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<TitreType>RECOMMENDATION FOR SECOND READING</TitreType>

<Titre>on the Council common position adopting a European Parliament and Council directive on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells</Titre>

<DocRef>(10133/3/2003 – C5‑0416/2003 – 2002/0128(COD))</DocRef>

<Commission>{ENVI}Committee on the Environment, Public Health and Consumer Policy</Commission>

Rapporteur: <Depute>Peter Liese</Depute>

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| Symbols for procedures |
| \* Consultation procedure *majority of the votes cast*  \*\*I Cooperation procedure (first reading) *majority of the votes cast*  \*\*II Cooperation procedure (second reading) *majority of the votes cast, to approve the common position majority of Parliament’s component Members, to reject or amend the common position*  \*\*\* Assent procedure *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) *majority of the votes cast*  \*\*\*II Codecision procedure (second reading) *majority of the votes cast, to approve the common position majority of Parliament’s component Members, to reject or amend the common position*  \*\*\*III Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*  (The type of procedure depends on the legal basis proposed by the Commission) |

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| 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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PROCEDURAL PAGE

At its sitting of 10 April 2003 Parliament adopted its position at first reading 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 – 2002/0128(COD)).

At the sitting of 4 September 2003 the President of Parliament announced that the common position had been received and referred to the {ENVI}Committee on the Environment, Public Health and Consumer Policy (10133/3/2003 – C5‑0416/2003).

The committee had appointed Peter Liese rapporteur at its meeting of {02/10/2002}2 October 2002.

It considered the common position and draft recommendation for second reading at its meetings of 6 October and 4 November 2003.

At the last meeting it adopted the draft legislative resolution by 43 votes to 5, with 4 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; María del Pilar Ayuso González, Robert Atkins (for Martin Callanan), **María Luisa** Bergaz Conesa, Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Philip Bushill-Matthews ( for Raffaele Costa), Niels Busk (for Astrid Thors), Dorette Corbey, Chris Davies, Anne Ferreira, Francesco Fiori (for Cristina Gutiérrez Cortines), Marialiese Flemming, Cristina García-Orcoyen Tormo, Robert Goodwill, Hedwig Keppelhoff-Wiechert (for Avril Doyle), Dieter-Lebrecht Koch (for Christa Klaß), Eija-Riitta Anneli Korhola, Hans Kronberger, Bernd Lange, Giorgio Lisi (for Françoise Grossetête), Caroline Lucas (for Patricia McKenna), Torben Lund, Minerva Melpomeni Malliori, Rosa Miguélez Ramos, Rosemarie Müller, Antonio Mussa (for Jim Fitzsimons), Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Marit Paulsen, Samuli Pohjamo (for Jules Maaten), Encarnación Redondo Jiménez (for Raquel Cardoso), Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Ursula Schleicher (for Karl-Heinz Florenz), Horst Schnellhardt, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Robert William Sturdy (for Emilia Franziska Müller), Antonios Trakatellis, Peder Wachtmeister, Phillip Whitehead.

The recommendation for second reading was tabled on12 November 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(10133/3/2003 – C5‑0416/2003 – 2002/0128(COD))

(Codecision procedure: second reading)

*The European Parliament*,

– having regard to the Council common position (10133/3/2003 – C5‑0416/2003),

– having regard to its position at first reading[[1]](#footnote-1) on the Commission proposal to Parliament and the Council (COM(2002) 319)[[2]](#footnote-2),

– having regard to the amended proposal (COM(2003) 340)[[3]](#footnote-3),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the {ENVI}Committee on the Environment, Public Health and Consumer Policy (A5‑0387/2003),

1. Amends the common position as follows;

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

|  |  |  |
| --- | --- | --- |
| Council common position |  | Amendments by Parliament |

<Amend>Amendment <NumAm>1</NumAm>

Recital -1 (new)

|  |  |
| --- | --- |
|  | ***(-1) The human body is inviolable and inalienable.*** ***Making the human body and its parts as such a source of financial gain is prohibited.*** |

Justification

Retabling of an amendment adopted in first reading (77). The second phrase of the amendment can be found in the Charter of fundamental rights and the fact that the Convention presented its draft constitution in which the Charter is included after the EP's 1st reading and after the meeting of the Council of Ministers on 2 June 2003 should encourage the EP even more to insist on this amendment.

</Amend>

<Amend>Amendment <NumAm>2</NumAm>

Recital 1

|  |  |
| --- | --- |
| (1) The transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases. The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases. | (1) The transplantation of tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases***.*** The quality and safety of these substances should be ensured, particularly in order to prevent the transmission of diseases. ***It is equally important for fundamental ethical principles to be observed.*** |

Justification

Reintroduction of some elements of amendment 2 of first reading.

</Amend>

<Amend>Amendment <NumAm>3</NumAm>

Recital 1a (new)

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

Justification

Reintroduction of amendment 3 from 1st reading.

</Amend>

<Amend>Amendment <NumAm>4</NumAm>

<Article>Recital 5</Article>

|  |  |
| --- | --- |
| (5)As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards. | (5)As tissue and cell therapy is a field in which an intensive worldwide exchange is taking place, it is desirable to have worldwide standards. ***The Community should therefore endeavour to promote the highest possible level of protection to safeguard public health regarding quality and safety of tissues and cells. The European Commission should include in its report to Council and Parliament information on the progress made in this respect.*** |

Justification

Amendment 5 of first reading as redrafted after consultation with Council and Commission.

</Amend>

<Amend>Amendment <NumAm>5</NumAm>

Recital 6

|  |  |
| --- | --- |
|  | (6) ***It is necessary to regulate the donation and procurement of all sources of human tissues and cells. The testing, processing, preservation, storage and distribution of all human tissues and cells used for transplantation purposes should also be regulated.*** |
| Tissues and cells intended to be used for industrially manufactured products, including medical devices, should be covered ***by this Directive*** only as far as donation, procurement and testing are concerned***,*** ***where the processing, preservation, storage and distribution are regulated by other Community legislation.*** ***The further manufacturing steps are covered by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.*** | Tissues andcells intended to be used for industrially manufactured products, including medical devices, should be covered only as far as donation, procurement and testing are concerned***.*** ***The further manufacturing steps are covered by the relevant legislation.*** |

Justification

Reintroduction of some elements of amendment 87 of first reading and the original Commission proposal.

</Amend><Amend>Amendment <NumAm>6</NumAm>

<Article>Recital 6a (new)</Article>

|  |  |
| --- | --- |
|  | ***(6a) This Directive should apply to tissues and cells including haematopoetic peripheral blood, umbilical cord (blood) and bone marrow stem cells; reproductive cells (eggs, sperm); foetal tissues and cells, adult and embryonic stem cells.*** |

Justification

This amendment incorporates the content of am 20 of first reading.

