragraph 2, subparagraph 1

| | |
|---|---|
| 1. The tests should be carried out by a qualified laboratory***, authorised by the competent authority in the Member State***. | 1. The tests ***authorised by the competent authority in the Member State*** should be carried out by a qualified laboratory. |

*Justification*

*Requiring laboratories to be authorised by the authorities represents an unnecessary administrative burden. The decisive factor in the quality of test results is that the type of test is standardised, and where appropriate authorised by an authority, and that it complies with set criteria as regards specificity and sensitivity. Carrying out these tests is a routine task for medical technical assistants (MTAs).*

Amendment 71

Annex V, paragraph 2, subparagraph 3

| | |
|---|---|
| 3. ***The type of test used shall be in agreement with the scientific knowledge***. | 3. ***Special requirements for laboratory tests in relation to the collection of umbilical cord blood*** |
| | ***a. The serological tests prescribed in Annex V, point 1 are to be carried out on the mother and, in the event of a positive result, are to be repeated on the umbilical cord blood.*** |
| | ***b. Suitable genetic tests to exclude the infectivity of the umbilical cord blood may replace serological tests on the mother.*** |
| | ***c. All umbilical cord blood must be tested for bacterial contamination using aerobic/anaerobic blood culture. Positive results exclude use for transplants, in accordance with the state of medical knowledge and technology at the time of transplantation.*** |

*Justification*

*On 3.a): The 'donor' of umbilical cord blood from the afterbirth is the newborn child and not the mother. However, serological tests on the child's umbilical cord blood detect only class IgG antibodies from the mother. The newborn child itself cannot yet produce any antibodies. All antibodies in the child's blood are transferred from the mother through the placenta. Only class IgG antibodies can pass through the placenta. However, serological tests generally require the detection of IgG and IgM antibodies in order to distinguish between current infections and previous immunity or vaccination. This is not possible if the child's blood is tested using serological methods. Consequently, the mother's blood should be tested in accordance with paragraph 1.*

*On 3.b): An infection detected in the mother does not necessarily mean an infection in the child's blood (for example, the children of HIV-positive mothers are not always HIV-positive themselves). Infectious material in the umbilical cord blood should therefore be tested using the most sensitive and safe genetic methods possible with a view to the direct detection of virus DNA, for example. Such methods, if evaluated, are far superior to indirect suspicion on the basis of serological results from the mother and can therefore replace these tests.*

*On 3.c): Bacteria can enter the umbilical cord blood 1. as a result of an infection to the foetus, 2. during blood collection, or 3. during processing. It is important to recognise such bacterial contamination in order to take corresponding countermeasures (for example, discarding of the umbilical cord blood, pre-treatment of the transplant material or the recipient). On the other hand, bacterial contamination should not always lead to the material being discarded, since contaminated bone marrow has on several occasions been successfully transplanted. It is not yet possible to say to what extent bacterial contamination will be a hindrance in the case of future tissue engineering from umbilical cord stem cells. Consequently, reference needs to be made to the state of scientific knowledge for each single germ type.*

Amendment 72
Annex V, paragraph 2, subparagraph 5

| | |
|---|---|
| 5. In the case of living donors (except allogeneic bone marrow and peripheral blood cells donors, for practical reasons), blood samples should be obtained at the time of donation, with an admitted margin of +/– 7 days ***and*** a repeat sample after 6 months. | 5. In the case of living donors (except allogeneic bone marrow and peripheral blood cells donors, for practical reasons), blood samples should be obtained at the time of donation, with an admitted margin of +/– 7 days***. In the case of allogeneic donors,*** a repeat sample after 6 months. |

*Justification*

*The requirement for repeat testing after 6 months is questioned, particularly for autologous products.*

Amendment 73

Annex V, Section 2a (new)

***2a. Tests required for novel sources of stem cells, and for cells and tissues derived from them, where in vitro propagation is involved***

***2a1. Tests required for embryonic stem cells, and cells and tissues derived from them***

***In addition to adhering to the Codes of Practice for cell and tissue culture in the Member States of the European Union, the additional tests shall be required for processing, storage and culture of embryonic stem cells:***

| ***Test / Check*** | ***Positive result*** |
|---|---|
| ***Teratoma or teratocarcinoma formation by the cells that are to be used for transplant*** | ***Contraindication to therapeutic use*** |
| ***Contamination with animal material*** | ***Contraindication to therapeutic use*** |
| ***Immune typing of stem cells and cells and tissues derived from them***<br><br>***Immune typing of human cells, serum and other material used for "feeder" layers*** | ***To be carried out to determine the need for immuno-suppression of the patient*** |
| ***Long-term risk of cancer formation*** | ***Contraindication to therapeutic use*** |
| ***Epigenetic instability, particularly DNA methylation status of both imprinted and non-imprinted genes. To include wide-ranging tests on the DNA methylation status of tumour suppressor genes, DNA repair genes, proto-oncogenes and potentially mutagenic mobile elements*** | ***Contraindication to therapeutic use*** |
| ***Genetic instability, to include uniparental disomy*** | ***Contraindication to therapeutic use*** |
| ***Difference in gene expression in cells and tissues to be used for transplant, from that of normal cells and tissues*** | ***Any change in expression of tumour suppressor genes, DNA repair genes, proto-oncogenes and potentially mutagenic mobile elements: Contraindication to therapeutic use***<br><br>***Other changes: to be assessed*** |
| ***Incorrect or poor functioning of differentiated derivatives of stem cells*** | ***To be assessed*** |
| ***Embryonic stem cell fusion in culture***<br><br>***Embryonic stem cell fusion with adult cells to be checked in vivo*** | ***To be assessed***<br><br>***Contraindication to therapeutic use if found to be at a level in vivo or in vitro that could cause a risk of cancer because of aneuploidy or chromosomal instability.***<br><br>***Contraindication to therapeutic use if there is a selective growth advantage of the fused cells*** |
| ***Egg and sperm donors, and donors of secondary human cells, serum or other human material which is used as a "feeder" layer, to be treated as allogeneic donors*** | ***Selection criteria for allogeneic donors (Annex IV 2.2) to be applied.*** |

| | |
|---|---|
| ***Genetic engineering*** | ***Cells that have been genetically engineered shall not be used until safety issues regarding gene therapy are resolved. They should then be subject to strict additional tests*** |

***2a2. Tests required for adult stem cells, and cells and tissues derived from them***

***In addition to adhering to the Codes of Practice for cell and tissue culture in the Member States of the European Union, the additional tests shall be required for processing, storage and culture of adult stem cells:***

| ***Test / Check*** | ***Positive result*** |
|---|---|
| ***Immune typing of adult stem cells, and cells and tissues derived from them, for allogeneic use***<br><br>***Human serum for allogeneic use to be immuno-typed*** | ***To be carried out to maximise compatibility with the patient, and determine any need for immuno-suppression*** |
| ***Genetically-engineered cells*** | ***Gene therapy and the use of all genetically engineered cells to be on hold until safety issues regarding gene therapy are resolved. The cells should then be subject to strict additional tests.***<br><br>***This includes cells that have been genetically engineered for immortalisation, or to reduce immunogenicity*** |
| ***Use of embryonic stem cells, embryonic germ cells or other embryonic cells to reprogramme somatic cells*** | ***To be treated as embryonic cells for the purposes of testing for safety*** |

| | |
|---|---|
| ***Senescence*** | ***Contraindication to use*** |
| ***Tests on the genetic stability, epigenetic stability, and the risk of tumour or cancer formation of new sources of stem cells to be carried out*** | ***To be assessed*** |
| ***Incorrect or poor functioning of adult stem cells and their differentiated derivatives*** | ***To be assessed*** |
| ***Donors of both serum and stem cells to be treated as allogeneic donors where appropriate*** | ***Selection criteria for allogeneic donors (Annex IV 2.2) to be applied.*** |

