



EUROPEAN PARLIAMENT

2009 - 2014

---

*Committee on the Environment, Public Health and Food Safety*

---

**2008/0238(COD)**

04.3.2010

# **AMENDMENTS**

## **57 - 203**

**Draft report**  
**Miroslav Mikolášik**  
(PE430.898v01-00)

Proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation

Proposal for a directive  
(COM(2008)0818 – C7-0480/2008 – 2008/0238(COD))

AM\_Com\_LegReport

**Amendment 57**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 1**

*Text proposed by the Commission*

(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the **most cost-effective** treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.

*Amendment*

(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the treatment **with the best risk/benefit ratio** for end-stage renal **and pancreatic** failure, while for end-stage failure of organs such as the liver, lung, **intestines** and heart it is the only available treatment.

Or.fr

*Justification*

*If the organ transplantations which are feasible according to the state of the art are to be listed, it is important to ensure that the list is as exhaustive as possible.*

**Amendment 58**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 2**

*Text proposed by the Commission*

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to **minimise** any risks **associated with the transmission of diseases**.

*Amendment*

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to **improve the risk/benefit ratio while minimising** any risks **inherent in the**

*logistics by which organs are obtained.*

Or.fr

*Justification*

*The risk of transmission of diseases is a major risk but not the only one in the chain between removal of the organ and the transplantation and post-transplantation stages.*

**Amendment 59**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Recital 2**

*Text proposed by the Commission*

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to **minimise** any risks associated with the transmission of diseases.

*Amendment*

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to **minimize** any risks associated with the transmission of diseases. ***Well-organized national transplant systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for patients.***

Or.en

*Justification*

*Immunological problems after transplantation are not the best example of the potential benefits of the Directive*

**Amendment 60**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Recital 2**

*Text proposed by the Commission*

*Amendment*

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases.

(2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. ***Well-organised national transplant systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for patients.***

Or.en

*Justification*

*Immunological problems after transplantation are not the best example of the potential benefits of the Directive*

**Amendment 61**  
**Horst Schnellhardt**

**Proposal for a directive**  
**Recital 2**

*Text proposed by the Commission*

*Amendment*

(2) Risks however are associated with the use of organs in transplantation. The ***extensive*** therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases.

(2) Risks however are associated with the use of organs in transplantation. The therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases.

Or.de

*Justification*

*The proposal for a Directive lays down basic quality and safety requirements for organ transplantation; the adjective 'extensive' is not appropriate in this context and the risks associated with transplantation are not made clear.*

**Amendment 62**  
**Sari Essayah**

**Proposal for a directive**  
**Recital 3**

*Text proposed by the Commission*

(3) In addition the availability of organs of human origin used for therapeutic purposes is dependent on Community citizens being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

*Amendment*

(3) In addition the availability of organs of human origin used for therapeutic purposes is dependent on Community citizens being prepared to donate them. ***The Member States have a responsibility to increase organ donations nationally since possible defects in their organ transplantation systems cannot be remedied by transporting organs or moving patients from one country to another.*** In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

Or.en

**Amendment 63**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) The principal challenge faced by the European Union and Member States with regard to organ transplantation is that of reducing the shortage of organs and donors. It is therefore crucial to expand the pool of available organs by acquiring the means, at Union level, of optimising the number of donations after brain death or cardiac failure, increase the number of living donors and broaden the pool of potential donors to cover persons who meet 'expanded' donor criteria.***

**Amendment 64**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 4**

*Text proposed by the Commission*

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of **expanding the pool of organs available and** ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

*Amendment*

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

Or.fr

*Justification*

*Matching donors and recipients is the prime reason for setting up European organ exchange organisations such as Scandinavtransplant or Eurotransplant. This model of pan-European exchanges, effective though it may be, does not have the aim of expanding the pool of available organs. In order to do so, new strategies need to be adopted both nationally and at Community level.*

**Amendment 65**  
**Anja Weisgerber**

**Proposal for a directive**  
**Recital 4**

*Text proposed by the Commission*

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of **expanding the pool of organs available and** ensuring

*Amendment*

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of ensuring a better match between donor and recipient

a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

Or.de

### *Justification*

*Though improving organ exchanges, as intended by the Directive, will improve the quality of transplants, it will not increase the pool of organs available. This depends on other factors, for instance the willingness of the population to donate organs.*

## **Amendment 66** **Thomas Ulmer, Anja Weisgerber**

### **Proposal for a directive** **Recital 6**

#### *Text proposed by the Commission*

(6) There is therefore a need for common quality and safety standards for the procurement, transport and use of human organs at Community level. These standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Community legislation should ensure that human organs comply with **acceptable** standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.

#### *Amendment*

(6) There is therefore a need, **while duly respecting the subsidiarity principle pursuant to Article 168(7) TFEU (formerly Article 152(5) TEC)**, for common quality and safety standards for the procurement, transport and use of human organs at Community level. These standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Community legislation should ensure that human organs comply with **recognised** standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in



their own country.

Or.de

*Justification*

*Art. 168 Abs. 7 AEUV bestimmt, dass bei der Tätigkeit der Union die Verantwortung der Mitgliedstaaten für die Festlegung ihrer Gesundheitspolitik sowie für die Organisation des Gesundheitswesens und die medizinische Versorgung gewahrt wird. Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für Organe lassen einzelstaatliche Regelungen über die Spende oder die medizinische Verwendung von Organen unberührt. Da sich die Begriffe Beschaffung und Spende teilweise überschneiden, ist der Hinweis auf das Subsidiaritätsprinzip unbedingt erforderlich. Nur anerkannte Qualitäts- und Sicherheitsstandards spiegeln den Stand der medizinischen Wissenschaft wider.*

**Amendment 67**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***(6a) In accordance with Article 168(7) of the Treaty of the Functioning of the European Union, the measures adopted under paragraph 4(a) of that Article do not affect national provisions on the medical use of organs. Therefore the surgical act of transplantation itself does not fall within the scope of this Directive. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include within the scope of this Directive certain provisions concerning the transplantation process and in particular provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.***

**Amendment 68****Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt****Proposal for a directive****Recital 7***Text proposed by the Commission*

(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.

*Amendment*

Does not apply to the English version.

Or.de

**Amendment 69****Sari Essayah****Proposal for a directive****Recital 7***Text proposed by the Commission*

(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should

*Amendment*

(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should

cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.

cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations. ***Participation of the Member States in organ exchange and in agreements with organisations for the cross-border exchange of organs should be voluntary and should not force the Member States to apply common waiting lists.***

Or.en

**Amendment 70**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 7**

*Text proposed by the Commission*

(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.

*Amendment*

(7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme, ***ensuring that they have a precise description of the donor and the organs.*** This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.

Or.fr

*Justification*

*Self-explanatory.*

**Amendment 71**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 8**

*Text proposed by the Commission*

(8) The conditions of procurement should be supervised by the Competent Authorities ***through the authorisation of identified procurement*** organisations. The authorisation should assume that proper organisation, qualified staff and adequate facilities and material are in place.

*Amendment*

(8) The conditions of procurement should be supervised by the Competent Authorities, ***taking into account the specific national situation as regards the selection of transplantation*** organisations. The authorisation should assume that proper organisation, qualified staff and adequate facilities and material are in place.

Or.fr

*Justification*

*It is not desirable that the Commission's text should propose a minority model as regards the organisation of national transplantation systems.*

**Amendment 72**  
**Marisa Matias, Andres Perello Rodriguez**

**Proposal for a directive**  
**Recital 10**

*Text proposed by the Commission*

(10) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow

*Amendment*

(10) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow

allocation to a suitable recipient.  
Information should be collected for complete characterisation of the organ and the donor.

allocation to a suitable recipient.  
Information *from clinical history, physical examination and complementary tests* should be collected for complete characterisation of the organ and the donor.  
*To obtain an accurate, reliable and objective history, the medical team should interview the living donor or the relatives of the deceased donor. This is essential since the time constraints of the process of deceased donation reduce the ability to rule out potentially serious transmissible diseases. During the interviews, the team should properly inform the interviewees of the risks and consequences of donation and transplantation so as to make them aware of the importance of providing the medical team with all relevant information.*

Or.en

#### *Justification*

*The importance of obtaining an appropriate medical history should be stressed as an essential point for ensuring the quality and safety of organs for transplantation. For that purpose the concept of properly informing donors/relatives to make them understand the potential risks for the recipient should be included.*

### **Amendment 73 Jo Leinen**

#### **Proposal for a directive Recital 13**

##### *Text proposed by the Commission*

(13) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Community system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the

##### *Amendment*

(13) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Community system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the

donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>10</sup>. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported in the tissue vigilance system as provided for in that Directive.

donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>10</sup>. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority **or body** and reported in the tissue vigilance system as provided for in that Directive.

*(This amendment should apply throughout the text)*

Or.en

#### *Justification*

*In some member states organ donation is handled not by state authorities but by other competent bodies (e.g. the German Deutsche Stiftung für Organtransplantation)*

#### **Amendment 74**

**Andres Perello Rodriguez**

#### **Proposal for a directive**

#### **Recital 14**

##### *Text proposed by the Commission*

(14) Personnel directly involved in the donation, **procurement**, testing, preservation, transport and transplantation of human organs should be **suitable** qualified **and trained**.

##### *Amendment*

(14) Personnel directly involved in the donation, testing, **characterisation**, **procurement**, preservation, transport and transplantation of human organs should be **suitably** qualified **and competent**.

