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Committee on the Environment, Public Health and Food Safety

2008/0238(COD)

16.12.2009

***I
DRAFT REPORT

on the proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008)0818 – C6-0480/2008 – 2008/0238(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Miroslav Mikolášik

Symbols for procedures

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

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

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008)0818 – C6-0480/2008 – 2008/0238(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0818),

– having regard to Article 251(2) and Article 152(4)(a) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0480/2008),

– having regard to the Communication from the Commission to the European Parliament and the Council entitled "Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures" (COM(2009)0665),

– having regard to Article 294(3) and Article 168(4) of the Treaty on the Functioning of the EU,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Legal Affairs (A7-0000/2009),

1. Adopts the position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text.

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

Amendment 1

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	(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.	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 medical expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs in patients such as rejection of the organ.***

Or. en

Justification

This Directive has the stated aim of improving the risk benefit ratio for patients. It should therefore be emphasised in the Recitals that mitigation of some of the risks is possible through the implementation of this Directive. A major element of the medical outcome is the acceptance of an organ by the patient. Steps to reduce organ rejection, hence improving the risk-benefit ratio for patients, should therefore be implemented.

Amendment 2

Proposal for a directive
Recital 14

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

Or. en

Justification

The listing of procedures provided in Article 2(1) also includes "characterisation".

Amendment 3

Proposal for a directive
Recital 16

Text proposed by the Commission	*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 and to take account of, as appropriate the Convention on human rights and biomedicine , 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).***	(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 , 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 ***that strict confidentiality rules and security measures are in place for the protection of the donors' and the recipients' personal data.***

Or. en

Justification

The concepts of 'traceability' and 'identifiability' are strongly connected to each other: whenever traceability of the holders of the biological materials is possible, either in a direct or indirect way, these holders can be considered as identifiable. From a data protection perspective, traceability and anonymity of data cannot appear at the same time since they are opposite to each other. However, the proposal still uses both terms and therefore creates a contradiction.

Amendment 4

Proposal for a directive
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) The competent authority shall consult with the national Data Protection Authority in relation to developing a framework for the transfer of organs' data to and from third countries. The

specific regime for the transfer of personal data to third countries as laid down in Articles 25 and 26 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[1] applies.
[1] OJ L 281, 23.11.1995, p. 31.

Or. en

Justification

A specific regime for transfer of personal data to third countries is laid down in Articles 25 and 26 of Directive 95/46/EC. Article 21 or the relevant Recital 15 of the proposal could state that the competent authority will consult with the national Data Protection Authority in order to develop the necessary framework for secure, but also fast and efficient transfer of organs' data to and from the third countries.

Amendment 5

Proposal for a directive
Recital 19

Text proposed by the Commission	*Amendment*
(19) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation. As emphasised by the Recommendation of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO) of the Council of Europe , it is preferable to have a single body which is officially recognised and non-profit making with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the repartition of competences within the Member States, a combination of local, regional, national and/or international bodies may work	(19) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation ***and throughout the patient's recovery based on best medical practice in post-transplantation treatment***. As emphasised by the Recommendation of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO) of the Council of Europe15, it is preferable to have a single body which is officially recognised and non-profit making with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the repartition of

together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency	competences within the Member States, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency

Or. en

Justification

The transplant process does not end when the patient has received an organ in the transplant operation. The recovery period, and treatment with anti-rejection therapies, are also imperative to the success, or not, of a transplanted organ for the patient. This fact should not be neglected as it is a vital part of whether the patient has undergone a successful transplant and is ultimately able to improve their health.

Amendment 6

Proposal for a directive
Recital 21

Text proposed by the Commission	*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.	(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. ***With regard to Article 25, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders should be consulted, including the European Data Protection Supervisor.***

Or. en

Justification

The legislator should ensure that, with regard to Article 25, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders are consulted, including the EDPS.

Amendment 7

Proposal for a directive
Recital 22

Text proposed by the Commission	*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 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.***	(22) ***In order to achieve the objectives of this Directive, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union concerning,*** 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.

Or. en

Justification

The legislator should ensure that, with regard to Article 25, in all cases where implementing measures affecting data protection and security are considered, all relevant stakeholders are consulted, including the EDPS.