*Justification*

*Paragraph 19 of the Explanatory Memorandum states that where preparation of cells or tissues to be transplanted into the body "includes steps that influence growth or differentiation of these cells, additional safety measures might need to be considered in the future."*

*However, transplantation of embryonic stem cells, or of cells or tissues generated from them, would of necessity involve growth and differentiation. Owing to the well-established inherent ability of embryonic stem cells to form tumours called teratomas or teratocarcinomas, and their potential to form cancer through many different routes, it is therefore proposed that the safety issues specific to embryonic stem cells, and cells and tissues derived from them, be addressed now.*

Amendment 74

Annex VI, part I

| | |
|---|---|
| ***I. Once the tissues have been retrieved, the deceased donor body should be reconstructed so that it is as similar as possible to its original anatomical shape. Reconstruction methods should minimise any impact on normal funeral procedures.*** | ***deleted*** |

*Justification*

*The reconstruction of the cadaver is a very important issue. It should not be left to a technical Annex, but should appear in the directive itself.*

Amendment 75

Annex VII, Part A, paragraph 7

| | |
|---|---|
| 7. Environments in which tissues are processed must be adequately controlled to minimise or avoid the potential for tissue contamination. Where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality of Grade A (< 3,500 particles per m3 of minimum 0.5 µm) is required, usually by using a laminar air flow (LAF) cabinet. The background environment must ***be suitable to maintain a Grade A in the LAF. Where tissues or cells are exposed to the environment during processing with a subsequent microbial inactivation process, a Grade C environment (< 350,000 particles per m3 of minimum 0.5 µm and < 2,000 particles per m3 of 5µm) is required.*** | 7. Environments in which tissues ***and cells*** are processed must be adequately controlled to minimise or avoid the potential for tissue ***and cell*** contamination. Where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality of Grade A (< 3,500 particles per m3 of minimum 0.5 µm) is required, usually by using a laminar air flow (LAF) cabinet. The background environment must ***guarantee an air quality of Grade B in accordance with the GMP guideline***. |

*Justification*

*.In accordance with the current European GMP guideline for the processing of open products which are not subsequently sterilised, processing must be carried out in air quality of Grade B. There is no reason to depart from this rule in the case of cells and tissue.*

Amendment 76

Annex VII, Part B, paragraph 3

| | |
|---|---|
| 3. Maximum storage time must be specified for each type of storage condition. | 3. Maximum storage time must be specified for each type of storage condition. ***If the maximum storage time has been reached,*** |

***the cells and tissues have not yet been used up and it can be guaranteed through validated tests that the cells and tissues are still capable of functioning, the storage time may be extended.***

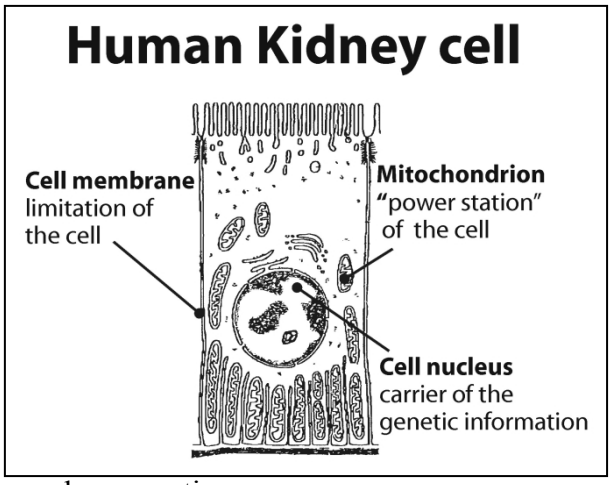
*Justification*

*The maximum storage time for individual procedures cannot yet be determined owing to the lack of empirical data from long-term experiments (e.g. in the case of the cryoconservation of living cells and tissue). It should therefore be possible to adapt storage time in line with scientific progress.*

**EXPLANATORY STATEMENT**

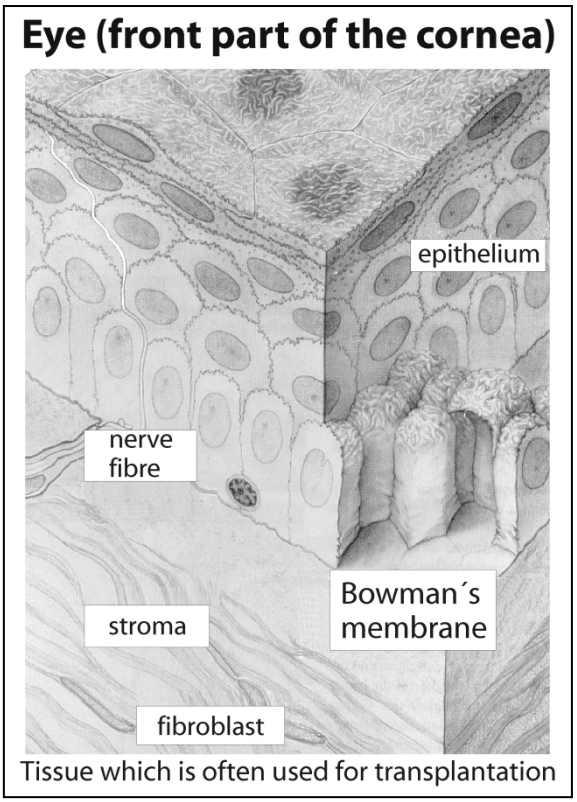
# I. Introduction

The transplantation of cells and tissue is a sharply expanding field of medicine. It offers great opportunities for patients who have so far been suffering from incurable diseases, and great potential for economic development. On the other hand, experience in the USA, for example, shows that this new therapy also carries with it certain risks.




## II. Scientific background

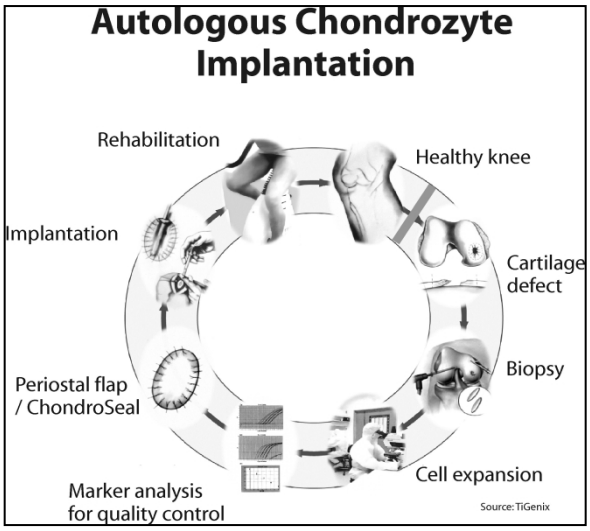
A **cell** is the smallest isolated structural and functional unit of an organism still capable of living and propagating.




**Tissue** is an aggregate of cells joined together by, for example, connective structures which perform the same particular function, **e.g. connective, muscle or nerve tissue or the cornea of the eye**.