<Amend>Amendment <NumAm>7</NumAm>

Recital 8

|  |  |
| --- | --- |
| (8) 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. | (8)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 just as important as the regulation of the quality and safety of tissues and cells. The Commission should therefore submit a proposal on that subject by the end of 2003.*** |

Justification

Reintroduction of amendment 6 from first reading. Though the Council has adopted the first sentence of the amendment, the 2nd and 3rd sentence was not taken into account. Also a slight change is needed, as the timeframe proposed by the EP has already expired. The more the EP should insist on a proposal until end of 2003.

</Amend>

<Amend>Amendment <NumAm>8</NumAm>

Recital 8a (new)

|  |  |
| --- | --- |
|  | ***(8a) Reprogrammed differentiated cells, and genetically modified tissues or cells for human therapy are still in the research phase, but nevertheless pose different regulatory problems that will need to be addressed in due course.*** |

Justification

Reintroduction of amendment 83 of first reading.

</Amend>

<Amend>Amendment <NumAm>9</NumAm>

Recital 11b (new)

|  |  |
| --- | --- |
|  | ***(11b) Genetic characteristics of germ cells are not to be considered as quality characteristics within the meaning of this Directive.*** |

Justification

In Article 28(j) of its common position the Council proposes that the conditions for the selection, evaluation and procurement of cells used for reproduction purposes should be determined within the framework of the comitology procedure. This provision could be misinterpreted to mean that special quality characteristics are to be determined for reproduction purposes in the context of genetic characteristics. In simple terms, it might appear that egg and sperm cells with good genes will be approved and those with ‘bad’ genes will not. Such an interpretation must be avoided, since first of all it can lead to eugenics, and secondly the decision as to whether testing should be carried out for genetic characteristics, e.g. genetic disorders, in the context of in vitro fertilisation is a decision which should rest with the Member States.

</Amend>

<Amend>Amendment <NumAm>10</NumAm>

<Article>Recital 13</Article>

|  |  |
| --- | --- |
| (13) It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors, and in the safety of the application process. | (13) It is necessary to increase confidence among the Member States in the quality and safety of donated tissues and cells, in the health protection of living donors and respect for deceased donors, and in the safety of the application process. ***Member States should also take steps to promote the Community's self-sufficiency in tissues and cells, and encourage bone marrow donor registration.*** |

Justification

Retabling of part of amendment 10 from first reading but moved to another recital to take account of the Council's common position.

</Amend><Amend>Amendment <NumAm>11</NumAm>

Recital 16

|  |  |
| --- | --- |
| (16) As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development. | (16) As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. ***In particular in the case of gamete donations, the lifting of donor anonymity could be authorised.***  Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development. |

Justification

Corresponds to amendment 16 of first reading. It is tabled at another place where it seems to be more appropriate.

</Amend>

<Amend>Amendment <NumAm>12</NumAm>

<Article>Recital 16a (new)</Article>

|  |  |
| --- | --- |
|  | ***(16a) Any establishment may also be accredited as cell and tissue establishments provided they comply with the standards.*** |

Justification

The amendment is the result of negotiations with Council and Commission regarding a possible compromise.

</Amend>

<Amend>Amendment <NumAm>13</NumAm>

Recital 17

|  |  |
| --- | --- |
| (17) The procurement of human tissues and cells must ***take into account*** ***the general principles of*** the Charter of Fundamental Rights of the European Union  ***and of the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine, in particular in relation to donor consent.*** | (17) 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 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

Reintroduction of amendment 13 of first reading.

</Amend>

<Amend>Amendment <NumAm>14</NumAm>

Recital 17a (new)

|  |  |
| --- | --- |
|  | ***(17a)******As far as compliance with legal rules protecting human dignity is concerned, the Commission and the Member States should endeavour 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****:* |
|  | ***- a ban on making the human body or its parts as such a source of financial gain, and*** |
|  | ***- the principle of informed consent.*** |

Justification

Reintroduction of parts of amendment 14 of first reading. A small modification in indent 1 ("as such") was necessary to make the wording compatible with the Charter of Fundamental Rights.

</Amend>

<Amend>Amendment <NumAm>15</NumAm>

Recital 17b (new)

|  |  |
| --- | --- |
|  | ***(17b) Member States should intensify their efforts to combat illegal trafficking in human tissues and cells and parts of the human body in general. Following adoption of this Directive and submission of a directive on the quality and safety of organs, the Council should adopt framework legislation based on Articles 29, 31(e) and 34(2)(b) of the EU Treaty addressing all those issues which could not be or were not resolved in the present Directive.*** |

Justification

Reintroduction of amendment AM 15 of first reading. The 2nd part makes reference to the activity of the Council (proposal of the Hellenic Republic).

</Amend>

<Amend>Amendment <NumAm>16</NumAm>

Recital 25

|  |  |
| --- | --- |
| (25) 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 State; | (25) 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; |
|  | ***- establish clear and evolutionary rules to facilitate revision of the technical rules of the Directive in the light of the rapid advance in biotechnology knowledge and practice in the sphere of human tissues and cells*.** |

Justification

Reintroduction of amendment 17 of first reading.

</Amend>

<Amend>Amendment <NumAm>17</NumAm>

Article 1

|  |  |
| --- | --- |
| This Directive lays down standards of quality and safety for human tissues and cells ***intended*** forhuman applications, in order to ensure a high level of protection of human health. | This Directive lays down standards of quality and safety for human tissues and cells ***used*** for human applications, in order to ensure a high level of protection of human health. |

Justification

Reintroduction of amendment 18 from first reading in a modified form.

</Amend>

<Amend>Amendment <NumAm>18</NumAm>

<Article>Article 2, paragraph 1, subparagraph 2</Article>

|  |  |
| --- | --- |
| ***Where such*** manufactured products ***are covered by other Directives***, this Directive ***shall apply*** 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

Retabling of second part of amendment 19 from first reading.

</Amend>

<Amend>Amendment <NumAm>19</NumAm>

<Article>Article 3, point b)</Article>

|  |  |
| --- | --- |
| b) "Tissue" ***means*** ***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.*** |

Justification

Reintroduction of the main part of amendment 24 of first reading. 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.

</Amend><Amend>Amendment <NumAm>20</NumAm>

Article 3, point (c)

|  |  |
| --- | --- |
| (c) 'Donor' ***means every human source, whether living or deceased, of human cells or tissues;*** | (c) ‘Donor’ ***shall mean a living or deceased individual, including non-natus, who is the source of tissues or cells. In this context, the term 'individual' is used synonymously with the term 'human being'.*** |

Justification

Reintroduction of amendment 25 of first reading.