Or.en

#### *Justification*

*It should be clarified that these requirements apply only to healthcare personnel involved in the process. Asking for such strict requirements for other personnel might lead to a necessary loss of organs. The steps are suggested to be ordered according to clinical practice and to be consistent with article 2 of the Directive. The new wording better captures the EU MS realities and clarifies that it is not intended to increase the administrative burden*

**Amendment 75**  
**Anja Weisgerber**

**Proposal for a directive**  
**Recital 15**

*Text proposed by the Commission*

(15) As a general principle, exchange of organs from/to third countries should be supervised by the Competent Authority. Authorisation should be granted only if standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account.

*Amendment*

(15) As a general principle, exchange of organs from/to third countries should be supervised by the Competent Authority. Authorisation should be granted only if standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account. ***It should also be possible for a blanket authorisation to be granted in respect of a third country or a procurement organisation located in a third country.***

Or.de

*Justification*

*This amendment makes it clear that not every case of an organ exchange with third countries requires individual authorisation, but that a blanket authorisation generally authorising organ exchanges with a third country or a specific organisation in a third country is sufficient, provided the standards there are equivalent to those provided for in the Directive. In the absence of such an arrangement, procedures might be drawn out for so long that organs would become unusable.*

**Amendment 76**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Recital 16**

*Text proposed by the Commission*

(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the

*Amendment*

(16) ***To ensure the quality and safety of organs for transplantation, organ transplantation programmes should be***

Charter of Fundamental Rights of the European Union<sup>11</sup>. In line with that charter **and to** take account of, as appropriate the Convention on human rights and biomedicine<sup>12</sup>, **organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).**

***founded on the principles of voluntary and unpaid donation. This is an essential aspect, since the violation of these principles might be associated with unacceptable risks and poor outcomes for recipients and living donors. When donation is not voluntary and/or provides for financial gain, the quality of the process of donation cannot be fully guaranteed, since improving the quality of life or saving the life of a person is not the main and/or the sole objective to be achieved. Even if the process is developed in accordance with appropriate quality standards, the clinical history obtained either from the potential living donor or the relatives of the potential deceased donor might not be accurate enough in terms of those conditions and/or diseases which are potentially transmissible from donors to recipients when donors are seeking financial gain or are subjected to any kind of coercion. This would imply a safety problem for potential recipients since the team would have a limited capability for performing an appropriate risk analysis.***

***This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In line with that Charter it should also take account of, as appropriate, the Convention on Human Rights and Biomedicine and the Revised World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation.***

Or.en

#### *Justification*

*Recital 16 should be more focused on reinforcing the relation between Chapter III (principles governing organ donation) and quality and safety of organs intended for transplantation.*



**Amendment 77**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Recital 16**

*Text proposed by the Commission*

(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In line with that charter **and to** take account of, as appropriate the Convention on **human rights and biomedicine**<sup>12</sup>, **organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).**

*Amendment*

(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In line with that charter **it should also** take account of, as appropriate, the Convention on **Human Rights and Biomedicine** and the **Revised World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation.**

Or.en

**Amendment 78**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 16**

*Text proposed by the Commission*

(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union<sup>11</sup>. In line with that charter and to take account of, as appropriate the Convention on human rights and biomedicine<sup>12</sup>, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).

*Amendment*

(16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union<sup>11</sup>. In line with that charter and to take account of, as appropriate the Convention on human rights and biomedicine<sup>12</sup>, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the **living** donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).

*Justification*

*It is more correct to refer to altruism only in the case of living donors.*

**Amendment 79**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Recital 16 a (new)**

*Text proposed by the Commission*

*Amendment*

***(16a) The competent authority may consult the national Data Protection Authority in relation to developing a framework for the transfer of data concerning organs to and from third countries.***

Or.en

**Amendment 80**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Recital 16 b (new)**

*Text proposed by the Commission*

*Amendment*

***(16b) As a general principle, the identity of the recipient(s) should not be disclosed to the donor or his/her family or vice versa, without prejudice to legislation in force in Member States which under specific conditions might allow such information to be made available to donor or donors' families and organ recipients, with the consent of both parties.***

Or.en

*Justification*

*The maintenance of anonymity between donor and recipient initially placed in recital 16 of*

*the original proposal is better to be explained in a new specific recital. This would clarify that this principle of anonymity is not referred to a procedure to ensure data protection, since this last one would be in contradiction with the traceability.*

## **Amendment 81**

**Andres Perello Rodriguez, Marisa Matias**

### **Proposal for a directive**

#### **Recital 17**

##### *Text proposed by the Commission*

(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>13</sup> prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition **principle** are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and **organisational** measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.

##### *Amendment*

(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and **organizational** measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. ***In line with that Directive, strict confidentiality rules and security measures should be in place for the protection of the donors' and the recipients' personal data. Moreover, the competent authority may also consult the national Data Protection Authority in relation to developing a framework for the transfer of data concerning organs to and from third countries.***

Or.en

##### *Justification*

*It is our suggestion to include any reference to data protection under this recital, which clearly establishes the obligation to comply with the requirements stated in Directive 95/46/EC.*

## Amendment 82

Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez

### Proposal for a directive

#### Recital 17

##### *Text proposed by the Commission*

(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>13</sup> prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.

##### *Amendment*

(17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>13</sup> prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. ***In line with that Directive, strict confidentiality rules and security measures should be in place for the protection of the donors' and the recipients' personal data. Moreover, the competent authority may also consult the national Data Protection Authority in relation to developing a framework for the transfer of data concerning organs to and from third countries.***

Or.en

##### *Justification*

*Confidentiality rules and security measures should be taken for the protection of the donors' and recipients' personal data. We make the reference under this recital which establishes clearly the obligation to comply with the requirements stated in Directive 95/46/EC.*

**Amendment 83**  
**Cristian Silviu Buşoi**

**Proposal for a directive**  
**Recital 21**

*Text proposed by the Commission*

(21) The measures needed to implement this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>16</sup>.

*Amendment*

(21) The measures needed to implement this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>16</sup>. ***With regard to Article 25 of this Directive, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders should be consulted.***

Or.en

**Amendment 84**  
**Frédérique Ries**

**Proposal for a directive**  
**Recital 22**

*Text proposed by the Commission*

(22) In particular, power should be conferred on the Commission to lay down, where the organs concerned are to be exchanged between Member States, the procedures for the transmission to transplantation centres of the information on the characteristics of the organs, the procedures needed to ensure the traceability of the organs, including labelling requirements, and the procedures for the reporting of serious adverse events or reactions. Since these measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive with new non-essential elements, they must be adopted in accordance with the regulatory procedure

*Amendment*

(22) In particular, power should be conferred on the Commission to lay down, where the organs concerned are to be exchanged between Member States, the procedures for the transmission to transplantation centres of the information on the characteristics of ***the donor and*** the organs, the procedures needed to ensure the traceability of the organs, including labelling requirements, and the procedures for the reporting of serious adverse events or reactions. Since these measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive with new non-essential elements, they must be adopted in accordance with the regulatory procedure

with scrutiny provided for in Article 5a of Decision 1999/468/EC.

with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Or.fr

**Amendment 85**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 1**

*Text proposed by the Commission*

This Directive lays down **rules to ensure high standards of** quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection.

*Amendment*

This Directive lays down **the framework for** quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection.

Or.fr

*Justification*

*This directive should fulfil two main objectives: ensuring the requisite legal certainty for the parties concerned and permitting the necessary flexibility in its application in order to cater for the fact that organ transplantations are performed in medical emergencies.*

**Amendment 86**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 1**

*Text proposed by the Commission*

This Directive lays down rules to ensure **high** standards of quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection.

*Amendment*

This Directive lays down rules to ensure standards of quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection

Or.en

**Amendment 87**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 2 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

**1a. It shall apply also to parts of organs if it is their function to be used for the same purpose as the entire organ in the human body and to complex tissues.**

Or.de

*Justification*

*The new wording broadens the scope of Article 2 compared to Article 2(2)(c) of the Human Tissues Directive and also covers complex tissues (for instance, face or limb - i.e. hand or arm - transplants)*

**Amendment 88**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 3 – point a**

*Text proposed by the Commission*

*Amendment*

(a) "**authorisation**" means **authorisation**, accreditation, designation or licensing, depending of the concepts used in each Member State;

(a) **authorization**‘ means **authorization**, accreditation, designation or licensing **or registration**, depending of the concepts used in each Member State;

Or.en

*Justification*

*The purpose of including "registration" is to increase the flexibility of the definition of authorisation in order to apply to all different healthcare systems within the EU, but there is no need of such detailed explanation, which complicates the definition unnecessary. To be assessed if this would be included as a recital*

**Amendment 89**  
**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**  
**Article 3 – point a**

*Text proposed by the Commission*

(a) ‘authorisation’ means **authorisation**, accreditation, **designation or** licensing, depending **of** the **concepts** used in each Member State;

*Amendment*

(a) ‘authorisation’ means accreditation, **authorisation**, licensing **or certification**, depending **on** the **regulatory approaches** used in each Member State;

Or.de

*Justification*

*The new wording is based on the concepts in the Tissues Directive 2004/23/EC and covers the various national regulatory approaches.*

**Amendment 90**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 3 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

**aa) "competent authority means one (or more than one) non-profit authority, body, organisation and/or institution responsible for implementing the requirements of this Directive.**

Or.en

**Amendment 91**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 3 – point a a (new)**



*Text proposed by the Commission*

*Amendment*

**(aa) 'competent authority' means one or more than one non-profit authority, body, organisation and/or institution responsible for implementing the requirements of this Directive.**

Or.en

*Justification*

*A definition of competent authority is essential*

**Amendment 92**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**

**Article 3 – point c**

*Text proposed by the Commission*

*Amendment*

(c) 'donor' means every **human source of** organs, **whether** living or deceased ;

This amendment does not apply to the English version.