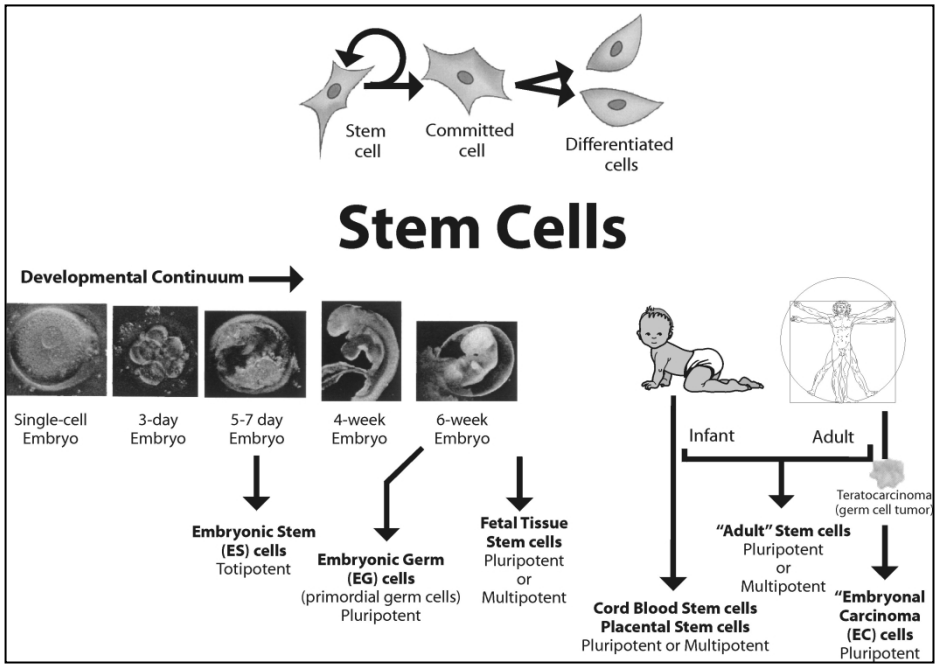
**Cell or tissue transplantation** is a process which involves retrieving cells or tissue from an organism and - possibly after several interim stages - implanting them either into the same organism (autologous transplantation) or into another organism (allogenous transplantation), in order to improve or restore **a function of a destroyed tissue, e.g. transplantation of the cornea, vessels, skin or bone marrow.**

**Tissue engineering** is a young bio-technological discipline which makes it possible, with the aid of biological products, to stimulate cell growth, differentiation and viability and to develop sound human tissue.




**Stem cells** fall within the scope of the directive. As they are the focus of public debate, your rapporteur makes a number of remarks on the subject. However, not all problems associated with stem cells can be resolved on the basis of the present Commission proposal. Moreover, most fields of human cell and tissue transplantation currently work without stem cells and in particular, embryonic stem cells have still not been transplanted into a human body anywhere in the world.

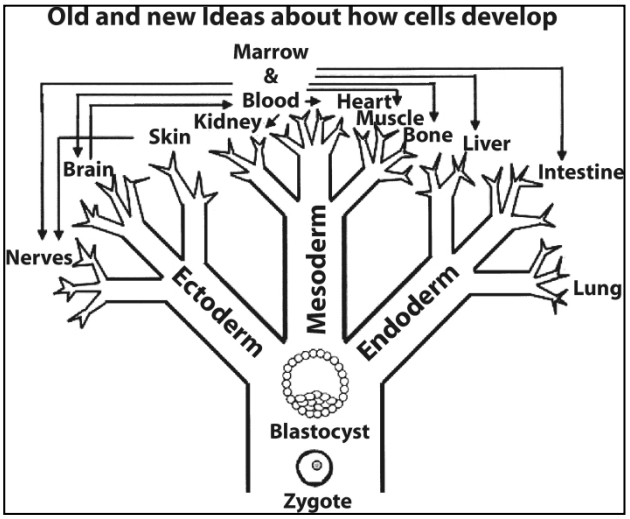
Stem cells are differentiable cells which have not yet acquired their definitive function

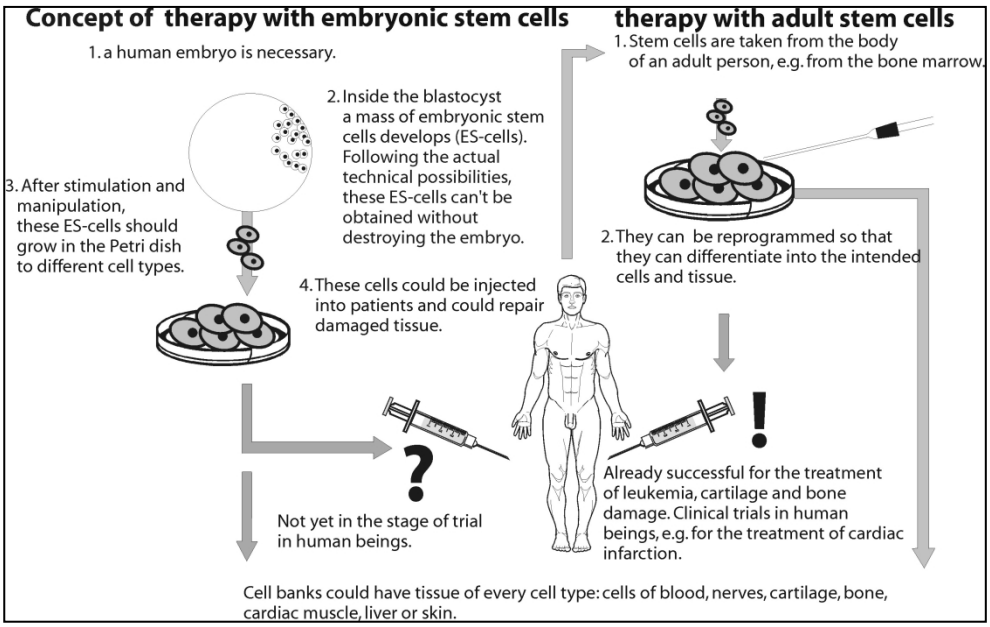



**Stem cells are present in every phase of human development**

Until a few years ago, it was assumed that all the various cells in the human body could only arise from embryonic stem cells. More recent scientific findings, however, show that adult stem cells can form practically all differentiated types. It has been possible, for example, to form nerve cells from bone marrow cells. In theory, both embryonic and adult stem cells could be used for cell therapy in the future. From a purely scientific point of view, embryonic stem cells have the advantage that they can be multiplied in the laboratory almost unlimitedly. From a scientific point of view, the biggest advantage of embryonic stem cells is also their biggest disadvantage. The ability constantly to divide entails a latent risk that embryonic stem cells, once implanted into the human body, may form malignant tumours. Owing to the practical problems, it is unlikely that this form of therapy will be tested on humans in the near future even in countries in which embryonic stem cell research is legal. From an ethical point of view, there is a problem that it will not be possible to extract embryonic stem cells without killing an embryo.