Amendment 8

Proposal for a directive
Article 2 - paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. 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 9

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) 'authorisation' means authorisation, accreditation, designation or licensing, depending of the concepts used in each Member State, ***or registration with a public body for the provision of health care provided that the functions of that public body include ensuring that the registered body complies with the rules laid down in this Directive.***

Or. en

Justification

It is indispensable that all member states with already well established health care and transplantation systems are able to maintain their organisational and administrative structures. In some Member States the registration is the equivalent of the authorisation or accreditation process.

Amendment 10

Proposal for a directive
Article 3 - point (a a) (new)

Text proposed by the Commission	*Amendment*
	(aa) "competent authority/organisation/institution" means one or more non-profit authority(ies), organisation(s) and/or institution(s), whether public or private, responsible for implementing the requirements of this Directive;

Or. en

Justification

In line with the definition given for an European organ exchange organisation also the body in charge of procurement and supervision of the rules of the directive as the basis of all transplantation systems it is essential to incorporate a definition of the competent body installed according to Article 18 for clarification purposes. This amendment therefore is supplementary to the proposed amendments (37, 38) of Article 18. It allows for a flexible organisation of organ donation and procurement when it comes to the implementation without cutting back on quality and safety.

Amendment 11

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 ***deceased or living person who donates one or several organs***

Or. en

Justification

As the human body is always a body of a person, even after death, the definition of a donor should be personalized.

Amendment 12

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 undertake procurement of human organs	(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***/organisation/institution*** to undertake procurement of human organs

Or. en

Justification

This amendment is a follow up to the amendment No. 9. The procurement organisation can have a double function by being a donor hospital (hospital or hospital department where organs for transplantation purposes are procured) or an external organisation (whether public or private) that is in charge of the coordination and organisation of the entire donation and procurement process. If the procurement organisation is not identical with the donor hospital it can also function as the competent authority/ organisation/institution. See also proposed amendment No. 17 of Article 5.

Amendment 13

Proposal for a directive
Article 4 - title

Text proposed by the Commission	*Amendment*
National quality programmes	National quality ***and safety*** programmes

Or. en

Justification

The amendment takes into account the scope of the directive.

Amendment 14

Proposal for a directive
Article 4 - paragraph 2 - point - a (new)

Text proposed by the Commission	*Amendment*
	(-a) standard operating procedures for the identification and referral of potential donors;

Or. en

Justification

Identification of potential donors in the intensive care units and their referral is the indispensable prerequisite for all organ donation activities. Numerous studies show that there is a potential between 40 to 50 donors per million population in every member state. This means that every member state can increase its organ donation rate by installing a systematic analysis of the existing donor potential in all donor hospital followed by measurement in

order to ensure that the donor potential is exhausted.

Amendment 15

Proposal for a directive
Article 4 - paragraph 3 - point b - indent 2

Text proposed by the Commission	*Amendment*
– the ***recall of organs*** as referred in Article 11(2),	– the ***management of serious adverse events and reactions*** as referred in Article 11(2),

Or. en

Justification

The measures to adopt for a severe adverse event or reaction do not include necessarily the recall of organs, as defined in this directive. Occasionally, the events or the reactions appear when the organ has already been transplanted and, in that case, the transplantectomy for the recall of the organ may not be the most appropriate measure to adopt. Besides, the management of a particular safety problem would also include the revision and assessment of the procedures and results, in order to introduce corrective or preventive measures.

Amendment 16

Proposal for a directive
Article 4 - paragraph 3 - point b - indent 3

Text proposed by the Commission	*Amendment*
– the responsibilities of procurement organisations and transplantation centres in the process of reporting.	– the responsibilities of procurement organisations and transplantation centres in the process of reporting ***and management***.

Or. en

Justification

When a serious adverse event or reaction appears it is mandatory to adopt a series of measures targeted to prevent. These measures do not necessarily include the recall of the organ, as defined in this Directive. Sometimes serious adverse events and reactions appear when the organ has been already grafted and transplantectomy (recall of the organ) might not be the most adequate measure to be adopted.

Amendment 17

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 required by the ***health care*** 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.

Or. en

Amendment 18

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 takes place in ***or by*** procurement organisations that comply with the rules laid down in this Directive.