Or.de

**Amendment 93**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 3 – point c**

*Text proposed by the Commission*

*Amendment*

(c) "donor" means every **human source of** organs, whether **living** or **deceased**;

(c) donor' means every **person who donates one or several** organs, whether **the donation occurred during that person's lifetime** or **after death**;

Or.en

*Justification*

*It is fundamental to clarify that what is essential is the moment of the donation and not whether at the moment of recovery the donor passed away or not. A living donor might die after organ donation but this does not make him a deceased donor*

**Amendment 94**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 3 – point c**

*Text proposed by the Commission*

*Amendment*

(c) "donor" means every **human source of** organs, whether **living or deceased** ;

(c) "donor" means every **person who donates one or several** organs, whether **the donation occurred during that person's lifetime or after death**;

Or.en

*Justification*

*It is fundamental to clarify that what is essential is the moment of the donation and not whether at the moment of recovery the donor passed away or not. A living donor might die after organ donation but this does not make him a deceased donor.*

**Amendment 95**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**

**Article 3 – point d**

*Text proposed by the Commission*

*Amendment*

(d) ‘donation’ means **donating** human organs for **transplantation**;

(d) ‘donation’ means **the provision of** human organs **intended for human applications** ;

Or.de

*Justification*

*The proposed wording defines the term ‘donation’ without repetition.*

**Amendment 96**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 3 – point e**

*Text proposed by the Commission*

(e) "donor **characterisation**" means the collection of the relevant information on the characteristics of the donor needed to undertake a proper risk assessment **in order to minimise** the risks for the recipient and to **optimise** organ allocation;

*Amendment*

(e) 'donor **characterization**' means the collection of the relevant information on the characteristics of the donor needed to **evaluate his/her suitability, to** undertake a proper risk assessment **and minimize** the risks for the recipient, and to **ensure an effective** organ allocation;

Or.en

*Justification*

*This new wording better reflects the purposes of the donor characterization.*

**Amendment 97**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 3 – point f**

*Text proposed by the Commission*

(f) "European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated **especially** to cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the Community;

*Amendment*

(f) 'European organ exchange organisation' means a non-profit organisation, whether public or private, dedicated to **national and/or** cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the Community;

Or.en

*Justification*

*All European Organ Exchange Organisations manage exchanges of organs within the territory of their MS and between countries.*

**Amendment 98**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 3 – point g**

*Text proposed by the Commission*

(g) ‘organ’ means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy;

*Amendment*

(g) ‘organ’ means **both** a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy **and parts of organs if it is their function to be used for the same purpose as the entire organ in the human body and complex tissues** ;

Or.de

*Justification*

*With the proposal for a Directive on standards of quality and safety of human organs intended for transplantation, the European Parliament and the Council seek to complete harmonised rules for the areas 'blood and blood products, cells, tissues and organs of human origin'. Against this backdrop, the scope of this proposal for a Directive is of essential importance in the context of existing pieces of legislation.*

**Amendment 99**

**Miroslav Mikolášik, Christa Klaß, Frédérique Ries, Peter Liese**

**Proposal for a directive**

**Article 3 – point g**

*Text proposed by the Commission*

(g) "organ" means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to

*Amendment*

(g) "organ" means **both** a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to

develop physiological functions with an important level of autonomy;

develop physiological functions with an important level of autonomy; **and parts of organs, if it is their function to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;**

Or.en

#### *Justification*

*Since, in Article 2(2)(c), the tissue directive 2004/23/EC excludes from its scope of validity parts of organs, consequently corresponding regulations for this field should be integrated into the draft directive, so that no loophole emerges. This concerns e.g. common practice of transplanting liver parts which can take over the functions of the entire organ.*

#### **Amendment 100**

**Andres Perello Rodriguez, Marisa Matias**

#### **Proposal for a directive**

#### **Article 3 – point g**

##### *Text proposed by the Commission*

(g) "organ" means a differentiated **and vital** part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy;

##### *Amendment*

(g) 'organ' means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy; **a part of an organ is also considered to fall within the scope of this definition if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;**

Or.en

#### *Justification*

*We propose this deletion under the assumption that an organ is considered vital only if an alternative replacement therapy does not exist in case of end stage organ disease. A second reason for deleting it is that it would open the door to future transplantation of non vital organs. It is also highlighted that a part of an organ is considered an organ only if it fulfils*

*the three requisites (function, structure and vascularisation). This would clarify that islets are not considered organs. Islets would partly meet the functionality criteria (just covering the endocrine function), but not the structure and vascularisation ones, so islets would not be considered organs according to this definition.*

#### **Amendment 101**

**Andres Perello Rodriguez, Marisa Matias**

#### **Proposal for a directive**

#### **Article 3 – point h**

*Text proposed by the Commission*

(h) "organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to undertake a proper risk assessment **in order to** minimise the risks for the recipient and to **optimise** organ allocation;

*Amendment*

(h) 'organ characterisation' means the collection of the relevant information on the characteristics of the organ needed to **evaluate its suitability, to** undertake a proper risk assessment **and** minimise the risks for the recipient, and to **ensure an effective** organ allocation;

Or.en

*Justification*

*This new wording better reflects the purposes of the organ characterization*

#### **Amendment 102**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

#### **Proposal for a directive**

#### **Article 3 – point i**

*Text proposed by the Commission*

(i) 'procurement' means a process by which the donated organs become available;

*Amendment*

(i) 'procurement' means a **coordinated** process by which the donated organs become available

Or.de

*Justification*

*The process of procurement must be appropriately coordinated.*

**Amendment 103**  
**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**  
**Article 3 – point i a (new)**

*Text proposed by the Commission*

*Amendment*

***ia)'making available' means the preparation, manipulation, preservation, packaging and transport of human organs;***

Or.de

*Justification*

*While the Tissues Directive 2004/23/EG defines the terms 'procurement', 'processing' and 'preservation', the proposal for a Directive under review only defines the terms 'procurement' and 'preservation'. This means that essential intermediary stages such as preparation, manipulation, packaging and transport of human organs are not defined and are therefore left unregulated.*

**Amendment 104**  
**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**  
**Article 3 –point j**

*Text proposed by the Commission*

*Amendment*

***(j) "procurement organisation" means a health care establishment, a team or a unit of a hospital or another body which is authorised by the competent authority to undertakes procurement of human organs;***

***(j) "procurement organisation" means one or more public or private non-profit making body or bodies/organisation(s)/institution(s) engaged particularly in the coordinated process of procuring and making available human organs;***

Or.de

*Justification*

*In defining the regulatory content of the Directive, it is essential to take into account the principle of subsidiarity in accordance with Article 168(7) TFEU (formerly Article 152(5) TEC). Admittedly, recital (19) partly does so. The definitions of Article 3 of the proposal for a Directive must be brought into line with this approach. Other provisions, for instance Article 18, will have to be changed accordingly.*

**Amendment 105**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**

**Article 3 – point j a (new)**

*Text proposed by the Commission*

*Amendment*

***ja) 'competent authority' means one or more public or private non-profit making, competent body or bodies/organisation(s)/institution(s) particularly involved in the implementation of this Directive;***

Or.de

*Justification*

*In defining the regulatory content of the Directive, it is essential to take into account the principle of subsidiarity in accordance with Article 168(7) TFEU (formerly Article 152(5) TEC). Admittedly, recital (19) partly does so. The definitions of Article 3 of the proposal for a Directive must be brought into line with this approach. Other provisions, for instance Article 18, will have to be changed accordingly.*

**Amendment 106**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**

**Article 3 – point k**

*Text proposed by the Commission*

*Amendment*

(k) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means

(k) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means



**during processing** to prevent or retard biological or physical deterioration **of** human organs from the procurement until the transplantation;

**while making available** human organs to prevent or retard **the** biological or physical deterioration **thereof** from the procurement until the transplantation;

Or.de

*Justification*

*This amendment brings the text into line with the added definition of 'making available' (see Amendment to Article 3(i)).*

**Amendment 107**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 3 – point m**

*Text proposed by the Commission*

(m) ‘serious adverse event’ means any unexpected occurrence associated with **any stage of the chain from donation to transplantation** that might lead to the transmission of **a communicable** disease, to death or life-threatening, disabling, **or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;**

*Amendment*

(m) ‘serious adverse event’ means any **undesired and** unexpected occurrence associated with **the procurement, preservation and making available of organs** that might lead to the transmission of **an infectious** disease, to death or **a** life-threatening **condition or to the** disabling of **donors or recipients, necessitate hospitalisation or cause another illness, providing it is not a matter of the side-effects of immune suppression;**

Or.de

*Justification*

*The definition of serious adverse unexpected event is so broad that it would inevitably lead to a large number of reports having nothing to do with quality or safety standards being filed. It should therefore be made slightly more restrictive, as proposed above.*

**Amendment 108**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 3 – point n**

*Text proposed by the Commission*

(n) ‘serious adverse reaction’ means an unintended response, including a communicable disease, in the donor or in the recipient associated with **any stage of the chain from donation to transplantation** that is fatal, life-threatening, disabling, incapacitating, or which results in, **or prolongs**, hospitalisation or morbidity;

*Amendment*

(n) ) ‘serious adverse reaction’ means an unintended **or unexpected serious** response, including a communicable disease, in the donor or in the recipient associated with **the donation, procurement, preservation, making available or transplantation of an organ**, that is fatal, life-threatening, disabling, incapacitating, or which results in hospitalisation or **unexpected morbidity; side-effects of immune suppression are excluded;**

Or.de

*Justification*

*The definition of serous adverse reaction is so broad that it would inevitably lead to a large number of reports having nothing to do with quality or safety standards being filed. It should therefore be made slightly more restrictive, as proposed above.*

**Amendment 109**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 3 – point n**

*Text proposed by the Commission*

(n) “serious adverse reaction” means an unintended response, including a communicable disease, in the donor or in the recipient associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling,