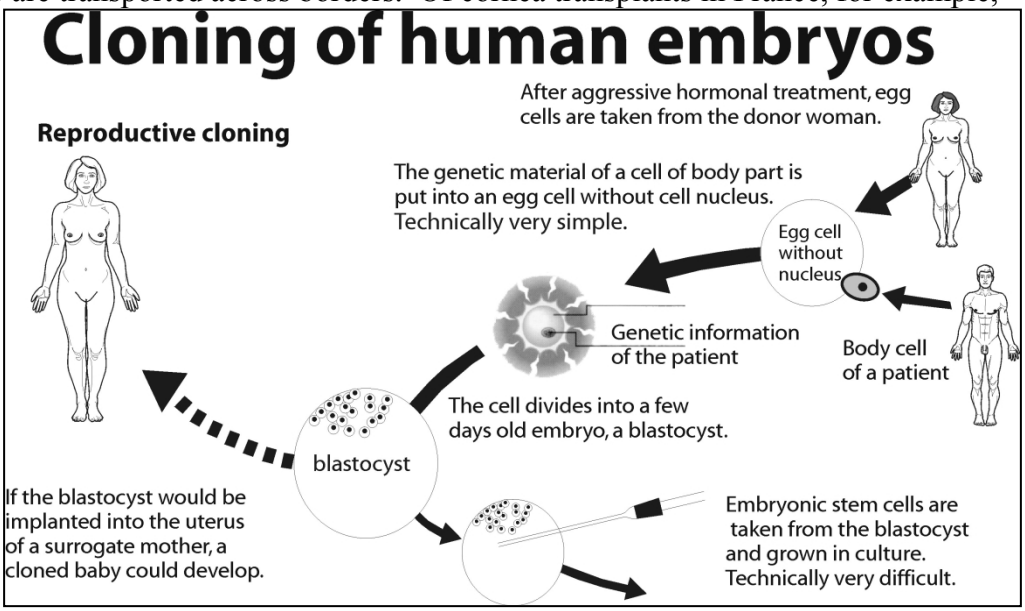
The problem with adult stem cells is that they cannot be readily reproduced in the laboratory. Nevertheless, tremendous progress has been made in this field in recent years. Moreover, too little research has yet been carried out to determine how adult stem cells can be differentiated selectively into other cells and tissues. Despite this, successful therapies have been developed on the basis of adult stem cells, e.g. in the treatment of leukaemia and cartilage and bone injuries. Other therapies are at the clinical testing stage, e.g. heart infarction therapy. The cloning of human embryos is related to the present report in as much as a denucleated human egg cell is still required to produce a cloned embryo. Furthermore, the cloning of embryos is to some extent advocated as a method for obtaining embryonic stem cells for cell therapy. In cloning, the nucleus of the egg cell is removed and then brought together with the nucleus of an adult cell from another person. This produces a genetically identical embryo, as was the case with the cloned sheep Dolly. Despite various reports that the cloning of human embryos has been achieved through the process of cell nucleus transfer, there is no scientific proof of this to date. In the event that it becomes possible to produce genetically identical human embryos by cell nucleus transfer, there are two options as to how to proceed with these embryos. They could be implanted into the uterus so that a cloned baby develops (reproductive cloning) or they could be used for research purposes. The latter is sometimes described as therapeutic cloning. Sometimes, however, something different is understood by 'therapeutic cloning', e.g. the work with adult stem cells. The scientific barrier both for reproductive cloning and for the production of cloned human embryos for research purposes is currently nucleus transfer, i.e. the production of embryos from denucleated egg cells and body cells.



## III. Why is the Directive necessary?

The increase in cell and tissue transplantation and tissue engineering is to be welcomed but care must be taken to ensure that quality and safety standards are observed and that fundamental ethical principles are respected. The scandal of HIV-contaminated blood products is painfully present in the minds of many. Cell and tissue transplants present a greater risk than treatment with blood products since, as a rule, there is no procedure for destroying pathogens and the therapy process is still very new. There have already been fatalities which could have been avoided by observing stricter standards. The directive must therefore establish appropriate framework conditions. A European approach is needed as cells and tissue are transported across borders. Of cornea transplants in France, for example, 25% are imported.[1] European citizens must be sure that transplants imported from other Member States and, possibly, even from third countries meet the same quality and safety standards.




## IV. The Commission proposal

The Commission's proposal provides that activities connected with the processing, conservation, storage and distribution of human tissue and cells for transplantation in humans in future will only be carried out by establishments already authorised by a competent authority for this purpose. They must be subject to a regular inspection by the competent authority. The head of the establishment must have appropriate experience and staff must also be qualified. Appropriate tests must be carried out to provide protection from infectious diseases, e.g. as protection against AIDS, an HIV test. Any incidents and unforeseen events must be reported and there must exist a system for tracing cells and tissue as well as donors so that in the event of an incident it would be possible to identify the cause. Advertising for cell and tissue donations is subject to prior authorisation, for example in order to prevent any dubious promises. The Directive is also to apply to imported cells and tissue as well as those for export.

On 21 January 2003, a large-scale public hearing was held on the subject. The statements of the experts are available on the Internet at: www.eutop.de/ct

[1] See opinion of the European Economic and Social Committee of 11.12.2002, point 4.1, p.2.

## V. Assessment of the Commission proposal

In the rapporteur's view, the Commission's proposal points in the right direction. On the whole, it provides for appropriate quality and safety standards to protect patients from infectious diseases. The establishment of EU-wide provisions will improve the development of cell and tissue therapy. There are proposals on some points, however, which are not based on fact and should therefore be simplified to stimulate developments better (see amendments).

**The ethical aspects of cell and tissue therapy**

The Commission touches on the ethical aspects in its proposal to some extent, which is to be welcomed. However, the manner in which the problems are dealt with is not always appropriate.

The view is expressed that it is not appropriate to regulate ethical issues such as informed consent or voluntary unpaid donations under a European directive. Your rapporteur firmly rejects this view. Discussion at European level, e.g. within the context of the Biopatent Directive, show that it is not possible to take a decision on regulating genetic and biotechnology without duly taking account of the ethical aspects. It is argued that this is not possible on legal grounds. However, the Directive on blood products, the Directive on clinical testing and the Biopatent Directive are unequivocal evidence that matters which are generally regarded as ethical issues can be regulated by the European Union on the basis of various articles of the Treaty. In addition, in the case of the present proposal, blood safety and quality of cells and tissues cannot be considered irrespective of the ethical issues, such as voluntary unpaid donations and informed consent, as it is obvious that the manner in which cells and tissue are obtained have an effect on quality and safety. Moreover, the wording of Article 152, paragraph 4(a)[1] cannot be construed as meaning that there should be no rules laid down to protect the donor or that matters which are generally regarded as ethical issues should not be regulated. Neither is there any case-law of the European Court of Justice forming a basis for such a narrow interpretation. It is important, however, to respect the fact that the basic ethical principles enshrined in the Directive represent only minimum standards and that there is no attempt at harmonisation. The Member States are in any case free to decide on their own ethical standards on the basis of more stringent measures.

## VI. The politically significant issues:

**1.** The Commission proposes that the Directive should apply in principle to all forms of human tissue and cells, e.g. also to gametes (egg and sperm cells). Cells which are intended for research purposes and not for re-implantation in the human body are exempt from the scope of the Directive. This also applies to organs. The Commission has given notice that it is working on a separate directive for this. The EP must consider whether the proposed scope of the directive is appropriate.

**2.** The Commission proposes that Member States should encourage voluntary and unpaid

[1] Article 152, paragraph 4(a): 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;'

donations. For an article in a European Directive, this provision is extremely imprecise and will lead to misunderstandings in both directions. Patients and industry required to give donors compensation for the costs associated with providing the donation so that sufficient preparations are available argue that compensation, by way of such an article, might discredit the procedure. Others fear that commercialisation of the body, which has already begun, e.g. the trade in egg and sperm cells for five figure amounts in Europe, cannot be brought under control by means of such a provision.