</Amend>

<Amend>Amendment <NumAm>21</NumAm>

Article 4, paragraph 2

|  |  |
| --- | --- |
| 2. This Directive ***shall not prevent a Member State from maintaining or introducing*** more stringent protective measures, ***provided*** that ***they*** 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

Reintroduction of amendment 28 of first reading.

</Amend>

<Amend>Amendment <NumAm>22</NumAm>

Article 7, paragraph 4a (new)

|  |  |
| --- | --- |
|  | ***(4a)*** ***Member States in collaboration with the Commission shall prepare guidelines******concerning the conditions of the inspections and control measures, and on the******training and qualification of the officials involved, in order to reach a consistent******level of competence and performance.*** |

Justification

Modified amendment which was adopted in first reading (AM 33). The modification was proposed by the European Commission.

</Amend>

<Amend>Amendment <NumAm>23</NumAm>

Article 8, paragraph 1

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

Justification

Reintroduction of amendment 38 from first reading in a modified form.

</Amend>

<Amend>Amendment <NumAm>24</NumAm>

Article 8, paragraph 1a (new)

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

Justification

Reintroduction of amendment 94 of first reading.

</Amend>

<Amend>Amendment <NumAm>25</NumAm>

<Article>Article 8, paragraph 3</Article>

|  |  |
| --- | --- |
| 3. All tissues and cells must be identified with a label that contains the information referred to in Article 28(g) and (i). | 3. All tissues and cells must be identified with a label that contains the information ***or references allowing a link to the information*** referred to in Article 28(g) and (i). |

Justification

New text of the Council could cause unnecessary bureaucracy. This wording is more appropriate.

</Amend><Amend>Amendment <NumAm>26</NumAm>

Article 8, paragraph 3a (new)

|  |  |
| --- | --- |
|  | ***3a. The data required to ensure full traceability in accordance with this Article shall be kept for at least thirty years.*** |

Justification

Reintroduction of an amendment adopted in first reading (AM 40).

</Amend>

<Amend>Amendment <NumAm>27</NumAm>

<Article>Article 8, paragraph 3b (new)</Article>

|  |  |
| --- | --- |
|  | ***3b. The traceability requirements for tissues and cells, as well as for products and materials coming into contact with these tissues and cells and having an effect on their quality and safety shall be established by the Commission in accordance with the procedure referred to in Art 29 (2).*** |

Justification

This amendment is a result of negotiations with Council regarding a possible compromise.

<Amend>

<Amend>Amendment <NumAm>28</NumAm>

<Article>Article 9, paragraph 1</Article>

|  |  |
| --- | --- |
| 1. Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those ***Member States*** that receive such imports from third countries shall ensure that they meet standards of quality and safety equivalent to the ones laid down in this Directive. | 1. Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities, ***that imported tissues and cells*** ***have been donated, procured and exported in accordance with the law of the third country, and that they can be traced from the donor to the recipient and vice versa in accordance*** ***with the procedures referred to in Article 8.*** Those ***tissue establishments*** that receive such imports from third countries shall ensure that they meet standards of quality and safety equivalent to the ones laid down in this Directive. |

Justification

Reflects those parts of 1st reading amendment 35 which Council has not accepted. The latter part makes it clear who is directly concerned.

</Amend>

<Amend>Amendment <NumAm>29</NumAm>

Article 10, paragraph 1

|  |  |
| --- | --- |
| 1. Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(g). They shall submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible. | 1. Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(g). They shall submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible ***to ensure optimal use and equal access.*** |

Justification

Reintroduction of part of amendment 32 from first reading.

</Amend>

<Amend>Amendment <NumAm>30</NumAm>

Article 11, paragraph 1

|  |  |
| --- | --- |
| Notification of ***serious*** adverse events and reactions | Notification ofadverse events and reactions |
| 1. Member States shall ensure that there is a system in place to report, ***investigate***, register and transmit information about ***serious*** adverse events and reactions ***which may influence the quality and safety of tissues and cells and which may be attributed*** to the procurement, testing, processing, storage ***and*** distribution of tissues and cells***, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.*** | 1. The Member States shall ensure that there is a system in place to report, register, and transmit information about adverse events and reactions ***related*** to the procurement, testing, processing, storage, distribution ***and*** ***transplantation*** of tissues and cells. |

Justification

Reintroduction of amendment 89 adopted in first reading and the original Commission proposal.

</Amend>

<Amend>Amendment <NumAm>31</NumAm>

Article 12, paragraph 1

|  |  |
| --- | --- |
| 1. Member States shall ***take the necessary measures to encourage*** voluntary and unpaid donations of human tissues and cells ***with a view to ensuring that, insofar as is possible, they are obtained from such donations.*** | 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.*** |
| Member States shall report to the Commission ***on these measures before ..... \* and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take at Community level.*** | Member States shall report to the Commission ***every two years after the entry into force of the Directive on the way in which they implement this requirement.*** |
| ***\* Two years after the entry into force of this Directive.*** |  |

Justification

Reintroduction of amendment 41 adopted in first reading.

</Amend>

<Amend>Amendment <NumAm>32</NumAm>

Article 12, paragraph 2

|  |  |
| --- | --- |
| 2. Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells ***comply with guidelines or legislative provisions laid down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on*** advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage. | 2. Member States shall take all necessary measures to ensure that any promotion and  publicity activities in support of the donation of human tissues and cells ***receive prior approval by the competent authority.*** Advertising the need for, oravailability of,  human tissues and cells, with a view to offering or seeking financial gain or  comparable advantage ***shall be prohibited***. |

Justification

<OptDelPrev>Reintroduction of the text of the original Commission proposal. The Council deleted the provision which states that advertising concerning tissues and cells requires prior approval. The wording of the Council is very unclear, that is why the wording of the Commission shall be reintroduced.</OptDelPrev>

</Amend>

<Amend>Amendment <NumAm>33</NumAm>

Article 12, paragraph 3

|  |  |
| --- | --- |
| 3. Member States shall ***encourage*** ***the procurement of*** tissues and cells ***to be carried out on a non-profit basis.*** | 3. Member States shall ***ensure that there is no trading in unmodified*** tissues and cells. |
|  | ***Where human tissues or cells are used as source material for manufacturing products for therapeutic use, such activities may be permitted for bodies and organisations operating on a profit basis.*** |

Justification

Amendment 81 of first reading.

</Amend>

<Amend>Amendment <NumAm>34</NumAm>

Article 12, paragraph 3a (new)

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

Justification

Amendment 45 from first reading.

</Amend>

<Amend>Amendment <NumAm>35</NumAm>

Article 12, paragraph 3b (new)

|  |  |
| --- | --- |
|  | ***3b. The procurement of tissues after an abortion shall require special rules. No abortion shall be performed to obtain foetal tissue. It shall be ensured by appropriate measures that no pregnant woman is put under any kind of pressure to undergo an abortion in order to obtain tissue.*** |
|  | ***The timing of an abortion and the way it is carried out shall not be influenced by the wish to obtain foetal tissue.*** |

Justification

Amendments 93 and 95 from 1st reading.