*Amendment*

(n) ‘serious adverse reaction’ means an unintended response, including a communicable disease, in the **living** donor or in the recipient **that might be** associated with any stage of the chain from donation to transplantation that is fatal, life-

incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

Or.en

*Justification*

*Only living donors can have health problems linked to 'donation'. Additionally, there are reactions which attributability cannot be fully demonstrated and should be investigated. This wording reflects this reality.*

**Amendment 110**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 3 – point p**

*Text proposed by the Commission*

(p) 'transplantation' means the process of restoring certain functions of the human body by transferring *equivalent* organs to a recipient;

*Amendment*

(p) 'transplantation' means the process of restoring certain functions of the human body by transferring *human* organs to a recipient;

Or.de

*Justification*

*Clarification of the meaning of 'transplantation'.*

**Amendment 111**

**Horst Schnellhardt**

**Proposal for a directive**

**Article 3 – paragraph 1 – point r**

*Text proposed by the Commission*

(r) 'traceability' means the ability for a competent authority to locate and identify the organ at each stage in the chain from donation to transplantation or disposal,

*Amendment*

(r) 'traceability' means the ability for a competent authority to locate and identify the organ at each stage in the chain from donation to transplantation or disposal;

*which under specified circumstances in this Directive is authorised to:*

- identify the donor and the procurement organisation*
- identify the recipient(s) at the transplantation centre(s)*
- locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;*

Or.de

*Justification*

*The rewording contains a clear proposal for a definition of the term 'traceability', leaving specifics to be regulated by Article 10 of the Directive.*

**Amendment 112**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Chapter II – title**

*Text proposed by the Commission*

*Amendment*

**THE QUALITY AND SAFETY OF  
ORGANS**

**Framework for quality and safety**

Or.en

*Justification*

*The term framework is preferred over the term programme since it is a broader one. In order to better capture the MS healthcare systems realities it is preferred not to specify whether this framework is a supranational, national or regional one.*

**Amendment 113**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – title**

*Text proposed by the Commission*

*Amendment*

**National quality programmes**

**Framework for quality and safety**

Or.en

*Justification*

*The term framework is preferred over the term programme since it is a broader one. In order to better capture the MS healthcare systems realities it is preferred not to specify whether this framework is a supranational, national or regional one.*

**Amendment 114**

**Theodoros Skylakakis**

**Proposal for a directive**

**Article 4 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States shall ensure that a national quality programme is established to cover all stages of the chain from donation to transplantation or disposal, in order to ensure compliance with the rules laid down in this Directive.

1. Member States shall ensure that a national quality programme is established to cover all stages of the chain from donation to transplantation or disposal, in order to ensure compliance with the rules laid down in this Directive, **and shall do so by setting up appropriate public control mechanisms.**

Or.el

*Justification*

*Owing to the sensitive and non-profit making aspect of the organ transplant procedure and the weak position of patients waiting for a transplant, provision must be made for stringent public control procedures for each phase of the procedure.*

**Amendment 115**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – introductory part**

*Text proposed by the Commission*

*Amendment*

2. The **national** quality **programmes** shall provide for the adoption and implementation of:

2. The **framework for** quality **and safety** shall provide for the adoption and implementation of:

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles*

**Amendment 116**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

(a) **standard operating** procedures for the verification of donor identity;

(a) procedures for the verification of donor identity;

Or.en

**Amendment 117**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

(b) **standard operating** procedures for the verification of the details of donor or donor family consent or authorisation in accordance with national rules;

(b) procedures for the verification of the details of donor or donor family consent or authorisation in accordance with national rules **applying where donation and procurement take place**;

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles.*

**Amendment 118**

**Frédérique Ries**

**Proposal for a directive**

**Article 4 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) standard operating procedures for the verification of the details of donor or donor family **consent or authorisation** in accordance with national rules;

*Amendment*

(b) standard operating procedures for the verification of the details of **the absence of any objection by the** donor or donor family in accordance with national rules;

Or.fr

*Justification*

*This amendment takes into account the 'opting-out' character of consent which applies in most Member States.*

**Amendment 119**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – point c**

*Text proposed by the Commission*

(c) **standard operating** procedures for the verification of the completion of the organ and donor characterisation in accordance with Article 7 and with the model set out in the Annex;

*Amendment*

(c) procedures for the verification of the completion of the organ and donor characterisation in accordance with Article 7 and with the model set out in the Annex;

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the*

*essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles*

**Amendment 120**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – point e**

*Text proposed by the Commission*

(e) **rules** for the transportation of human organs in accordance with Article 8.

*Amendment*

(e) **procedures** for the transportation of human organs in accordance with Article 8.

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles*

**Amendment 121**

**Andres Perello Rodriguez, Marisa Matias**

**Proposal for a directive**

**Article 4 – paragraph 2 – points a – ec (new)**

*Text proposed by the Commission*

*Amendment*

***ea) procedures to ensure traceability, guaranteeing compliance with the legal requirements on the protection of personal data and confidentiality. such procedures shall include the responsibilities of procurement organizations and transplantation centres with regard to traceability;***

***eb) procedures for the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1), including the responsibilities of procurement organizations and transplantation centres***



*with regard to such reporting;  
ec) procedures for the management of serious adverse events and reactions as referred in Article 11(2), including the responsibilities of procurement organizations and transplantation centres with regard to such management.*

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework. Further specifications on the different elements are provided in corresponding articles.*

**Amendment 122**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – paragraph 3 – introductory part**

*Text proposed by the Commission*

*Amendment*

3. *The national* quality programmes shall

**3. *In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal is suitably qualified and competent, and shall develop specific training programmes for such personnel***

Or.en

*Justification*

*This new structure, highly supported by Member States, helps to better understand the essential elements of the quality and safety framework: (a) and (b) have been moved (reworded) to paragraph 2. “Healthcare” has been included in order to leave out drivers, pilots etc. involved in the process. Including the word “competencies” better captures national realities. This should be taken into consideration for the entire text of the Directive. General agreement on adding “such”, as it refers to healthcare personnel It is very difficult to recognize international standards in most of the cases*

**Amendment 123**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

***The national quality programmes shall*** ***deleted***

***(a) lay down rules to ensure the traceability of organs at all stages of the chain from donation to transplantation or disposal, in accordance with Article 10, including***

- the standard operating procedures under which the traceability of organs is ensured at national level,***
- the data necessary to ensure traceability and how the legal requirements on the protection of personal data and confidentiality are complied with,***
- the responsibilities of procurement organisations and transplantation centres with regard to traceability.***

Or.en

**Amendment 124**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point b – introductory part**

*Text proposed by the Commission*

*Amendment*

***(b) establish the standard operating procedures for:*** ***deleted***

- the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1),***
- the recall of organs as referred in Article 11(2),***
- the responsibilities of procurement***

*organisations and transplantation centres  
in the process of reporting.*

Or.en

**Amendment 125**  
**Anja Weisgerber**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point b – indent 3**

*Text proposed by the Commission*

– the responsibilities of procurement  
organisations and transplantation centres in  
the process of reporting.

*Amendment*

– the responsibilities of procurement  
organisations and transplantation centres in  
the process of reporting ***pursuant to  
Article 11(1).***

Or.de

*Justification*

*Die Änderung dient der Klarstellung, dass es Standardverfahrensanweisungen für die  
Zuständigkeit der Beschaffungsorganisation und Transplantationszentren nur bei der  
Meldung gemäß Artikel 11 Absatz 1 geben soll. Sie entspricht der Formulierung in den beiden  
vorhergehenden Spiegelstrichen. Andernfalls könnte die Richtlinie bei evtl. zukünftig  
hinzukommenden oder außerhalb des Anwendungsbereichs der Richtlinie bestehenden  
Zuständigkeiten dieser Einheiten für andere Meldungen dahingehend missverstanden werden,  
dass für jegliche Meldung eine Standardverfahrensanweisung festgelegt hat.*

**Amendment 126**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point b a (new)**

*Text proposed by the Commission*

*Amendment*

***(ba) authorise, in life-threatening  
emergencies, transplant operations using  
an organ which is not optimal, after  
consultation between the medical staff  
and the patient or his close family if the  
patient is unable to state his choice.***

**Amendment 127**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

*Amendment*

*(c) establish the qualifications required by the personnel involved at all stages of the chain from donation to transplantation or disposal, and develop specific training programmes for personnel in accordance with recognised international standards.*      *deleted*

Or.en

**Amendment 128**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point c**

*Text proposed by the Commission*

*Amendment*

(c) establish the qualifications required **by** the personnel involved at all stages of the chain from donation to transplantation or disposal, and develop specific training programmes for personnel **in accordance with recognised international standards.**

(c) establish the qualifications **or competencies** required **for** the **healthcare** personnel involved at all stages of the chain from donation to transplantation or disposal, and develop specific training programmes for **such** personnel.

Or.en

*Justification*

*Including the word “competencies” better captures national realities.*

**Amendment 129**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 4 – paragraph 3 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

**(ca) determine the status of transplant coordinators from the organ donation stage to monitoring of the recipient.**

Or.fr

*Justification*

*In Paragraph 12 of its resolution of 22 April 2008, the European Parliament stressed the central role played by transplant coordinators with a view to actively identifying potential donors. It is therefore essential that the national quality programmes referred to in Article 4(3) should provide for the establishment of a status of transplant coordinator.*

### **Amendment 130**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

#### **Proposal for a directive**

#### **Article 5 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States shall ensure that the procurement takes place ***in procurement organisations*** that comply with the rules laid down in this Directive.

1. Member States shall ensure that the procurement ***and making available of organs*** take place through ***one or more public or private non-profit making body or bodies/organisation(s)/institution(s)*** that comply with the rules laid down in this Directive.