**3.** In Article 12, paragraph 3, the Commission proposes: 'Member States shall encourage that the procurement of tissues and cells is carried out on a non-profit basis'. This wording may lead to misunderstandings. The question of voluntary and unpaid donations is often confused with the question of whether the institutions in the cell and tissue sector work on a non-profit basis; the two issues must be strictly separated.

**4. 'Informed consent'** is an important principle which is enshrined in the Charter of Fundamental Rights, for example. In your rapporteur's view, it is not enough to refer to the Member States' rules. Particularly in the light of the accession of ten states whose rules are not yet clear, guidelines and minimum standards at least must be laid down in the directive. The directive on clinical testing shows that this is possible.

**5.** The Commission proposes that donors should in principle be anonymous and, for example, not be known to the recipient of the transplant. This is a rational proposal as otherwise it could indirectly promote trade in cells and tissue. However, in the case of eggs and sperm cells, provision must be made for an exception.

**6.** The Commission proposes that it should be possible to amend all annexes to the directive by way of the comitology procedure, i.e. without codecision of Parliament. This proposal is appropriate for annexes concerned with technical issues. If, for example, a new disease emerges and there is an appropriate test for it, that test should be introduced immediately and no codecision procedure should be required. On the other hand, the annexes also contain crucial policy issues. For example, what information should be given to the donor.

**7.** There is great controversy in the Member States and in the European Parliament over the use of human embryonic stem cells and the cloning of human embryos. A majority of MEPs have always rejected the production of embryos for research purposes and the cloning of humans at all phases of their development[1]. There are differing opinions, however, on what approach to adopt to embryos produced for the purpose of artificial insemination and to embryonic stem cells in the laboratory. In the Caudron report, Parliament voted by a slim majority to authorise research on these embryos and cells. In other opinions, such research was to some extent vigorously rejected[2]. In principle, it is possible to regulate these matters on the basis of Article 152, given that in one respect, the health of the donor is under certain circumstances endangered. For example, in the process of cloning human embryos, the woman who provides the egg cells is subjected to a hazardous form of hormone treatment. In

[1] E.g. in the Caudron report on the 6th Research Framework Programme and the Damião report on the biotechnology action plan.
[2] Nistico report on quality and safety standards of blood and blood components, Casini report on artificial in-vivo and in-vitro insemination, Rothley report on ethical and legal problems of genetic engineering.

the view of many lawyers, protection of the donor also includes the human embryo. Above all, however, there is a considerable risk for the recipient through the danger of embryonic stem cells degenerating into cancer and cells produced by cloning human embryos growing uncontrollably. An expert opinion drawn up by the Centre for European Law at the University of Passau in August 2001 for the EPP/ED Group also states that the European Union is competent to regulate in the matter of embryonic stem cells and the cloning of human embryos. Despite that, your rapporteur makes no proposal for such regulation in the draft report, pending debate in the European Parliament and in the Member States. The decision as to whether and, if so, under what conditions, research with human embryonic stem cells is to be authorised must naturally be taken first in the Member States. The EP should however discuss the issue of whether, in the event of a national parliament deciding to authorise embryonic stem cell research, certain minimum criteria must be observed.

**VII. Procedural remarks**

The amendments 1, 2, 4, 5, 6, 8, 10 and 13 by the Legal Affairs Committee have been incorporated in the report without a vote in conformity of Rule 162a, as they do not contradict the other amendments adopted by the Environment Committee.

The amendment 11 by the Legal Affairs Committee has been ruled inadmissible. In the view of the Environment Committee, fundamental ethical principles, as referred to in Legal Affairs Committee's amendment 11 fall clearly outside the scope of the competence conferred by Article 152 of the Treaty. It follows, therefore, that since the Rules of procedure are based on the Treaty only amendments, which are not contrary to the Treaty, may be admissible. This is confirmed, moreover, by the interpretative note to Article 140(3) of the rules of procedure, and is inherent in the system of the Community legal order.

The remaining amendments of the Legal Affairs committee have been voted normally, as they address the same issues as amendments tabled by ENVI members and in the view of the Environment Committee, do not fall under exclusive competence of the Legal Affairs Committee.

19 February 2003

# OPINION OF THE COMMITTEE ON BUDGETS

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells
(COM(2002) 319 – C5-0302/2002 – 2002/0128(COD))

Draftsman: Kyösti Tapio Virrankoski

## PROCEDURE

The Committee on Budgets appointed Kyösti Tapio Virrankoski draftsman at its meeting of 18 July 2002.

It considered the draft opinion at its meetings of 19 February 2003.

At the last meeting it adopted the following amendments unanimously.

The following were present for the vote: Terence Wynn, chairman; Reimer Böge, vice-chairman; Anne Elisabet Jensen, vice-chairman; Franz Turchi, vice-chairman; Kyösti Tapio Virrankoski, draftsman; Kathalijne Maria Buitenweg, Joan Colom i Naval, Den Dover, Göran Färm, Markus Ferber, Salvador Garriga Polledo, Anne-Karin Glase (for Ioannis Averoff), Jutta D. Haug, María Esther Herranz García, Constanze Angela Krehl, Armin Laschet (for Per Stenmarck), Jan Mulder, Juan Andrés Naranjo Escobar, Joaquim Piscarreta, Giovanni Pittella, Esko Olavi Seppänen (for Francis Wurtz), Ralf Walter and Brigitte Wenzel-Perillo.

## SHORT JUSTIFICATION

*Introduction*

The Commission has presented a Proposal for a Directive on setting standards of quality and safety for human tissues and cells.

The Proposal aims to cover human cells and tissues used for application to the human body, with the exception of blood, blood products and organs. Tissues and cells used as autologous graft and autologous cells used for the manufacturing of medicinal products are also excluded from the scope of the Proposal.

The Proposal, which is based on Art. 152 TEC, in particular al.4 (a) and whose adoption is consequently under the co-decision procedure, lays down:

- certain obligations on Member States authorities, with regard notably to the supervision of tissue procurement, the accreditation and registration of tissue banks, inspection and control measures, traceability, etc.;

- provisions for the selection and evaluation of donors (consent, data protection);

- provisions for quality and safety in tissue processing, notably personnel qualifications and training;

- provisions for exchange of information and reporting;

- and finally, provisions on comitology, reference being made to Art. 5 to 8 of Decision 1999/468/EC [1](Regulatory Committee).

*Budgetary Aspects*

The envisaged action falls under the umbrella of the programme of Community action in the field of public health 2003-2008 (hereafter the Public Health Programme)[2] and its funding is provided for by the overall financial envelope of the Public Health Programme. Among its general objectives, the Public Health Programme aims at enhancing the capability of responding rapidly and in a coordinated fashion to threats to health. One action considered under this framework is directed at the safety and quality of substances of human origin, including tissues and cells.[3]

The financial framework of the Public Health Programme is set at € 312 million for the period 2003-2008 under budget line B3-4308. This is a reference amount, with annual appropriations

[1] O.J L 184/23 of 17.7.1999

[2] Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) - OJ L 271/1 of 09.10.2002.

[3] In particular, Objective 2.6 as laid down in the Annex to this Decision aims at "enhancing the safety and quality of organs and substances of human origin, including blood, blood components and blood precursors by developing high standards of quality and safety for the collection, processing, storage and distribution and use of these substances."

being decided on a yearly basis by the budgetary authority.