</Amend>

<Amend>Amendment <NumAm>36</NumAm>

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 Member States on the conditions for disclosure | 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 the anonymity requirement in order to respect the right of children to know their genetic parents.*** |

Justification

Amendment 49 from first reading.

</Amend>

<Amend>Amendment <NumAm>37</NumAm>

Article 15, paragraph 5

|  |  |
| --- | --- |
| ***5. In the case of cells used for reproduction purposes, the conditions for donor selection, evaluation and procurement shall be laid down in accordance with the requirements referred to in Article 28(j).*** | ***deleted*** |

Justification

This paragraph was newly introduced by the Council into the Common position. Conditions for donor selection, evaluation and procurement which differ from the directive should be regulated in Comitology without involvement of the Parliament. Thus the Council proposes to adopt rules, which can totally differ from the directive in a very sensitive area completely without control possibilities for the European Parliament.

</Amend>

</Amend>

<Amend>Amendment <NumAm>38</NumAm>

<Article>Article 15, paragraph 5a (new)</Article>

|  |  |
| --- | --- |
|  | ***5a. Cloned human embryos, and human - animal hybrid embryos produced by cloning, aggregation or any other procedure, and tissues and cells derived from them, shall be excluded as sources of material for transplantation.*** |

Justification

Reintroduction of amendment 51 adopted in 1st reading.

<Amend>Amendment <NumAm>39</NumAm>

Chapter IV, Title

|  |  |
| --- | --- |
| PROVISIONS ON THE QUALITY AND SAFETY OF TISSUES AND CELLS | PROVISIONS FOR QUALITY AND SAFETY OF TISSUES AND CELLS ***IN THEIR ENTIRETY*** |

Justification

Amendment 52 from first reading.

</Amend>

<Amend>Amendment <NumAm>40</NumAm>

Article 16, paragraph 3, indent 6a (new)

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

Justification

Amendment 53 from first reading.

</Amend>

<Amend>Amendment <NumAm>41</NumAm>

Article 16, paragraph 5

|  |  |
| --- | --- |
| 5. Tissue establishments shall keep the data ***required for full traceability for a minimum of 30 years.*** Data storage may also be in electronic form. | 5. Tissue establishments shall keep the data ***necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use.*** Data storage may also be in electronic form. |

Justification

Amendment 54 from first reading in a modified form.

</Amend>

<Amend>Amendment <NumAm>42</NumAm>

Article 17, paragraph 1, point (b)

|  |  |
| --- | --- |
| (b) at least ***two*** years' practical experience in the relevant fields. | (b) ***he/she shall have*** at least ***three*** years' practicalexperience in the relevant fields. |

Justification

Amendment 55 from first reading is partly reintroduced. The 2nd part of the Council's wording seems acceptable, the 1st part though, which provides a prolongation from 2 to 3 years was not accepted by the Council and is therefore retabled.

</Amend>

<Amend>Amendment <NumAm>43</NumAm>

Article 19a (new)

|  |  |
| --- | --- |
|  | ***Article 19a*** |
|  | ***Reconstruction of cadaver*** |
|  | ***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.*** |

Justification

Amendment 56 from first reading.

</Amend>

<Amend>Amendment <NumAm>44</NumAm>

<Article>Article 21, paragraph 4a (new)</Article>

|  |  |
| --- | --- |
|  | ***4a. Member States shall ensure that tissue establishments have procedures in place to ensure the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishments accredited, designated, authorised or licensed according to Article 6.*** |

Justification

Amendment 44 of first reading redrafted after consultation with Council and Commission.

</Amend><Amend>Amendment <NumAm>45</NumAm>

Article 24, paragraph 1, point b)

|  |  |
| --- | --- |
| (b) where a third party provides goods and services that affect tissue or cell quality and safety assurance. | (b) where a third party provides goods and services that affect tissue or cell quality and safety assurance ***including their distribution***. |

Justification

Amendment 57 from first reading in a modified form.

</Amend>

<Amend>Amendment <NumAm>46</NumAm>

Article 24a (new)

|  |  |
| --- | --- |
|  | ***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

Amendment 58 from first reading and the Commission original text reintroduced. Art 25 to which the original amendment of the EP referred was left out in the Common position. But the article seems to make sense as well as the changes proposed by the European Parliament make sense.

</Amend>

<Amend>Amendment <NumAm>47</NumAm>

Article 24b (new)

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

Justification

Amendment 59 from first reading. Art 25 to which the original amendment of the EP referred was left out in the Common position. But the article seems to make sense as well as the changes proposed by the European Parliament make sense.

</Amend>

<Amend>Amendment <NumAm>48</NumAm>

Article 28

|  |  |
| --- | --- |
| Technical requirements and their adaptation to scientific and technical progress | Technical requirements and their adaptation to scientific and technical progress |
| ***The following*** technical requirements ***and their adaptation*** to scientific and technical progressshall be decided in accordance with the procedure referred to in Article 29(2)**:** | ***The adaptation of the*** technical requirements ***set out in Annexes I, II, VI and VII*** to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 29(2)**.** |
| ***(a) Requirements for the accreditation, designation, authorisation or licensing of tissue establishments;*** | ***In order to modify Annexes III, IV and V, the Commission shall present a proposal to the Parliament and the Council.*** |
| ***(b) Requirements for the procurement of human tissues and cells;*** |  |
| ***(c) Quality system, including training;*** |  |
| ***(d) Information to be provided on the donation of cells and/or tissues;*** |  |
| ***(e) Selection criteria for the donor of tissues and/or cells;*** |  |
| ***(f) Laboratory tests required for donors;*** |  |
| ***(g) Cell and/or tissue procurement procedures and reception at the tissue establishment;*** |  |
| ***(h) Requirements for the tissue and cell preparation process;*** |  |
| ***(i) Tissue and cell processing, storage and distribution;*** |  |
| ***(j) Determination of conditions for the selection, evaluation and procurement of cells used for reproduction purposes;*** |  |
| ***(k) Requirements for the direct distribution to the recipient of specific tissues and cells.*** |  |

Justification

Reintroduction of amendment 60 of first reading. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes. Modifications to technical annexes can be adopted through comitology but modifications to other annexes should be adopted in co-decision.

</Amend>

<Amend>Amendment <NumAm>49</NumAm>

Article 31a (new)

|  |  |
| --- | --- |
|  | ***Article 31a*** |
|  | ***Human organs*** |
|  | ***The Commission is invited to bring forward as soon as possible and in any case before 31 December 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

Amendment 62 from first reading, date changed from July 2003 to December 2003.