Or.de

*Justification*

*This amendment brings the text into line with the definition of authorities and the making available of organs.*

**Amendment 131**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 5 – paragraph 2 – introductory part**

*Text proposed by the Commission*

*Amendment*

**2. The organisational structure and operational procedures of procurement organisations shall include:**

*deleted*

**(a) an organisational chart which clearly defines job descriptions, accountability and reporting relationships;**

**(b) standard operating procedures as specified in national quality programmes.**

Or.fr

*Justification*

*These excessively precise details should not be included in the body of the directive.*

**Amendment 132**  
**Cristian Silviu Buşoi**

**Proposal for a directive**  
**Article 6 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States shall ensure that medical activities in procurement organisations, such as donor selection, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.

1. Member States shall ensure that medical activities in procurement organisations, such as donor selection, ***the quality, effectiveness and integrity of the donation process***, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.

Or.en

**Amendment 133**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 6 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

2. Member States shall ensure that procurement takes place in dedicated facilities, which ***are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or other contamination of procured human organs in accordance with best medical practices.***

*Amendment*

2. Member States shall ensure that procurement takes place in dedicated facilities which ***comply with normal standards for operating theatres.***

Or.fr

**Amendment 134**  
**Peter Liese**

**Proposal for a directive**  
**Article 6 – paragraph 2 – subparagraph 1**

*Text proposed by the Commission*

2. Member States shall ensure that ***procurement*** takes place in ***dedicated*** facilities, which are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or other contamination of procured human organs in accordance with best medical practices.

*Amendment*

2. Member States shall ensure that ***donation*** takes place in ***appropriate*** facilities, which are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or other contamination of procured human organs in accordance with best medical practices. ***These facilities shall meet operating theatre standards.***

Or.de

*Justification*

*Clarification.*

**Amendment 135**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 6 – paragraph 2 – subparagraph 2 – introductory part**

*Text proposed by the Commission*

*Amendment*

*Those facilities shall comply with normal standard for operating theatres, including:*

*deleted*

*(a) Restricted access;*

*(b) personnel that are appropriately dressed for sterile operations, wearing sterile gloves, hats and facemasks.*

Or.fr

*Justification*

*Such details should not be included in a European directive.*

**Amendment 136**  
**Peter Liese**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

*Amendment*

*(a) the organisations, **bodies or companies** involved in the transportation of organs **have appropriate standard operating procedures in place to ensure the integrity of** the organ **during transport and that transport time is minimised.***

*(a) the organisation involved in the transportation of organs **ensure that** the organ **is transported with due care;***

Or.de

*Justification*

*This amendment seeks to cut red tape. What is essential is that the organ should be treated according to the rules during transport.*



**Amendment 137**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) the organisations, bodies or companies involved in the transportation of organs have appropriate ***standard operating*** procedures in place to ensure the integrity of the organ during transport and that transport time is minimised.

*Amendment*

(a) the organisations, bodies or companies involved in the transportation of organs have appropriate procedures in place to ensure the integrity of the organ during transport and that transport time is ***optimised and where possible*** minimised.

Or.en

*Justification*

*Agree on the concept although the wording might vary as a different wording (and that a suitable transport time is ensured) under the same idea has been suggested at the council. Please note that the term “standard operating procedure” has been replaced by procedure, consistently through the text keeping the same definition (written instructions describing the steps in a specific process, including the materials and methods to be used and the expected outcome)*

**Amendment 138**  
**Thomas Ulmer**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point b – indent 1**

*Text proposed by the Commission*

– identification of the procurement organisation, including its address and telephone number;

*Amendment*

– identification of the procurement organisation ***and the donor's hospital***, including its address and telephone number;

Or.de

*Justification*

*The proposed amendment takes due account of the quality and safety requirements and addresses the specific requirements relating to organ transplantation.*

**Amendment 139**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point b – indent 3**

*Text proposed by the Commission*

– a statement that the package contains a human organ and marked **HANDLE WITH CARE**;

*Amendment*

– a statement that the package contains a human organ and marked **'HUMAN ORGAN'**;

Or.fr

*Justification*

*This is the existing practice. There is no reason to change it, particularly if one wishes the transport of organs always to be performed transparently rather than clandestinely.*

**Amendment 140**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point b – indent 4**

*Text proposed by the Commission*

– **recommended transport conditions, including instructions for keeping the container at a certain temperature and in a certain position**

*Amendment*

**deleted**

Or.fr

*Justification*

*This amendment deletes a proposal which is quite simply impossible to apply in practice. Even in Member States where the system is most advanced, temperature monitoring is too costly and it is necessary more prosaically to ensure that organs are well preserved in suitable blocks of ice.*

**Amendment 141**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 8 – paragraph 1 – point b – indent 4**

*Text proposed by the Commission*

*Amendment*

**– recommended transport conditions,  
including instructions for keeping the  
container at a certain temperature and in  
a certain position**

**deleted**

Or.en

*Justification*

*Agree on the concept although the wording might vary as a different wording (and that a suitable transport time is ensured) under the same idea has been suggested at the council. Please note that the term “standard operating procedure” has been replaced by procedure, consistently through the text keeping the same definition (written instructions describing the steps in a specific process, including the materials and methods to be used and the expected outcome)*

**Amendment 142**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 9 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. The Competent authority shall indicate in the accreditation, designation, authorisation or licence which **activities** the transplantation centre concerned may undertake.

2. The Competent authority shall indicate in the accreditation, designation, authorisation or licence which **programmes** the transplantation centre concerned may undertake.

Or.fr

*Justification*

*This amendment is intended to reflect the variety which exists among transplantation centres, as some perform all types of transplantation while others are approved only for certain transplantation programmes, for example for kidney transplants but not heart transplants.*

**Amendment 143**  
**Thomas Ulmer, Anja Weisgerber**

**Proposal for a directive**  
**Article 9 – paragraph 2**

*Text proposed by the Commission*

2. The *Competent* authority shall indicate in the **accreditation, designation, authorisation or licence** which activities the transplantation centre concerned may undertake.

*Amendment*

2. The *Competent* authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake.

Or.de

*Justification*

*This amendment seeks to improve lawmaking and to facilitate application of the law. The terms for authorisation variously used by Member States of accreditation, designation, authorisation and licensing are covered by the term 'authorisation' in Article 3(a) defined for the purposes of the Directive. This definition should be used throughout to avoid misunderstandings in the Directive.*

**Amendment 144**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 9 – paragraph 4**

*Text proposed by the Commission*

4. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

*Amendment*

4. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres. **Member States shall seek to render authorisation criteria uniform throughout the Union.**

Or.fr

*Justification*

*The directive must set ambitious objectives for Member States, including in terms of more uniform criteria for transplantation centres.*

**Amendment 145**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 10 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that ***this donor identification system are designed and selected in accordance with the aim of collecting, processing or using no personal data or as little personal data as possible. In particular, use is to be made of the possibilities for pseudonymisation or rendering individuals anonymous.***

*Amendment*

2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that the ***confidentiality of patient data is respected in accordance with national rules.***

Or.en

*Justification*

*Too detailed since the reference to the data protection directive has been already established.*

**Amendment 146**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 10 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that ***this donor***

*Amendment*

2. Member States shall ensure the implementation of a donor identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that the

*identification system are designed and selected in accordance with the aim of collecting, processing or using no personal data or as little personal data as possible. In particular, use is to be made of the possibilities for pseudonymisation or rendering individuals anonymous.*

*confidentiality of patient data is respected in accordance with national rules.*

Or.en

*Justification*

*The reference to the data protection Directive has been already established*

**Amendment 147**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive  
Article 11 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the **procurement**, testing, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

*Amendment*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the testing, **characterisation, procurement, preservation** and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

Or.en

*Justification*

*Characterisation is also included under the scope - Article 2(1). Procurement should move after testing in order to follow the clinical process.*

**Amendment 148**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the **procurement**, testing, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

*Amendment*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the testing, **characterisation, procurement, preservation** and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities

Or.en

*Justification*

*Characterisation is also included under the scope - Article 2(1). Procurement should move after procurement in order to follow the clinical process*

**Amendment 149**  
**Peter Liese**

**Proposal for a directive**  
**Article 11 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the procurement, testing, and transport of organs, as well as any serious adverse reaction observed during or after

*Amendment*

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious **unexpected** adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the procurement, testing, and transport of organs, as well as any serious adverse reaction observed during or

transplantation which may be connected to those activities.

after transplantation which may be connected to those activities.

Or.de

**Amendment 150**  
**Glenis Willmott**

**Proposal for a directive**  
**Article 12 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 12a***

***Third Parties***

***1. Procurement organisations and transplantation centres may establish written agreements with third parties for the carrying out of their functions.***

***2. If procurement organisations and transplantation centres enter into written agreements as referred to in paragraph 1 they shall:***

***(a) evaluate and select third parties on the basis of their ability to meet the standards laid down in this Directive;***

***(b) keep a complete list of the agreements as referred to in paragraph 1 that they have concluded with third parties;***

***(c) specify the responsibilities of the third parties and detailed procedures;***

***(d) provide copies of agreements with third parties at the request of the Competent Authority.***

Or.en

*((These arrangements were foreseen in the Tissues and Cells Directive, see Article 24 of Directive 2004/23/EC.))*

*Justification*

*There are likely to be activities which procurement organisations or transplant centres need*



to carry out that they would like to be carried out by third parties either now or in the future, for example the running of IT systems. This Article would ensure that these third parties comply with the quality and safety standards set out in this Directive.

**Amendment 151**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Chapter III – title**

*Text proposed by the Commission*

*Amendment*

DONOR AND **RECIPIENT**  
**PROTECTION**

DONOR **SELECTION** AND  
**EVALUATION**

Or.en

*Justification*

*Articles included in this chapter are aimed at the donor selection and evaluation. Rewording of the title intends to make evident that such provisions are contained in the Directive due to their association with organ quality and safety (see proposal of Recital 16). This wording is also used in Directive 2004/23/EC (tissues and cells)*

**Amendment 152**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 13 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid.

1. Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid. ***This should not prevent living donors from receiving compensation, which shall be strictly limited to making good the expense and inconvenience involved in the donation. In that case, Member States shall define the conditions under which compensation may be granted.***

Or.en

**Amendment 153**  
**Frédérique Ries**

**Proposal for a directive**  
**Article 13 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid.

*Amendment*

1. Member States shall ensure that donations of human organs from deceased and living donors are voluntary and unpaid. ***The principle of non-payment must not prevent a living donor from receiving compensation for expenses incurred or for loss of income, provided that this does not constitute a financial benefit.***

Or.fr

*Justification*

*This is the position which the European Parliament has consistently stated concerning non-payment for donation since 2002 and the European directive on blood and blood products. The position is recalled with reference to organ donation in Paragraph 22 of its resolution of 22 April 2008: donation without payment but with moral and social compensation.*

**Amendment 154**  
**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**  
**Article 13 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall prohibit ***advertising the need for or, availability of,*** human organs ***where such advertising has*** a view to offering or seeking financial gain or comparable advantage.

*Amendment*

2. Member States shall prohibit ***the offering or making available of*** human organs ***with*** a view to offering or seeking financial gain or comparable advantage.

Or.de

*Justification*

*The proposal is intended to ban all trade in organs and ensure that organ donation is*

*governed by a spirit of altruism.*

**Amendment 155**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive  
Article 13 – paragraph 3**

*Text proposed by the Commission*

3. Member States shall ensure that the procurement of organs is ***carried out on a non-profit basis.***

*Amendment*

3. Member States shall ensure that the procurement of organs is ***not commercialised.***

Or.de

*Justification*

*The proposal is intended to ban all trade in organs and ensure that organ donation is governed by a spirit of altruism.*

**Amendment 156**

**Frédérique Ries**

**Proposal for a directive  
Article 14 – paragraph 1**

*Text proposed by the Commission*

Procurement shall only be carried out only after compliance with all ***mandatory consent or authorisation*** requirements in force in the Member State concerned.

*Amendment*

Procurement shall only be carried out only after compliance with all requirements ***relating to the absence of any objection to organ donation*** in force in the Member State concerned.

Or.fr

*Justification*

*See the amendment to Article 4(2) concerning national quality programmes.*

**Amendment 157**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 14 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a In order to meet the quality and safety requirements laid down in this Directive, Member States shall endeavour to obtain all necessary information from living donors and to provide them with the information which they need to understand the consequences of donation. In the case of deceased donation, Member States shall endeavour to obtain such information from relatives or other persons authorizing donation. Member States shall also make all parties from whom information is requested aware of the importance of the swift transmission of such information.***

Or.en

*Justification*

*Agree on the concept of the need of providing information to donors (or relatives) on the process of donation and transplantation. However, in order to keep this concept under the competencies of the EU conferred by article 168 of the TFEU, it is suggested to focus on the risks for recipients as a result of the quality and safety of the organs. As this is implicitly linked to obtaining a complete, objective and reliable clinical history by the medical team, it is also suggested to include this provision under article 7, related to the characterisation of donors and organs. We are still working on the final wording and studying the most appropriate place to locate this provision in this Directive*

**Amendment 158**  
**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 14 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***In order to meet the quality and safety requirements laid down in this Directive,***

***Member States shall endeavour to obtain all necessary information from living donors and to provide them with the information which they need to understand the consequences of donation. In the case of deceased donation, Member States shall endeavour to obtain such information from relatives or other persons authorizing donation. Member States shall also make all parties from whom information is requested aware of the importance of the swift transmission of such information.***

Or.en

*Justification*

*There is a need of providing information to donors or their relatives on the process of donation and transplantation. It is also essential to obtain a complete, objective and reliable clinical history by the medical team.*

**Amendment 159**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 15 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

***1. Member States shall take all necessary measures to ensure that potential living donors are provided with all the information necessary, as to the purpose and nature of the donation, the consequences and risks, and on alternative therapies for the potential recipient to enable them to make an informed decision. . The information shall be supplied in advance of the donation.***      ***deleted***

Or.en

*Justification*

*Unfortunately, the protection of the living donor does not fall under the competencies of the*

*EU conferred by Article 168 of the TFEU. Reference to this important principle is reflected in Recital 18. Priority Action number 3 of the Action Plan “Exchange of best practices on organ donation living programmes” could further develop this point.*

**Amendment 160**

**Oreste Rossi**

**Proposal for a directive**

**Article 15 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. Living donations shall be seen as subsidiary to post-mortem donations and only serve as a last resort where no suitable alternative such as an organ from a deceased donor is available. Living donations shall in general, due to the implicit danger of exploitation, be restricted to donations among close relatives and spouses and within stably cohabiting couples.***

Or.it

*(See rapporteur's amendment 31)*

*Justification*

*Stably cohabiting couples too may be included, in principle, among those who may be permitted to make living donations.*

**Amendment 161**

**Miroslav Mikolášik, Christa Klaß, Peter Liese**

**Proposal for a directive**

**Article 15 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. Living donations shall be seen as complementary to post-mortem donations and only serve as a last resort where no suitable alternative, such as an organ from a deceased donor, is available.***

*Living donations shall in principle be restricted to donations among close relatives and spouses due to the implicit danger of exploitation.*

Or.en

**Amendment 162**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive  
Article 15 – paragraph 2**

*Text proposed by the Commission*

2. Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified and trained professionals. Such assessments may provide for the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves.

*Amendment*

2. Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified and trained professionals. Such assessments may provide for the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves. ***Member States shall also ensure that living donors are legally insured.***

Or.de

*Justification*

*Legal insurance cover is important to protect living donors. In altruistically donating organs, living donors face a significant health risk which such a measure will help to mitigate.*

**Amendment 163**

**Oreste Rossi**

**Proposal for a directive  
Article 15 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. In order to comply with the principle of non-commercialisation of the human body, Member States shall ensure that any compensation to living donors is strictly limited to making good the expenses directly related to the donation (such as travelling expenses, childminding costs, loss of earnings due to the need to convalesce, loss of work or incapacity for work), avoiding any financial incentives for a potential donor.***

Or.it

*(See rapporteur's amendment 32)*

*Justification*

*It is necessary to make it clear that the loss of earnings due to donation may also consist of loss of work or incapacity for work.*

**Amendment 164**

**Miroslav Mikolášik, Christa Klaß, Peter Liese**

**Proposal for a directive**

**Article 15 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. In order to comply with the principle of non-commercialisation of the human body, Member States shall ensure that possible compensation for living donors is strictly limited to ensuring healthcare insurance for donation-related long-term medical conditions and to making good the expenses relating to the donation, such as travel expenses, child minding costs, loss of earnings or costs of recovery, and prohibiting any financial incentives for a potential donor.***

Or.en



*Justification*

*Financial incentives for organ donations are excluded. Nonetheless, it needs to be ensured that the living donor does not suffer financial losses for his donation. It also needs to be clarified that, while there has to be a strict causal relationship between the organ transplantation and the expenses incurred, this relationship does not have a temporal limit and covers the costs of recovery including the care for long-term temporal or permanent sufferings incurred by the transplantation.*

**Amendment 165**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 15 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a. Donors may receive compensation, which shall be strictly limited to making good the expense and inconvenience involved in the donation. In such cases, Member States shall define the conditions under which compensation may be granted.***

Or.en

*Justification*

*The wording suggested has been taken from the Directive of tissues and cells in order to ensure consistency between both EU documents.*

**Amendment 166**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 15 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2a This should not prevent living donors from receiving compensation, which shall be strictly limited to making good the expense and inconvenience involved in the donation. In such cases, Member***

***States shall define the conditions under which compensation may be granted.***

Or.en

*Justification*

*This reference should be included in Art. 13 (Principles governing organ donation) in order to make clear that the concept of unpaid donation has exceptions. This provision is in line with the Convention on Human Rights and Biomedicine, the WHO Guiding Principles on Human Transplantation and the Declaration of Istanbul on organ trafficking and transplant tourism. The wording suggested has been taken from the Directive of tissues and cells in order to ensure consistency between both EU documents*

**Amendment 167**  
**Oreste Rossi**

**Proposal for a directive**  
**Article 15 – paragraph 2 b (new)**

*Text proposed by the Commission*

*Amendment*

***2b. A person who has suffered undue damage resulting from an intervention shall be entitled to fair compensation.***

Or.it

*(See rapporteur's amendment 33)*

*Justification*

*The fairness of the compensation payable to a person who has suffered undue damage on account of an intervention is established case by case by the appropriate judicial authority. It is therefore not possible to set limits to it a priori in the directive.*

**Amendment 168**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 15 – paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. Member States shall ensure that the

3. Member States shall ensure that the

competent authority keeps a register of the living donors *after the donation*, in line with provisions on the protection of the personal data and statistical confidentiality, *and collects information on their follow up and, and specifically, on complications related to their donation that might appear in the short, mid and long term.*

competent authority keeps a register of the living donors, in line with provisions on the protection of the personal data and statistical confidentiality,

Or.en

*Justification*

*To ensure organ quality and safety it would be ideal that all countries could create and maintain a register on the follow up of living donors, but it is not feasible and seems to be a very stringent measure for a Directive. A register of living donors (not on their follow up) it is feasible and essential for the purpose of traceability.*

**Amendment 169**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 15 – paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3 a. Member States shall ensure that living donors are followed up in accordance with national provisions, in order to identify, report, and manage any event potentially relating to the quality and safety of the donated organ, and hence of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.***

Or.en

*Justification*

*See amendment 33a*

**Amendment 170**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 16 – paragraph 1**

*Text proposed by the Commission*

Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Community provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) of that Directive.