With regard to this particular measure on tissues and cells, the Commission proposes to allocate €12 million in commitment for the period of implementation (2003-2008). An indicative schedule of appropriations is presented in Table 1 below.

*Table 1 -Commitments in € million, indicative amounts, Budgetline B3-4308 and B3-4308A*

| | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | **Total** |
|---|---|---|---|---|---|---|---|
| Heading 3 Financial Intervention | 1,25 | 1,25 | 1,5 | 1,5 | 1,5 | 1,5 | 8,5 |
| Heading 3 Admin. Expenditures | 0,3 | 0,7 | 0,7 | 0,6 | 0,6 | 0,6 | 3,5 |
| ***Sub Total*** | ***1,55*** | ***1,95*** | ***2,2*** | ***2,1*** | ***2,1*** | ***2,1*** | ***12*** |
| | | | | | | | |
| Heading 5 Human Resources | 0,22 | 0,22 | 0,22 | 0,22 | 0,22 | 0,22 | **1,32** |

*Conclusion*

The draftsman considers that the Proposal has no additional financial impact on Heading 3. However, he feels that, for the sake of clarity, the text of the Proposal should establish a clear link with the Public Health Programme, which constitutes the legal foundation for the implementation of the measures foreseen in the field of tissues and cells.

The draftsman is of the opinion that the reporting as laid down in Art. 27 of the Proposal should be reinforced and suggests that an annual report be sent to the European Commission by Member States and that the Commission provide the European Parliament with an annual evaluation report.

As regards comitology, the draftsman considers that, in line with the traditional approach of the Budget Committee, the advisory procedure as laid down in Art. 3 of Decision 1999/468/EC[1] should apply.

[1]O.J L 184/23 of 17.7.1999

## AMENDMENTS

The Committee on Budgets calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

## AMENDMENT TO THE LEGISLATIVE TEXT

*[The European Parliament]*

Considers that the financial statement of the Commission Proposal attached to the current report is compatible with the ceiling of heading 3 of the Financial Perspective without restricting existing policies.

*Justification*

*The indicative funding for this action, which is set at €12 million, is provided for by the financial framework of the Public Health Programme 2003-2008 under budget line B3-4308.*

## AMENDMENTS TO THE LEGISLATIVE TEXT

| Text proposed by the Commission[1] | Amendments by Parliament |
|---|---|
| Amendment 2<br>Recital 25(new) | |
| | ***This Directive is in accordance with Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), in particular point 2.6 of its Annex.*** |

*Justification*

*Reference should be made in the text of the proposed Directive to the Public Health*

[1] OJ C .

*Programme.*

Amendment 3
Article 1

| | |
|---|---|
| This Directive lays down standards of quality and safety of human tissues and cells used for application to the human body, in order to ensure a high level of protection of human health | This Directive lays down standards of quality and safety of human tissues and cells used for application to the human body, in order to ensure a high level of protection of human health***, in accordance with Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), in particular point 2.6 of its Annex.*** |

*Justification*

*Reference should be made in the text of the proposed Directive to the Public Health Programme.*

Amendment 4
Recital 24

| | |
|---|---|
| ***Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[12], they should be adopted by use of the Regulatory Procedure provided for in Article 5 of that Decision.*** | ***Measures for the implementation of this Directive should be adopted by use of the Advisory Procedure provided for in Article 3 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. [12]*** |
| [12] OJ L 184, 17.7.1999, p.23 | [12] OJ L 184, 17.7.1999, p.23 |

*Justification*

*In line with the traditional approach of the Committee on Budgets with regard to comitology, the draftsman considers that the advisory procedure, as it facilitates implementation and reduces administrative burden, should apply.*

Amendment 5
Article 27

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|---|---|
| 1. Member States shall send the Commission, ***three years*** after the implementation date indicated in Article 32 (1), and every ***three years*** thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control. | 1. Member States shall send the Commission, ***one year*** after the implementation date indicated in Article32 (1), and every ***year*** thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control<br>***3.The Commission, when presenting the Preliminary Draft Budget, shall submit to the budgetary authority the results of a quantitative and qualitative evaluation based on the annual implementation plan and on performance indicators.*** |

*Justification*

*A reporting on a yearly basis seems more appropriate in view of the activities to be undertaken by the Commission under the proposed Directive. In addition, an annual evaluation report will ensure that the budget authority takes an informed decision with regard to the annual appropriation under budget line B3-4308.*

Amendment 6
Article 30

| ***Regulatory procedure*** | ***Advisory procedure*** |
|---|---|
| 1. The Commission shall be assisted by a Committee, composed of ***representatives of the Member States*** and chaired by the representative of the Commission. | 1. The Commission shall be assisted by a Committee, composed of ***one representative of each Member State*** and chaired by the representative of the Commission. |
| 2. Where reference is made to this paragraph, Articles ***5*** and 7 of | 2.Where reference is made to this paragraph, Articles ***3*** and 7 of |

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| Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. | Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. |
| ***3. The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months*** | 3. ***Delete*** |

*Justification*

In line with the traditional approach of the Committee on Budgets with regard to comitology, the draftsman considers that the advisory procedure, as it facilitates implementation and reduces administrative burden, should apply. Each Member State should allocate one representative only in order to improve the decision-making process of the Committee. Paragraph 3 is deleted, as it does not apply to the advisory procedure.

18 March 2003

# OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND THE INTERNAL MARKET

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells

(COM(2002) 319 – C5-0302/2002 – 2002/0128(COD))

Draftsman(*): Paolo Bartolozzi

(*) Enhanced cooperation between committees

## PROCEDURE

The Committee on Legal Affairs and the Internal Market appointed Paolo Bartolozzi draftsman at its meeting of 11 July 2002.

It considered the draft opinion at its meetings of 19 February and 17-18 March 2003.

At the latter meeting it adopted the following amendments by 23 votes to 1, with 1 abstention.

The following were present for the vote: Giuseppe Gargani (chairman), Willi Rothley (vice-chairman), Ioannis Koukiadis (vice-chairman), Paolo Bartolozzi (draftsman), Charlotte Cederschiöld (for Rainer Wieland), Bert Doorn, Janelly Fourtou, Evelyne Gebhardt, Fiorella Ghilardotti, José María Gil-Robles Gil-Delgado, Malcolm Harbour, The Lord Inglewood, Hans Karlsson (for Carlos Candal), Kurt Lechner, Klaus-Heiner Lehne, Toine Manders, Manuel Medina Ortega, Marcelino Oreja Arburúa (for Joachim Wuermeling), Anne-Marie Schaffner, Marianne L.P. Thyssen, Ieke van den Burg (for Maria Berger pursuant to Rule 153(2)), Alexandre Varaut, Diana Wallis, Matti Wuori (for Neil MacCormick) and Stefano Zappalà.

## SHORT JUSTIFICATION

Therapeutic activities based on the use of human-derived tissues and cells which are carried out in Europe every year now concern hundreds of thousands of patients. The sector is also certain to expand, not only in the traditional field of transplants (e.g. corneal and skin grafts and heart valves), but also, as a result of advances in biotechnology, in those of reconstructive surgery, reproductive medicine and the treatment of disorders such as cancer, diabetes and Parkinson's disease.