Or. en

Justification

The majority of donor hospitals is not able to ensure all the rules of the directive without assistance. In particular the organ donor characterisations according to Art. 7. In order not to jeopardize the willingness of hospitals to participate in organ donation the directive should facilitate that either the donor hospital ensures all necessary steps itself or that there is an external organ procurement organisation that assists the hospitals and ensures that all provisions of the directive are met in order to ensure high quality and safety standards for the potential recipients.

Amendment 19

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 ***and evaluation***, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.

Or. en

Amendment 20

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 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 ***optimised and where possible*** minimised.

Or. en

Justification

often to ensure the integrity of the organ during trasport is better to not to minimize the time and to wait for the most appropriate one.

Amendment 21

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	- recommended transport conditions, including instructions for keeping the container at ***an appropriate*** temperature and in ***an appropriate*** position

Or. en

Amendment 22

Proposal for a directive
Article 10 - paragraph 2

Text proposed by the Commission	*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 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.***	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 ***the implementation of a*** donor ***and recipient*** identification system ***that*** are designed and selected in accordance with the aim of collecting, processing or using ***as little personal data as possible, making in particular use of pseudonymisation methods, as well as that the necessary technical and organisational measures are in place for the security of those data.***

Or. en

Justification

The concepts of 'traceability' and 'identifiability' are strongly connected to each other: whenever traceability of the holders of the biological materials is possible, either in a direct or indirect way, these holders can be considered as identifiable. From a data protection perspective, traceability and anonymity of data cannot appear at the same time since they are opposite to each other. However, the proposal still uses both terms and therefore creates a contradiction.

Amendment 23

Proposal for a directive
Article 10 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall, in accordance with Article 24, lay down rules on penalties applicable to:
	(a) the unauthorised accessing of data or systems permitting the identification of donors or recipients;
	(b) any use which is made of systems or data permitting the identification of donors or recipients with a view to tracing donors or recipients other than for necessary medical purposes.

Or. en

Justification

Penalties are needed to deter people from attempting to use the systems for unauthorized searches.

Amendment 24

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*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 procurement, testing, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to	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, ***preservation*** and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be

those activities.	connected to those activities.

Or. en

Justification

The listing of procedures provided in Article 2(1) also includes "preservation" and it seems potentially beneficial to take issues relating to preservation into account as a cause for serious adverse events.

Amendment 25

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 ***altruistic,*** voluntary and unpaid.

Or. en

Justification

Organ donation is a gift based on solidarity and compassion for a fellow human being. Not to require an organ donation to be altruistic means to belittle the gift and the dignity of the deceased or living donor. The European Parliament acknowledged this specific requirement already in its resolution of 22 April 2008 (Resolution on organ donation and transplantation (A6-0090/2008), § 22) and the Commission took it up in § 23 of its Explanatory Memorandum.

Amendment 26

Proposal for a directive
Article 13 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission, in close cooperation with Member States, the European Parliament and relevant stakeholders, shall examine the possibility of developing a system whereby the wishes expressed by

citizens consenting to the donation of organs after they are deceased are taken into account in as many Member States as possible.

Or. en

Justification

As people live, travel and work in several countries of the European Union, they also die in other countries than the one of which they are citizens or residents.

Amendment 27

Proposal for a directive
Article 13 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Member States shall ensure that systems and registers are in place which are easily accessible for the purposes of recording the wishes of future donors and that the competent authorities give priority to the wishes expressed by a donor over any possible contrary wishes of a spouse, first-degree relative or other person.

Or. en

Justification

Member States should be urged to ensure that there are systems in place to communicate a wish to become a donor and that this expressed wish should be respected as a priority.

Amendment 28

Proposal for a directive
Article 13 – paragraph 3 c (new)

Text proposed by the Commission	*Amendment*
	3c. Member States shall ensure that organs are allocated to recipients

according to transparent, non-discriminatory and scientific criteria.

Or. en

Justification

This rule regarding the allocation of organs is the direct result of the application of the principles of equality and of justice in healthcare resource allocation.

Amendment 29

Proposal for a directive
Article 13 – paragraph 3 d (new)

Text proposed by the Commission	*Amendment*
	3d. Member States shall ensure that organs are not removed from a deceased person unless that person has been certified dead in accordance with national law.