</Amend>

<Amend>Amendment <NumAm>50</NumAm>

Annex I (new)

**Amendment by Parliament**

# *REQUIREMENTS FOR THE PROCUREMENT OF HUMAN TISSUES OR CELLS*

***The establishment responsible for tissue and cells procurement has to ensure certain minimum requirements and other conditions. It must:***

***a) Have links with a medical/surgical team that specialises in cell/tissues procurement, and has the staff with the necessary training and experience required to do this work;***

***b) Have a co-operation agreement with the team responsible for donations. The written contractual documents will specify the terms of the relationship as well as the protocols to be followed;***

***c) Have Standard Operation Procedures (SOPs) for the procurement, packaging, and transportation of the cells and / or tissues until the moment they are processed;***

***d) Have a quality management system;***

***e) Ensure that, in addition to the tests described in Annex V, appropriate investigations are carried out to prevent the presence of known transmissible diseases;***

***f) Have the facilities and material resources needed for the procurement and packaging of the cells and/or tissues;***

***g) Have the staff and services needed for body reconstruction and other mortuary procedures when cell / tissue are retrieved from a deceased person;***

***h) Ensure that the procedures for the procurement or collection of the cells and / or tissues are carried out according to Annex VI;***

***i) Maintain a register to ensure adequate traceability of the cells / tissues obtained and delivered. Details must be maintained on the procurement procedures, the donor (donor identification, consent and clinical data), the tissues donated, the intended use or destination of the tissues, the date of removal and the tests carried out. Access to this register will be restricted to persons, authorised by the responsible person, who will be required to comply with the confidentiality requirements laid down in the Directive.***

# *CRITERIA FOR ACCREDITATION OF TISSUE BANKS*

***In order to be accredited, tissue banks must:***

***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 may exempt tissue banks which provide only tissues and cells for which there is no urgency from the requirement to operate on a 24-hour basis.***

***b) Have documentation showing the links that will be maintained with third parties (medical and non-medical institutions) with which the bank will collaborate. Third party agreements will specify the terms of the relationship as well as the protocols to be followed;***

***c) Have staff with adequate training and suitable facilities to carry out the activities for which accreditation is sought, in accordance with the standards laid down in this Directive;***

***d) Have a quality assurance programme relating to the activities for which accreditation is sought, in accordance with the standards laid down in this Directive;***

***e) Ensure, in accordance with scientific knowledge, that the risks inherent in the use and handling of biological material are minimised;***

***f) Have access to a serum bank that maintains at least one sample from each allogeneic donor for a minimum period of 2 years from the distribution of the last anatomical piece of the donor, so that required tests can be performed after grafting;***

***g) Have a register with access restricted to persons authorised by the responsible person in order to ensure adequate traceability of the cells / tissues received and distributed. These records should contain information on all donors, anatomical pieces, and tissues and cells with the data required for their identification. The register must meet the confidentiality requirements laid down in the Directive; and***

***h) Work according to Standard Operation Procedures, which shall conform to the standards laid down in this Directive.***

Justification

<OptDelPrev>Reintroduction of Annex I of the original Commission proposal and first reading amendment 63. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes.

</OptDelPrev>

</Amend>

<Amend>Amendment <NumAm>51</NumAm>

Annex II (new)

**Amendment by Parliament**

***QUALITY MANAGEMENT SYSTEM***

1. ***The basic elements of a quality system are:***

***a) A well-defined quality policy;***

***b) A clearly-defined organisational structure and accountability;***

***c) Clearly-defined and effective documentation;***

***d) Standard Operating Procedures (SOPs);***

***e) Correct maintenance of all registers; and***

***f) Process validation by the personnel directly involved.***

1. ***The main functions of a quality system include but are not limited to:***

***a) Ensuring that all processes are correct, verified and documented;***

***b) Ensuring the appropriate analysis and the communication of results to the competent authorities in those cases where: the integrity and function of a human cellular or tissue-based product could be affected, the product could possibly be contaminated, or the product could potentially transmit a communicable disease;***

***c) Ensuring that, if needed, appropriate corrective actions are taken and registered;***

***d) Ensuring that the proper training and education are provided to the staff for each of the activities in which they are involved;***

***e) Establishing and maintaining an appropriate monitoring system;***

***f) Establishing and maintaining a records system;***

***g) Investigating and documenting product deviations and the corrective actions taken; and***

***h) Conducting evaluations, investigations, audits, and other actions necessary to ensure the quality of tissues / cells, products and processes.***

1. ***The basic and on-going training for staff in charge of tissue / cell procurement and staff of the tissue banks shall be:***

***a) Carried out within two months of their joining the tissue establishment and after intervals no longer than two years;***

***b) Carried out when a new activity or a new technology is introduced; and***

***c) Controlled, reviewed and updated periodically, but at least every two years, and be adequate to their needs.***

1. ***The on going training shall cover at least the following subjects:***

***4.1 General topics:***

***a) General review of the procedures for obtaining and / or processing human cells and tissues for transplant purposes;***

***b) Legal aspects;***

***c) Ethical aspects;***

***d) Organisational aspects;***

***e) Quality control programmes;***

***f) Quality and safety criteria for the evaluation, procurement, processing and monitoring of cells and tissues for transplantation; and***

***g) Safety at work.***

***4.2 Specific topics:***

***a) Technical knowledge and specific protocols for each of the tissue bank’s activities;***

***b) Management of registers and data analysis programmes;***

***c) Handling of the equipment used for each activity;***

***d) Knowledge of the quality control guidelines and general operation of the health care establishment;***

***e) Knowledge of the personal safety guidelines; and***

***f) Bio-monitoring systems operating at the health care establishment.***

Justification

<OptDelPrev>Reintroduction of Annex II of the original Commission proposal. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes.</OptDelPrev>

</Amend>

<Amend>Amendment <NumAm>52</NumAm>

Annex III (new)

**Amendment by Parliament**

***INFORMATION TO BE PROVIDED ON THE DONATION OF CELLS AND/OR TISSUES***

# *Autologous (au) and allogeneic (al) living donors*

1. ***The person in charge of the donation process shall ensure that the donor has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph 4.***
2. ***The information must be given in an appropriate and clear manner, using terms that are easily understood by the donor.***
3. ***The person providing the information must be required and able to answer any questions asked by the donor.***
4. ***The information must cover: the purpose and nature of the procurement, its consequences and risks; analytical tests, if they are performed; recording and protection of donor data, medical confidentiality; and therapeutic purpose.***
5. ***For the allogeneic living donor (AL), information must be provided to the donor on the evaluation procedure: i.e. the reasons for requiring the donor’s medical and personal history, a physical examination, and analytical tests.***
6. ***Information must be given to donors on the applicable safeguards that are intended to protect them.***
7. ***The donor must be informed that he has the right to receive the confirmed results of the analytical tests clearly explained. He shall be free to execise this right or not.***
8. ***Information must be given on the necessity for requiring the applicable mandatory consent, certification, and authorisation in order that the tissue and / or cell procurement can be carried out.***