It must also be stressed that the so-called 'engineering' of such human-derived material, whereby the latter is incorporated into or combined with other medical devices, may constitute a field which is undoubtedly of interest to European research centres and firms. It is highly desirable for the European Union to take action in this field; in this respect, the proposal for a directive in question regulates the procurement, testing, processing, storage, and distribution of human tissues and cells which are intended to be applied to the human body. The aims of the proposal (the legal basis of which is Article 152(4)(a) of the EC Treaty, which requires the adoption of measures setting high standards of quality and safety for substances of human origin with the aim of health protection) are particularly noteworthy. The requirements relating to the suitability of donors of tissues and cells are strengthened; the requirements that the Member States must impose when accrediting centres which handle human-derived products (tissue banks, etc.), as well as a European system of controls, are laid down; common standards for training those who work in the sector are laid down; standards are set for the traceability of tissues and cells from donor to patient, and vice versa; finally, a system to provide uniform regulation of imports of human-derived substances from third countries is established, to ensure compliance with the same quality and safety standards as those obtaining in the European Union. The measures also appear to comply with the principle of subsidiarity and proportionality, given the transnational dimension of the activities concerned, in respect of which a joint approach and effective cooperation make sense. Moreover, the provisions do not prevent the Member States introducing more stringent national protective measures, and they do not affect national rules on donation and the medical use of specific human tissues and cells (such as stem cells, for instance).

With regard to the use of embryonic and foetal germ and stem cells procured and stored in accordance with the standards laid down by this directive, it will be for the Member States to regulate such use by means of appropriate national legislation.

A number of fundamental ethical principles in this field must be observed, in order to protect personal dignity and personal freedom, as well as the common good.

The first issue concerns the ethical imperative of ensuring complete safety from the point of view of health. In this connection the quality and safety standards relating to the procurement and handling of human tissues and cells, laid down on the basis of the most advanced scientific and technical findings, must prevent or reduce the risk of disease transmission. The principle that the route from donor to patient, and vice versa, must be traceable, while still ensuring the protection of data relating to personal privacy and medical confidentiality, also reflects the aim of protecting human health. Finally, the requirement to ensure that the same quality and safety standards exist and can be verified in the case of human tissues and cells from third countries is also consistent with the same principle.

Secondly, respect for the human body must be assured with regard to removal from both living and deceased donors. In this connection, the requirement for informed consent on the part of the donor, supplied in a specific form either by the donor or by next of kin is particularly important.

The third issue concerns respect for privacy and protection of the confidentiality of the information collected when tissues are removed. Donation must be anonymous as regards both the donor and the recipient (except for the requirements regarding traceability). Personal and family data may not be disclosed to third parties (e.g. employers or insurance companies); this is also to avoid the risk of unjustified discrimination.

The fourth principle concerns the fact that donation is unpaid. This represents a voluntary act of human solidarity which may, however, be appropriately encouraged by specific measures and by proper information on the part of the Member States. This requirement must be retained, not least with regard to imports from third countries.

## AMENDMENTS

The Committee on Legal Affairs and the Internal Market calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

| Text proposed by the Commission[1] | Amendments by Parliament |
|---|---|
| Amendment 1<br>Recital 7 | |
| (7) ***This*** Directive ***does not interfere with*** decisions ***made by Member States*** concerning the ***use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health and guarantee respect for fundamental rights. Moreover, this Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual'***. | (7) ***The*** Directive ***explicitly recognises the right of Member States to take*** decisions concerning the ***banning of donation, experimentation, processing, storage, distribution and use of any other kind of particular cells or human tissues or of cells of a particular origin. If any Member State takes such a decision the ban may also be extended to imports of cells or tissues of such kinds. Member States also have the right to ban products originating from particular cells, to ban particular tissues or cells having a particular origin and to ban their importation. For ethical reasons, and for reasons connected with the high risks of a medical nature connected with human cloning, Member States must also explicitly ban the use of*** |

[1] OJ C 227, 24.9.2002, p. 505.

***tissues and cells from cloned human embryos and of hybrids derived from germ cells or totipotent cells of human and animal origin***.

*Justification*

*The use of cells and tissues derived from cloned human embryos and human and animal hybrids cannot be permitted for ethical reasons, and for reasons connected with the extremely high medical risks involved.*

*Parliament and the Council of Europe have also repeatedly expressed their opposition to any form of human cloning. On this issue see:*

*(a) in the case of Parliament, its resolutions of 16 March 1989 on the ethical and legal problems of genetic engineering and 'in vivo' and 'in vitro' artificial insemination; 28 October 1993 on the cloning of human embryos; 20 September 1996 and 12 March 1997 on cloning; 15 January 1998 on human cloning; 30 March 2000 and 7 September 2000 on human cloning; European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, and*

*(b) in the case of the Council of Europe, the Convention for the protection of human rights and the dignity of the human person with regard to the application of biology and medicine; the Convention on Human Rights and Biomedicine and the annexed protocol, prohibiting the cloning of human beings; and Recommendation 1046 of the Council of Europe Parliamentary Assembly on the use of human embryos and foetuses in scientific research.*

*On the other points, the amendment reflects progress in the debate in the Council of Ministers and highlights the application of the subsidiarity principle. It is normal practice for Member States to be able to set more stringent standards than those laid down by Community directives, in accordance with Article 152 of the Treaty.*

Amendment 2
Recital 7 a (new)

***(7a) There is no consensus within the European Union as to whether, and in what circumstances, embryonic stem cells may be processed. The processing of stem cells, and in particular the creation of stem cells in cases in which the embryo from which they originate has to be destroyed, is scientifically and ethically controversial and illegal in many Member States.***

***However, the processing of adult stem***

***cells and of stem cells from the umbilical cord is legal and ethically non-controversial in all the Member States.***

***Such alternative solutions to the use of embryonic stem cells should be specifically promoted by the European Union and by the Member States. Obstacles to the processing of adult stem cells and stem cells from the umbilical cord must be removed.***

*Justification*

*The amendment essentially corresponds to an amendment adopted by the European Parliament as part of the Nisticò report on the proposal for a European Parliament and Council directive setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Council Directive 89/381/EEC. The amendment was rejected by the Commission and the Council, on the grounds that such a provision should not appear in the Directive on blood, but in that relating to tissues and cells. Hence it appears here in its natural place.*

Amendment 3
Article 4, paragraph 2 a (new)

***2a. Member States shall prohibit the use, as sources of supply for tissues and cells, of cloned human embryos and of hybrids derived from germ or totipotent cells of human and animal origin.***

***The Directive shall explicitly recognise the right of Member States to take decisions on the banning of donation, experimentation, processing, storage, distribution and use of any other kind of particular cells or human tissues or of cells of a particular origin.***

***If any Member State takes such a decision the ban may also be extended to imports of cells or tissues of such kinds.***

***Member States shall also have the right to ban products originating from particular cells, to ban particular tissues or cells having a particular origin and to ban their importation.***

*Justification*

*The use of cells and tissues derived from cloned human embryos and human and animal hybrids cannot be permitted for ethical reasons, and for reasons connected with the extremely high medical risks involved.*

*Parliament and the Council of Europe have also repeatedly expressed their opposition to any form of human cloning. On this issue see:*

*(a) in the case of Parliament, its resolutions of 16 March 1989 on the ethical and legal problems of genetic engineering and 'in vivo' and 'in vitro' artificial insemination; 28 October 1993 on the cloning of human embryos; 20 September 1996 and 12 March 1997 on cloning; 15 January 1998 on human cloning; 30 March 2000 and 7 September 2000 on human cloning; European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, and*