*Amendment*

Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ **donation and** transplantation activities, in conformity with Community provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) of that Directive.

Or.en

*Justification*

*Protection of personal data also implies donors.*

**Amendment 171**

**Anja Weisgerber, Thomas Ulmer**

**Proposal for a directive**

**Article 17 – title**

*Text proposed by the Commission*

***Anonymisation of donors and recipients***

*Amendment*

***Data protection***

Or.de

**Amendment 172**

**Horst Schnellhardt**

**Proposal for a directive**

**Article 17 – title**

*Text proposed by the Commission*

***Anonymisation*** of donors and recipients

*Amendment*

***Data protection and confidentiality*** of

donors and recipients

Or.de

**Amendment 173**

**Peter Liese**

**Proposal for a directive**

**Article 17**

*Text proposed by the Commission*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients processed within the **scope** of this Directive are rendered anonymous so that **neither** donors **nor** recipients **remain identifiable**.

*Amendment*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients **gathered and** processed within the **framework** of this Directive **to which third parties have access** are rendered anonymous **or pseudonymous** so that donors and recipients **are protected**.

Or.de

*Justification*

*The terms 'traceability' and 'rendering...anonymous' used in the proposal are in contradiction with one another. The wording should therefore be altered in line with the relevant data protection directives.*

**Amendment 174**

**Horst Schnellhardt**

**Proposal for a directive**

**Article 17**

*Text proposed by the Commission*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients processed within the **scope** of this Directive are rendered

*Amendment*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients **gathered and** processed within the **framework** of this

anonymous so that **neither** donors **nor** recipients **remain identifiable**.

Directive **to which third parties have access** are rendered anonymous **or pseudonymous** so that donors and recipients **are protected**.

Or.de

#### *Justification*

*The terms 'traceability' and 'rendering...anonymous' used in the proposal are in contradiction with one another. The wording should therefore be altered in line with the relevant data protection directives.*

#### **Amendment 175**

**Anja Weisgerber, Thomas Ulmer**

#### **Proposal for a directive**

#### **Article 17**

##### *Text proposed by the Commission*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients processed **within the scope** of this Directive are rendered **anonymous so that neither** donors **nor** recipients **remain identifiable**.

##### *Amendment*

Member States shall take all necessary measures to ensure that all personal data of donors and recipients **gathered and processed in connection with the implementation** of this Directive **in the organ donation process** are rendered **pseudonymous in order to protect** donors **and recipients from identification by unauthorised third parties**.

Or.de

#### *Justification*

*Eine Anonymisierung kann hier nicht als Option zugelassen werden, weil die Rückverfolgbarkeit gewährleistet bleiben muss. Auf einschlägige Pseudonymisierungsverfahren sollte zurückgegriffen werden, um die Spenderidentifikation in bestimmten Einzelfällen über die Anwendung eines Schlüssels durch berechtigte Personen zu ermöglichen. Die (Ent-)Pseudonymisierung muss zwischen den Mitgliedstaaten abgestimmt werden, um gerade bei grenzüberschreitenden Beschaffungswesen im Einzelfall die Rückverfolgbarkeit - unter Beachtung der Anforderungen des Datenschutzes - sicherzustellen.*

## Amendment 176

Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt

### Proposal for a directive

#### Article 18 – title

*Text proposed by the Commission*

*Amendment*

Designation and tasks of competent **authorities**

Designation and tasks of **the** competent **body or bodies, organisation(s) or institution(s)**

Or.de

#### *Justification*

*Bei der Abgrenzung der Regelungsinhalte der Richtlinie ist der Subsidiaritätsgrundsatz gemäß Art. 168 Abs. 7 AEUV (Art. 152 Abs. 5 EGV alt) unbedingt zu beachten. Dem wird z. T. zwar durch den Erwägungsgrund (19) Rechnung getragen, indem festgestellt wird: „Je nach Zuständigkeitsverteilung in den Mitgliedstaaten kann jedoch auch eine Kombination lokaler, regionaler, nationaler und/oder internationaler Stellen zusammenarbeiten, um Spende, Zuteilung und/oder Transplantation zu koordinieren, sofern es einen Rahmen gibt, der Rechenschaftspflicht, Zusammenarbeit und Effizienz sicherstellt.“ Allerdings wird dieser Subsidiaritätsgrundsatz in den einzelnen Artikeln des Richtlinienentwurfs nur bedingt berücksichtigt.*

## Amendment 177

Theodoros Skylakakis

### Proposal for a directive

#### Article 18 – paragraph 1

*Text proposed by the Commission*

*Amendment*

Member States shall designate the competent authority, or authorities (hereafter competent **authority**), responsible for implementing the requirements of this Directive.

Member States shall designate the competent authority, **organisation or institution** or authorities, **organisations or institutions** (hereafter competent **authority/authorities, organisation(s) or institution(s)**) responsible for implementing the requirements of this Directive. **The head of the competent authority of each Member State may not**

*have a legal interest or employment relationship with the bodies carrying out the procedures set out in this Directive. Representatives of the social stakeholders representing potential organ recipients may also take part in the public authorities' decision-taking procedure in order to further ensure the transparency of the procedures.*

Or.el

### *Justification*

*Για να διατηρηθούν οι επιτυχημένες και εγκεκριμένες οργανωτικές δομές των κρατών μελών, το άρθρ. 18 πρέπει να επιτρέπει την δημιουργία ενός ή περισσότερων αρμόδιων φορέων εντός του υπάρχοντος πλαισίου. Είναι απαραίτητο να αποσαφηνίζεται ρητά ότι μπορεί να πρόκειται για οποιονδήποτε οργανισμό, ίδρυμα ή αρχή, εφόσον πρόκειται για μη κερδοσκοπικό φορέα, όπως αναφέρει ο νέος ορισμός στο άρθρο 3 (τροπολογία 3). [Στη Γερμανία, για παράδειγμα, η δωρεά και η διάθεση οργάνωνονται από ιδιωτικούς μη κερδοσκοπικούς φορείς που υποβάλλουν αναφορές στο Υπουργείο Υγείας, όπως προβλέπει η γερμανική Πράξη για τις μεταμοσχεύσεις, του 1997]. Επιπροσθέτως, για να διασφαλιστεί η απαιτούμενη αυξημένη διαφάνεια ενόψει των σημαντικών διλημάτων που συνεπάγεται η διαδικασία μιας μεταμόσχευσης.*

### **Amendment 178**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

### **Proposal for a directive Article 18 – paragraph 1**

#### *Text proposed by the Commission*

Member States shall designate the competent ***authority, or authorities (hereafter competent authority)***, responsible for implementing the requirements of this Directive.

#### *Amendment*

Member States shall designate the competent ***public or private, non-profit making body or bodies/organisation(s)/institution(s) particularly involved in the implementation of these provisions*** responsible for implementing the requirements of this Directive.



*Justification*

*Bei der Abgrenzung der Regelungsinhalte der Richtlinie ist der Subsidiaritätsgrundsatz gemäß Art. 168 Abs. 7 AEUV (Art. 152 Abs. 5 EGV alt) unbedingt zu beachten. Dem wird z. T. zwar durch den Erwägungsgrund (19) Rechnung getragen, indem festgestellt wird: „Je nach Zuständigkeitsverteilung in den Mitgliedstaaten kann jedoch auch eine Kombination lokaler, regionaler, nationaler und/oder internationaler Stellen zusammenarbeiten, um Spende, Zuteilung und/oder Transplantation zu koordinieren, sofern es einen Rahmen gibt, der Rechenschaftspflicht, Zusammenarbeit und Effizienz sicherstellt.“ Allerdings wird dieser Subsidiaritätsgrundsatz in den einzelnen Artikeln des Richtlinienentwurfs nur bedingt berücksichtigt.*

**Amendment 179****Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez****Proposal for a directive  
Article 18 – paragraph 1***Text proposed by the Commission*

Member States shall designate the **competent authority, or authorities** (*hereafter* competent authority), responsible for implementing the requirements of this Directive.

*Amendment*

Member States shall designate the competent authority, responsible for implementing the requirements of this Directive.

*Justification*

*To be in line with the definition of "competent authority".*

**Amendment 180****Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt****Proposal for a directive  
Article 18 – paragraph 2 – introductory part***Text proposed by the Commission*

The competent **authorities** shall, in

*Amendment*

The competent **authority or institution(s)**

particular, take the following measures:

shall, in particular, take the following measures:

Or.de

**Amendment 181**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 18 – paragraph 2 – point a**

*Text proposed by the Commission*

*Amendment*

(a) put in place and keep updated a ***national*** quality ***programme*** in accordance with Article 4;

(a) put in place and keep updated a ***framework for*** quality ***and safety*** in accordance with Article 4;

Or.en

*Justification*

*To be in line with the change in Article 4*

**Amendment 182**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 18 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) Each Member State may delegate, or may allow a Competent Authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed appropriate under national provisions. Such a body may also assist a Competent Authority in carrying out its functions.***

Or.en

*Justification*

*Agree with the need of introducing the concept of the possibility of delegation. This wording is more flexible. This paragraph should be placed before the measures to take (18.2)*

**Amendment 183**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 18 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

*(aa) Each Member State may delegate, or may allow a Competent Authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed appropriate under national provisions. Such a body may also assist a Competent Authority in carrying out its functions.*