***9. Allogeneic germ cell donors shall be informed about possible legal implications and consequences of their donation.***

# *Deceased donor*

1. ***All information must be given to the donor’s relatives and all necessary consents and authorisations must be obtained prior to the procurement of cells / tissues in accordance with the applicable legislation.***

***2. The confirmed results of the donor’s evaluation must be communicated, and clearly explained, to the donor’s relatives in accordance with the legislation of the Member States.***

***C. 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 tissue and cells. In the event of commercial storage of umbilical cord blood, the woman or parents concerned must be informed that many of the possible new treatments are at a very experimental stage.***

Justification

<OptDelPrev>Reintroduction of Annex III of the original Commission proposal and first reading amendments 64, 65, 66 and 67. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original texts.</OptDelPrev>

</Amend>

<Amend>Amendment <NumAm>53</NumAm>

Annex IV (new)

**Amendment by Parliament**

***SELECTION CRITERIA FOR THE DONOR OF TISSUES AND/OR CELLS***

***1. DECEASED DONOR***

# *General criteria for exclusion*

***Deceased donors shall be excluded from donation if any of the following conditions are met:***

***1. Cause of death unknown.***

***2. Ingestion of, or exposure to, a toxic substance that may be transmitted in a toxic dose to the tissue recipients.***

***3. Presence or previous history of malignant disease, except for primary basal cell carcinoma, carcinoma in situ of the uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to the current consensus document of the Council of Europe ‘Standardisation of organ donor screening to prevent transmission of neoplasic diseases’. Donors with malignant diseases could be evaluated and considered for cornea donation, except for those with retinoblastoma, melanoma of the anterior pole, haematological neoplasm, and malignant tumours that could affect the anterior pole of the eye.***

***4. Risk of transmission of diseases caused by prions. This includes:***

1. ***specific selection criteria for people diagnosed with Creutzfeldt–Jakob Disease or having family history of non-iatrogenic Creutzfeldt-Jakob Disease;***
2. ***people with a history of rapid progressive dementia or degenerative neurological diseases of unknown origin;***
3. ***recipients of hormones derived from the human pituitary gland (e.g. growth hormones) and recipients of dura mater.***
4. ***Infection which is not controlled at the time of the donation, including bacterial diseases, systemic viral and fungal infections.***
5. ***History, clinical evidence, or confirmed positive laboratory tests of HIV infection, acute or chronic hepatitis B or hepatitis C infection. (For haematopoietic progenitor cells donors, Annex V about the donors with positive tests for HBV and HCH shall be applied).***

***7. People with a history of chronic haemodialysis.***

1. ***Haemodilution of donor samples:***

***With potential donors who have received blood, blood components, colloids within the 48 hours preceding death, or crystalloids within the 1 hour preceding death, a sample of blood taken before the transfusion will have to be available if calculations using the algorithm set out below indicate a haemodilution of over 50%. If a sample is not available, the donor must be excluded owing to the effect of the haemodilution on the results of the serology tests.***

***9. Evidence of any other risk factors.***

# *Specific exclusion criteria for child donors*

1. ***Any child who may present with any of criteria listed in part A will be excluded as a donor.***
2. ***Any children born from mothers with HIV infection or that meet any of the exclusion criteria described in part A must be excluded as donors until the risk of transmission of infection can be definitely ruled out.***

***a) Children aged less than 18 months born from mothers with HIV, hepatitis B or hepatitis C infection or at risk of such infection, or who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests;***

***b) Children who have not been breastfed by their mothers during the previous 12 months, and for whom analytical tests, physical examinations, and reviews of medical records do not provide evidence of HIV, hepatitis B or hepatitis C infection, can be accepted as donors.***

# *External Physical inspection*

***A physical examination of the body shall be performed to detect any signs that may be sufficient in themselves to exclude the donor, or which may be assessed in the light of the donor’s medical and personal history. Attention should be given to the following: tumours (e.g. melanoma), infections (e.g. genital ulcers, anal condylomas), risk factors for transmissible diseases (e.g. vessel puncture, tattoos, piercing), traumas to the donor’s body, and scars from recent or old operations.***

# *Specific selection criteria*

***Specific selection criteria for tissues from deceased donors shall be taken into account case by case on the basis of current scientific knowledge.***

***2. LIVING DONOR***

***2.1. AUTOLOGOUS LIVING DONOR***

1. ***The medical doctor responsible for the patient-donor must determine, based on the patient’s medical history and therapeutic indications, and document the viability of the transplant.***
2. ***If the removed cells or tissues are stored or cultured, the same serology tests must be carried out as for an allogeneic living donor. Positive results will not rule out the person undergoing the treatment.***

***2.2 ALLOGENEIC LIVING DONOR***

1. ***The selection criteria for the allogeneic living donor shall be established and documented by the responsible physician based on the donor’s physical status, clinical and personal record, the results of clinical analyses, and other laboratory tests establishing the donor’s health.***

***2. The same exclusion criteria as for deceased donors have to be followed, but others may need to be added: e.g. pregnancy (except for donors of haematopoietic progenitors cells and amniotic membrane) and breastfeeding. The specific exclusion criteria for each tissue/cells shall also need to be taken into account.***

***2.3. CLONED HUMAN EMBRYOS AND HUMAN – ANIMAL 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

<OptDelPrev>Reintroduction of Annex IV of the original Commission proposal and amendment 68 from first reading. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes.

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. The legal basis for this directive is Article 152. The use of cloned embryos as a source of material for transplant is incompatible with sections (1), (4)(a) and (4)(b) of this Article.

</OptDelPrev></Amend>

<Amend>Amendment <NumAm>54</NumAm>

Annex V (new)

**Amendment by Parliament**

***LABORATORY TESTS REQUIRED FOR DONORS***

***1. Serology tests required for donors***

|  |  |
| --- | --- |
| ***Infection*** | ***Tissues and cells: recommendation in case of positive result*** |
| ***HIV 1 and 2*** | ***Contraindication to donation*** |
| ***Hepatitis B*** | ***HBs Ag positive is a contraindication to donation.***  ***Anti HBc positive requires complementary tests*** |
| ***Hepatitis C*** | ***Contraindication to donation*** |
| ***Treponema pallidum*** | ***Requires tests to detect specific antibodies for T. pallidum. A positive result contraindicates donation.*** |
| ***HTLV-I and II in donors living or coming from high incidence areas, or their sexual partners or children.*** | ***Contraindication to donation*** |

***2. General requirements to be met when determining serological markers***

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

***2. The serological tests will be carried out on the donor’s serum or plasma; they should not be performed on other fluids or secretions such as the aqueous or vitreous humour.***

***3. The type of test used shall be in agreement with the scientific knowledge.***

***4. Special requirements for laboratory tests in relation to the collection of umbilical cord blood***

***a. The serological tests prescribed in Annex V, section 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.***

***5. All blood samples should be obtained immediately prior or after the tissue procurement in case of a deceased donor.***

***6. 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.***

***7. In case of an allogeneic haematopoietic progenitor cell transplantation, blood samples shall be tested within 30 days prior to donation.***

***8. If in a living donor (except allogeneic haematopoietic progenitor cell donors) the blood sample is drawn 6 days after procurement and tested by nucleic acid amplification technique (NAT), a repeat blood sample is not necessary for HIV, HBV and HCV.***

Justification

<OptDelPrev>Reintroduction of Annex V of the original Commission proposal and first reading amendments 70, 85 and 72. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes.