*(b) in the case of the Council of Europe, the Convention for the protection of human rights and the dignity of the human person with regard to the application of biology and medicine; the Convention on Human Rights and Biomedicine and the annexed protocol, prohibiting the cloning of human beings; and Recommendation 1046 of the Council of Europe Parliamentary Assembly on the use of human embryos and foetuses in scientific research.*

*On the other points, the amendment reflects progress in the debate in the Council of Ministers*

*and highlights the application of the subsidiarity principle. It is normal practice for Member States to be able to set more stringent standards than those laid down by Community directives, in accordance with Article 152 of the Treaty.*

Amendment 4
Article 4, paragraph 4 a (new)

***4a. Should the Member States not prohibit the use of germ cells and embryonic and foetal stem cells obtained and stored in accordance with the standards laid down in this Directive, they shall regulate such use by means of appropriate legislation.***

*Justification*

*It is essential that the Member States specifically regulate the use of cells of an ethically 'sensitive' origin.*

Amendment 5
Article 9, paragraph 3

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| 3. The competent authority shall approve imports of human tissues and cells from third countries only when equivalent standards of quality and safety to the ones laid down in this Directive are ensured. | 3. The competent authority shall approve imports of human tissues and cells from third countries only when equivalent standards of quality and safety to the ones laid down in this Directive***, and likewise respect for fundamental ethical principles,*** are ensured. |

*Justification*

*Like compliance with quality and safety standards, it must be ensured that, where human tissues and cells imported from third countries are concerned, the ethical principles governing the field (including the free, informed consent of donors, or unpaid donation) are followed, in order to protect human dignity.*

Amendment 6
Article 9, paragraph 4

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| 4. The procedures for verifying the equivalent standards of quality ***and*** safety in accordance with paragraph 3 shall be | 4. The procedures for verifying the equivalent standards of quality***, safety and respect for fundamental ethical principles*** |

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| established by the Commission in accordance with the procedure referred to in Article 30(2). | in accordance with paragraph 3 shall be established by the Commission in accordance with the procedure referred to in Article 30(2). |

*Justification*

*See justification to Amendment 5.*

Amendment 7
Article 12, paragraph 1

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| 1. Member States shall ***encourage voluntary and unpaid donations*** of tissues and cells ***with a view to ensuring that they are in so far as possible provided from such*** donations. | 1. Member States shall ***ensure that the necessary provision*** of tissues and cells ***takes place voluntarily and on the basis of*** donations. |

*Justification*

*Makes it clearer that donations of tissues and cells should occur only on a voluntary basis and without payment. Article 3 of the Charter of Fundamental Rights stipulates that the commercialisation of humans or human body parts is prohibited. This obviously also applies to cells and tissues.*

Amendment 8
Article 12, paragraph 1 a (new)

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| | ***1a. Member States shall provide the public with information about the circumstances in which donated tissues and cells are used, with particular reference to the benefits for public health and to the requirements that tissue banks comply with standards of quality, safety and respect for fundamental ethical principles.*** |

*Justification*

*Appropriate information about the benefits of donation, on the one hand, and the respectability of tissue banks, on the other, may encourage the propensity to donate on the part of the public.*

Amendment 9
Article 12, paragraph 3

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| 3. Member States shall ***encourage*** that the procurement of tissues and cells is carried out on a non-profit basis. | 3. Member States shall ***ensure*** that the procurement of tissues and cells is carried out on a non-profit basis.<br>***The reimbursement of expenses shall be regarded as compatible with the principle of free donation.***<br>***When human tissues are used as the basis for obtaining, through engineering, products that require sophisticated medical techniques, such activities may be permitted for bodies and organisations operating on a profit basis.*** |

*Justification*

*Makes it clearer that donations of tissues and cells should occur only on a voluntary basis and without payment. Article 3 of the Charter of Fundamental Rights stipulates that the commercialisation of humans or human body parts is prohibited. This obviously also applies to cells and tissues.*

*This takes up the Council of Europe definition of blood donation and was approved by Parliament in the Nisticò report on the proposal for a European Parliament and Council directive setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components (A5-0272/2001 – 2002/98/EC).*

*As a matter of principle, the operation of tissue banks should be restricted to public health bodies or other non-profit-making organisations. However, in the event that tissue engineering cannot take place other than in an industrial context, a derogation from the non-profit principle may be permitted.*

Amendment 10
Article 12, paragraph 3 a (new)

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| | ***3a. (i) The removal of tissues from foetuses originating from the voluntary interruption of pregnancy shall not be permitted.***<br>***(ii) In the event of spontaneous interruption of pregnancy, any removal of foetal tissue shall require proof of the specific, free and informed consent of the parents.*** |

*Justification*

*Parliament's resolution of 16 March 1989 on the ethical and legal problems of genetic engineering opposes the use for this purpose of foetuses from the voluntary interruption of pregnancy.*

Amendment 11
Article 12, paragraph 3 a (new)

***3a. Member States shall ensure that fundamental ethical principles are respected. These shall include:***

***– respect for the human body,***

***– the donor's informed consent,***

***– donations by persons incapable of giving their consent are permitted only if removal is directly connected with the person's illness and the donation is such as to be of direct benefit to that person's health,***

***– confidentiality of information about the donor and the recipient,***

***– the principle that donation is unpaid.***

*Justification*

*The rapporteur's Amendment 12 should not merely appear in the annex, but should have full validity in the legal text. There is also a particular need to protect from exploitation those who are not capable of giving their consent.*

Amendment 12
Article 13, paragraph 1

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|---|---|
| 1. The procurement of human tissues or cells shall be carried out only after all mandatory consent requirements ***in force in the Member State*** are met. | 1. The procurement of human tissues or cells shall be carried out only after all mandatory consent requirements are met. ***Consent must have been given expressly and specifically either in written form or before an official body.*** |

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| | ***In the case of persons who are incapable of giving their consent, such consent must be given in writing or before an official body by the persons authorised for their care.*** |

*Justification*

*The consent requirements are consistent with those provided for by Article 19 of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 4 April 1997.*

*Ways must be found of ensuring respect for the dignity of persons incapable of giving their consent, such as small children, patients in a coma and patients with severe dementia, by involving the persons authorised for their care. The need for written consent is common sense.*

Amendment 13
Article 25, paragraph 1

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| 1. Member States shall ensure that public and private establishments involved in health care, and establishments authorised to manufacture medicinal products or medical devices, have access to human tissue and cells, without prejudice to the provisions in force in Member States on the use of certain tissues and cells. | 1. Member States shall ensure***, with due regard for the principle of transparency,*** that public and private establishments involved in health care, and establishments authorised to manufacture medicinal products or medical devices, have access to human tissue and cells, without prejudice to the provisions in force in Member States on the use of certain tissues and cells. |

*Justification*

*The increasing use of products of human origin and the prospects for medical research in this field come up against the problem of the amount of tissues and cells available, which is still limited. Consequently, in addition to promoting donation Member States must ensure maximum accessibility and forestall any possible discrimination.*

Amendment 14
Article 29

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| The adaptation of the technical requirements set out in Annexes I to VII to technical and scientific progress shall be decided by the Commission in accordance | The adaptation of the technical requirements set out in Annexes I***, II and IV*** to VII to technical and scientific progress shall be decided by the |

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| with the procedure referred to in Article 30(2). | Commission in accordance with the procedure referred to in Article 30(2). |

*Justification*

*Annex III deals with vital ethical issues, such as donors' and their relations' rights to information, and should be amendable only in the proper legislative process*