Or.en

*Justification*

*There is a need of introducing the concept of the possibility of delegation.*

**Amendment 184**

**Theodoros Skylakakis**

**Proposal for a directive**

**Article 18 – paragraph 2 – point b**

*Text proposed by the Commission*

*Amendment*

(b) ensure that procurement organisations and transplantations centres are **controlled** and audited on a regular basis to ascertain compliance with the requirements of this Directive;

b) ensure that procurement organisations and transplantations centres are **subject to public controls** and audited on a regular basis to ascertain compliance with the requirements of this Directive;

Or.el

*Justification*

*Owing to the sensitive and non-profit making aspect of the organ transplant procedure and the weak position of patients waiting for a transplant, provision must be made for stringent public control procedures for each phase of the procedure.*

**Amendment 185**

**Theodoros Skylakakis**

**Proposal for a directive**

**Article 18 – paragraph 2 – point e**

*Text proposed by the Commission*

(e) issue appropriate guidance to health care establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal;

*Amendment*

e) issue appropriate guidance to health care establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal ***as well as subsequent treatment and recovery in post-transplantation. They shall ensure that special protocols are created governing procedures for operative and post-operative stages under the responsibility of the respective operating teams, specialist pathologists and specialists in other necessary fields;***

Or.el

*Justification*

*Η διαδικασία της μεταμόσχευσης δεν τελειώνει όταν ο ασθενής έχει δεχθεί ένα μόσχευμα στην εγχείρηση μεταμόσχευσης. Η μετεγχειρητική περίοδος ανάρρωσης και θεραπείας με θεραπευτικές αγωγές για την πρόληψη της απόρριψης είναι εξίσου απαραίτητη για την επιτυχία της μεταμόσχευσης στον ασθενή. Το γεγονός αυτό δεν πρέπει να παραβλέπεται, εφόσον έχει καίρια σημασία για την επιτυχία της μεταμόσχευσης και τη βελτίωση της υγείας του ασθενούς. Το εθνικό κέντρο μεταμοσχεύσεων θα πρέπει, συνεπώς, να καθοδηγεί τις νοσοκομειακές μονάδες σε θέματα παρακολούθησης ασθενών μετά από μεταμόσχευση. Τα ειδικά πρωτόκολλα θα διευκολύνουν τη λειτουργία των μεταμοσχευτικών κέντρων και τη διαφάνεια των διαδικασιών .*

**Amendment 186**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt**

**Proposal for a directive**

**Article 19 – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

1. Member States shall ensure that the competent **authority**:

1. Member States shall ensure that the competent **body or bodies, organisation(s) or institution(s)**:

Or.de

*Justification*

*This is intended as clarification, taking into account the various national models for organising health systems.*

**Amendment 187**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive**

**Article 19 – paragraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

(c) establishes and maintains a register of **procurement organisations** and transplantation centres.

(c) establishes and maintains a register of **health care establishments, teams or departments of a hospital or another establishment authorised to procure human organs** and transplantation centres.

Or.de

*Justification*

*This is intended as clarification, taking into account the various national models for organising the health systems.*

## Amendment 188

Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese

### Proposal for a directive Article 19 – paragraph 2

*Text proposed by the Commission*

2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of **procurement organisations** and transplantation centres.

*Amendment*

2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of **health care establishments, teams or departments of a hospital or another establishment authorised to procure human organs** and transplantation centres.

Or.de

*Justification*

*This is intended as clarification, taking into account the various national models for organising the health systems.*

## Amendment 189

Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt

### Proposal for a directive Article 20 – paragraph 1

*Text proposed by the Commission*

1. The Commission shall set up a network of the competent **authorities** with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

*Amendment*

1. The Commission shall set up a network of the competent **body (bodies), organisation(s) or institution(s)** with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

Or.de

*Justification*

*This amendment follows on from the amendment to Article 19(1).*

**Amendment 190**  
**Horst Schnellhardt**

**Proposal for a directive**  
**Article 21 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that *all* exchanges of organs from or to third countries, are authorised by the competent authority.

*Amendment*

1. Member States shall ensure that exchanges of organs from or to third countries, are authorised by the competent authority.

Or.de

**Amendment 191**  
**Peter Liese**

**Proposal for a directive**  
**Article 21 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall ensure that *all* exchanges of organs from or to third countries, are authorised by the competent authority.

*Amendment*

1. Member States shall ensure that exchanges of organs from or to third countries, are authorised by the competent authority.

Or.de

**Amendment 192**  
**Peter Liese**

**Proposal for a directive**  
**Article 21 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1 a. Responsibility for authorising organ exchanges with third countries may be transferred by the Member States to European organ exchange organisations.***

Or.de

*Justification*

*The existing, tried and tested system for organising organ transplantation, which also provides for organ exchanges with third countries, should be maintained. However, not every organ exchange with third countries should require authorisation, only organ exchanges generally with a specific third country. In individual cases, responsibility for granting such authorisation may also be transferred to a European organisation for organ exchanges.*

**Amendment 193**

**Horst Schnellhardt**

**Proposal for a directive**

**Article 21 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. Responsibility for authorising organ exchanges with third countries may be transferred by Member States to European organ exchange organisations.***

Or.de

*Justification*

*The existing, tried and tested system for organising organ transplantation, which also provides for organ exchanges with third countries, should be maintained. However, not every organ exchange with third countries should require authorisation, only organ exchanges generally with a specific third country. In individual cases, responsibility for granting such authorisation may also be transferred to a European organisation for organ exchanges.*



**Amendment 194**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 23 – paragraph 1**

*Text proposed by the Commission*

1. Member States shall report to the Commission before .....and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.

*Amendment*

1. Member States shall report to the Commission before .....\*.and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.

***\* 6 years after the entry into force of this Directive.***

Or.en

*Justification*

*These new periods of time have been suggested by the Commission as a result of the experience with the Tissues and Cells Directive.*

**Amendment 195**  
**Andres Perello Rodriguez**

**Proposal for a directive**  
**Article 23 – paragraph 2**

*Text proposed by the Commission*

2. Before ..... and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions ,a report on the implementation of this Directive

*Amendment*

2. Before .....\*\* and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions ,a report on the implementation of this Directive

***\*\*5 years after the entry into force of this Directive***

Or.en

*Justification*

*These new periods of time have been suggested by the Commission as a result of the experience with the Tissues and Cells Directive*

**Amendment 196**

**Thomas Ulmer, Anja Weisgerber, Peter Liese**

**Proposal for a directive**

**Article 25 – paragraph 1 – point a**

*Text proposed by the Commission*

(a) rules for the updating and transmission of information on human organs characterisation as detailed in the Annex;

*Amendment*

(a) rules for the updating and transmission of information on human organ **and donor** characterisation as detailed in the Annex;

Or.de

*Justification*

*The additions take into account the connection between human organ and donor characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).*

**Amendment 197**

**Thomas Ulmer, Anja Weisgerber**

**Proposal for a directive**

**Article 25 – paragraph 1 – point c**

*Text proposed by the Commission*

(c) procedures for ensuring the reporting of serious adverse events and reactions.

*Amendment*

(c) procedures for ensuring the reporting of **unexpected** serious adverse events and reactions.

Or.de

*Justification*

*The additions take into account the connection between human organ and donor*

*characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).*

**Amendment 198**

**Thomas Ulmer, Anja Weisgerber**

**Proposal for a directive**

**Article 25 – paragraph 2 – point a**

*Text proposed by the Commission*

(a) the interconnection between the reporting systems on adverse events and reactions referred to in Article 11 (3);

*Amendment*

(a) the interconnection between the reporting systems on **unexpected** adverse events and reactions referred to in Article 11 (3);

Or.de

*Justification*

*The additions take into account the connection between human organ and donor characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).*

**Amendment 199**

**Thomas Ulmer, Anja Weisgerber**

**Proposal for a directive**

**Article 25 – paragraph 2 – point b**

*Text proposed by the Commission*

(b) the establishment and **functioning** of the network of the competent authorities referred to in Article 20.

*Amendment*

(b) the establishment and **ability to function** of the network of the competent authorities referred to in Article 20.

Or.de

*Justification*

*The additions take into account the connection between human organ and donor characterisation (1a) and the definition provided in Article 3 (m) and (n) of the proposal for a Directive (1c, 2a and b).*

**Amendment 200**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 27 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a 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.***

Or.en

*Justification*

*More stringent measures can be applied if Member States wish. This is consistent with the Tissues and Cells Directive.*

**Amendment 201**

**Andres Perello Rodriguez**

**Proposal for a directive**

**Article 27 – subparagraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. 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.***

Or.en

**Amendment 202**

**Marisa Matias, Kartika Tamara Liotard, Andres Perello Rodriguez**

**Proposal for a directive**

**Article 27 – paragraph 2**

*Text proposed by the Commission*

*Amendment*

2. Member States shall communicate to the Commission the text of the **main** provisions of national law which they adopt in the field covered by this Directive.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Or.en

*Justification*

*The Member States should communicate all provisions of national law in the field covered by the Directive*

**Amendment 203**

**Thomas Ulmer, Anja Weisgerber, Horst Schnellhardt, Peter Liese**

**Proposal for a directive  
Annex – Introduction**

*Text proposed by the Commission*

*Amendment*

For the purpose of Article 7 the following information shall be gathered by the procurement organisation or procurement team on the characteristics of the organ and of the donor, **following testing where necessary** and processed in line with the legal requirements on the protection of personal data and confidentiality:

For the purpose of Article 7 the following information shall be gathered by the procurement organisation or procurement team on the characteristics of the organ and of the donor, **bearing in mind the individual circumstances**, and processed in line with the legal requirements on the protection of personal data and confidentiality. **In the absence of data, a decision shall be taken about the transplant after individual risk assessment of the donor and the recipient.**

Or.de

*Justification*

*The addition makes allowances for the fact that all the information and data provided for in the Annex or organ and donor characterisation are not always available or obtainable. This must not rule out transplants in individual cases. Without this addition, the number of donor organs would fall still further.*