</OptDelPrev></Amend>

<Amend>Amendment <NumAm>55</NumAm>

Annex VI (new)

**Amendment by Parliament**

***CELL AND/OR TISSUE PROCUREMENT PROCEDURES, AND  
RECEPTION AT THE TISSUE BANK***

# *Verification Procedure*

***Consent***

***Before the procurement of tissues or cells, the person responsible from the procurement team shall confirm that the consent for the procurement has been obtained according with the legislation in place on the Member State.***

***Donor identification***

***a) Donor and donation data shall be registered and maintained in a manner that ensures correct donor identification and traceability of each individual tissue and cell.***

***b) The data registration system has to be validated to ensure that the recorded information ensures correct identification and traceability.***

# *Facilities and Procedures for the procurement of tissues and cells*

***Donations shall be retrieved in appropriate facilities that minimise bacterial contamination of procured tissues or cells. For living donors, the procurement environment must also ensure their health and safety.***

# *Procurement procedures for tissues and cells*

***The procurement procedures shall be appropriate for the type of donor and the type of tissue/cells donated. They should also protect those properties of the tissue/cells that are required for their ultimate clinical use, and at the same time avoid microbiological contamination during the process. In the case of deceased donations, the time interval from death to procurement shall be specified so as to ensure the protection of the required biological properties.***

# *Donor Documentation*

1. ***For each donor, there should be a dossier that contains: donor identification, the consent form, clinical data, laboratory test results, and results of other tests carried out. Data related with the procurement process shall also be registered.***
2. ***In case an autopsy was carried out, the results shall be included in the dossier.***
3. ***All the records must be legible and permanent and shall be in compliance with data protection legislation.***
4. ***Donor clinical records shall be maintained for at least 30 years in the registry of the procurement establishment.***
5. ***The date and time of procurement (start and end) must be recorded.***

# *Data to be registered*

***The data that must be registered in the tissue bank includes:***

***a) Consent;***

***b) Donor identification and characteristics: type of donor, age, sex, cause of death, and presence of risk factors;***

***c) Review of clinical data against donor selection criteria;***

***d) Results of physical examination, of laboratory tests and of other tests (autopsy report when one was conducted);***

***e) Date and time of the death/perfusion;***

***f) Date and time of the procurement, and health care establishment where the procurement is carried out;***

***g) Conditions under which the cadaver is kept: refrigerated (or not), time of start of refrigeration and time of transfer to procurement site;***

***h) Place of procurement, procurement team, and person in charge of procurement;***

***i) Degree of asepsis;***

***j) Details about the preservation solutions used during procurement, including composition, lot, date of expiry, temperature, amount, concentration and preparation method;***

***k) Grafts obtained and relevant characteristics;***

***l) Relevant incidents that have occurred before, during, and after procurement;***

***m) Destination of the cells/tissues procured;***

***n) Method of preservation until arrival of tissues/cells at the bank;***

***o) In the case of cellular cultures, it is necessary also to document:***

***- Characteristics of the lesion to be treated;***

***- Medicinal allergies (e.g. antibiotics) of the recipient.***

# *Packaging*

1. ***Following procurement, all donations shall be packed individually in a manner that minimises the risk of contamination and preserves the required characteristics and biological function of the cells/tissues.***
2. ***The packaged cells/tissues shall be shipped in a rigid container suitable for transport, which maintains the integrity of the contents and the specified temperature.***
3. ***Any accompanying tissue or blood samples for testing shall be correctly labelled and identified.***

# *G. Labelling of the retrieved tissue /cells*

***Every package containing tissues or cells must be labelled at least with:***

***a) Donor identification number or code; and***

***b) Type of tissue/cells.***

# *H. Labelling of the shipping container*

***When tissues/cells are shipped, every shipping container must be labelled at least with:***

***a) Identification of the tissue/cells;***

***b) Identification of the procurement establishment (address and phone number) and the person in charge of the delivery;***

***c) Identification of the tissue bank of destination (address and phone number) and the person in charge of the reception at the destination;***

***d) Date and time of harvesting;***

***e) In the cases of haematopoietic progenitors, the following shall be added: DO NOT IRRADIATE; and***

***f) In the case of ‘autologous’ donors, the following shall be added: ‘for autologous use only’.***

# *I. Receipt of the tissue/cells at the processing/storage establishment*

***When the retrieved tissues/cells arrive at the processing/storage establishment, there shall be a documented verification that the consignment, including, transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Annex and the specifications of the receiving bank. Each bank shall have a documented procedure for handling non-conforming consignments of tissues/cells.***

Justification

<OptDelPrev>Reintroduction of Annex VI (original part I excluded due to the reintroduction of first reading amendment 74) of the original Commission proposal. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes. </OptDelPrev>

</Amend>

<Amend>Amendment <NumAm>56</NumAm>

Annex VII (new)

**Amendment by Parliament**

***CELL AND TISSUE PROCESSING, STORAGE, AND DISTRIBUTION***

***A. PROCESSING***

***1. Every tissue and cell processing facility must have an adequate system of process control.***

***2. When technical procedures cannot be verified at any particular time throughout the process, they must be continuously monitored to ensure that the established Standard Operating Procedures are met.***

***3. Where a microbial inactivation procedure is applied to the tissue or cells, it must be specified, documented, and validated.***

***4. Where any processing step is carried out by a third party, an agreement must be documented to demonstrate the required performance specification and validation.***

***5. The processes should undergo regular critical evaluation to ensure that they continue to achieve the intended results.***

***6. Before new processes are implemented, they must be validated to demonstrate that they will consistently result in tissues that comply with the SOPs of the tissue bank. Where any significant change in processing occurs, involving new or modified equipment, major overhauls or change of location, these validation steps must be repeated and documented.***

***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 (Good Microbiological Practice) guideline.***

***B. STORAGE***

***1. Storage conditions, including relevant parameters such as temperature, must be defined to maintain the required tissue and cell properties.***

***2. Critical parameters (e.g. temperature, humidity, sterility) must be controlled, monitored, and recorded continuously to demonstrate compliance with the specified conditions.***

***3. Maximum storage time must be specified for each type of storage condition. If the maximum storage time has been reached, the tissues and cells have not yet been used up and it can be guaranteed through validated tests that the tissues and cells are still capable of functioning, the storage time may be extended.***

***4. The selected period must reflect possible deterioration of the required tissue and cell properties, changing donor selection and testing criteria over time and the availability of alternative treatments.***

# *DISTRIBUTION*

1. ***Transport conditions, including relevant parameters such as temperature, must be defined to maintain the required tissue and cell properties.***
2. ***Packaging must ensure that the tissue is maintained in the condition established in the Standard Operating Procedures. If the packaging has not received market validation for this purpose, then critical parameters, such as temperature and humidity must be continuously controlled during the delivery process.***
3. ***Where distribution is carried out by a contracted third party, a documented agreement must be in place to ensure that the required conditions are maintained.***
4. ***A documented system must in place for the recall of tissue or cells in the event that a potential risk to the recipient(s) is identified following distribution.***

# *FINAL LABELLING FOR DISTRIBUTION*

1. ***Every unit of tissue / cells distributed has to be accompanied by a label with at least the following information:***

***a) Identification number or code of the tissue /cells;***

***b) Characteristics of the tissue or cell;***

***c) Identification of the tissue bank;***

***d) Lot number.***

1. ***The following information shall be provided either on the label or in accompanying documentation:***

***a) Morphology and functional data;***

***b) Date of distribution of the tissue /cell;***

***c) Serological determinations carried out on the donor and results;***

***d) Storage recommendations;***

***e) Instructions for opening the container, package, and any required manipulation;***

***f) Expiry date after opening/manipulation; and***

***g) Instructions on reporting serious adverse reactions and /or events.***

# *EXTERNAL LABELLING OF THE SHIPPING CONTAINER*

***Every container shall be labelled with at least the following information:***

***a) Identification of the originating tissue bank;***

***b) Identification of the health care establishment of destination;***

***c) A statement that the package contains human tissue/cells;***

***d) In the case of haematopoietic progenitors, the following shall be added: ‘DO NOT IRRADIATE’;***

***e) Recommended transport conditions (e.g. keep cool, in upright position, etc.); and***

***f) Safety instructions / method of cooling (when applicable) [for instance: liquid N2 poses a hazard for transport, manipulation of dry ice with bare hands also, etc.]***

Justification

*<OptDelPrev>Reintroduction of Annex VII of the original Commission proposal and first reading amendments 75 and 76. Council deleted all the annexes of the original Commission proposal and referred them to comitology. Parliament should, however, have a say on the original annexes.<OptDelPrev>*

EXPLANATORY STATEMENT

Parliament took up a position on the Commission proposal at first reading on 10 April 2003. After an intense debate with two public hearings, a position was adopted by an overwhelming majority which welcomed the Commission proposal in principle but made significant changes to it.

Parliament’s chief concerns were:

* Clear rules on voluntary and unpaid donations of cells and tissues. Compensation should be possible in accordance with national laws;
* A ban on trade in unmodified cells and tissues. Industrial activity in this area should however be possible where complex technical procedures are used to process cells and tissues;
* Submission by the Commission of a separate proposal for a directive on the quality and safety of organs as soon as possible, since this issue is just as urgent as the quality and safety of cells and tissues.

Following intense negotiations, compromise amendments were adopted on all these matters by an overwhelming majority (e.g. amendment 41 on voluntary and unpaid donations 425:40).

On 2 June 2003 the Council of European Health Ministers reached a political agreement in which almost all of Parliament’s main amendments were rejected. Only six amendments were taken up in full in the common position, while some further amendments were incorporated in part. This disappointing result is all the more difficult to understand given that, at the public Council meeting of 2 June 2003, seven Ministers or Secretaries of State declared that they shared Parliament’s concerns and hoped that more amendments could be taken up at second reading. On the question of voluntary and unpaid donations, the Council President and Italian Health Minister Professor Sirchia stated in a letter to Caroline Jackson dated 9 July 2003: ‘We also reject the idea that payment may be taken into consideration for cell and tissue donors. This is extremely dangerous since it would suggest that a part of human body is a commodity rather than a gift...’.

The formal justification given by the Commission and Council for the rejection of most of the amendments is the lack of a legal basis and the fact that the amendments address so-called ‘ethical issues’ for which the EU has no regulatory competence. After consulting a large number of legal experts, the rapporteur takes the view that this justification is by no means valid. The legal basis of the Directive is Article 152 of the EC Treaty, which deals with health matters, but all the ‘ethical issues’ addressed by Parliament are also linked to protecting the health of donors and recipients. Any donation made in dubious circumstances, e.g. in response to financial pressure , is also a danger for the recipient of cells and tissues. This view is also widely shared within the Council. In other words, while Parliament’s amendments do touch on ethical issues, they are all linked to health protection and, consequently, a debate is possible on the basis of Article 152. Even if it is argued that the link between the conditions under which donations are made and the safety of recipients is scientifically controversial, it is surely possible to deal cautiously with the topic in keeping with the precautionary principle.

It should be added that, since Parliament’s first reading and since the political agreement of the beginning of June, the Convention on the Future of Europe has submitted the draft European Constitution. This regards the Charter of Fundamental Rights as a key component of the Constitution. Article 3(2) of the Charter states that: *‘In the fields of medicine and biology, the following must be respected in particular: (...) the prohibition on making the human body and its parts as such a source of financial gain, (...).’* This is a further argument in favour of Parliament’s position.

The rapporteur therefore proposes that the Council’s superficial justification (no legal basis) should on no account be followed but that Parliament should insist on the positions it adopted at first reading. In view of the devastating result following the Council’s consideration of Parliament’s amendments, the rapporteur does not consider it appropriate to concentrate on a limited number of amendments at this point. Given that the Council has made so few concessions to Parliament up to now, we must make our basic standpoint at first reading clear once again. The rapporteur has consequently re-introduced a number of amendments adopted by Parliament at first reading where they were not taken up by the Council. Evidently, this approach does not rule out useful adjustments to the text. Some of the amendments have not been adopted in committee in 2nd reading but the above mentioned key points have been adopted with a big majority. The rapporteur once again appeals urgently to the Commission and Council to address Parliament’s concerns more intensively and to work towards a genuine compromise. This is the only way of avoiding a conciliation procedure and possibly the failure of the entire Directive.

1. Texts Adopted, 10.04.2003, P5\_TA(2003)0182. [↑](#footnote-ref-1)
2. OJ C 227 E, 24.9.2002, p. 505. [↑](#footnote-ref-2)
3. Not yet published. [↑](#footnote-ref-3)