Or. en

Justification

Demanding a death certificate regarding a deceased donor before allowing the organ removal is a requirement deriving from the principle of inviolability of human life and physical integrity as laid down in Article 16 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin.

Amendment 30

Proposal for a directive
Article 14 – paragraph 2 (new)

Text proposed by the Commission	*Amendment*
	Member States shall take all necessary measures to ensure that donors are provided with comprehensive, concrete and unbiased information on organ donation covering the transplantation process, the specific scope, potential use

and the risks, including risks of misuse.

Or. en

Justification

While finding an answer to the severe organ shortage in Europe is very important, it is also necessary to underline that the free choice to donate or not to donate an organ needs to be respected and protected as well. Without sufficient, appropriate and non-directive information, the decision to donate or not to donate an organ will not be "voluntary". The European Parliament acknowledged this principle in § 7 and § 37 of its Resolution of 22 April 2008 (A6-0090/2008).

Amendment 31

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

Or. en

Justification

When it comes to living donors particular safeguards need to be put in place, as they are in position prone to exploitation. Art. 9 and 10 of the Additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin underline the subsidiary character of living donations, as did the European Parliament in § 15 of its resolution of 22 April 2008 (A6-0090/2008). Limiting living donations to persons closely related to the donor is a general principle shared by a large majority of Member States.

Amendment 32

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 a possible compensation to living donors is strictly limited to making good the expenses directly related to the donation such as travelling fees, childminding costs or loss of earnings, avoiding any financial incentives for a potential donor.

Or. en

Justification

Organ donation out of financial motivation is unethical. It degrades the gift of an organ to a mere commodity of the market and constitutes a violation of human dignity. It is also in conflict with the principle of non-commercialisation of the human body and its parts, explicitly stated in Article 3 § 2 of the EU Charter on Fundamental Rights. The European Parliament confirmed that in § 22 of its Resolution of 22 April 2008 (A6-0090/2008)).

Amendment 33

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

Text proposed by the Commission	*Amendment*
	2b. The person who has suffered undue damage resulting from an intervention shall be entitled to fair compensation strictly limited to making good the expenses and inconveniences related to the donation.

Or. en

Justification

See Justification Article 15, paragraph 2, 2a.

Amendment 34

Proposal for a directive
Article 15 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall ensure that no organ removal may be carried out on a person who under national law does not have the capacity to consent to it.

Or. en

Justification

Persons not having the capacity to consent to a medical procedure are in an especially dire need of protection. This may concern minors, but also adult persons lacking legal capacity. While reflecting Article 14 § 1 of the Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, this amendment leaves it to the Member States to determine under which conditions a person is or is not capable to consent to a medical procedure.

Amendment 35

Proposal for a directive
Article 16 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall take all necessary measures to ensure that donors and recipients whose data are being processed within the scope of this Directive are only identifiable for persons who can establish a need to know their identities.

Or. en

Justification

The concepts of 'traceability' and 'identifiability' are strongly connected to each other: whenever traceability of the holders of the biological materials is possible, either in a direct or indirect way, these holders can be considered as identifiable and they should include

recipients and donors.

Amendment 36

Proposal for a directive
Article 16 - paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Member States shall take all necessary measures to ensure the confidentiality, integrity, accountability and availability of the personal data of donors and recipients.

Or. en

Justification

It is of utmost importance to implement an information security policy based on strict and sound security measures at the relevant national services, especially in order to meet the confidentiality requirements for the donors and recipients set out in the proposal, as well as to safeguard integrity, accountability and availability of these data.

Amendment 37

Proposal for a directive
Article 17

Text proposed by the Commission	*Amendment*
Article 17	***deleted***
Anonymisation of donors and recipients	
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.	

Or. en

Justification

Article 17 as such could be deleted, incorporating its content (in terms of confidentiality needs) in a new paragraph of Article 16 on the Protection of personal data, confidentiality and security of processing.

Amendment 38

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 authorities***/organisations/institutions***

Or. en

Justification

The existing organisational structures for organ donation, allocation and transplantation in the Member States are closely connected to the organisation of the national health care system in general. Recital 19 states that within Members States, a combination of local, regional, national and/or international bodies may work together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency. See also Amendment 38.

Amendment 39

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/institution***, or authorities***/organisations/institutions*** (hereafter competent authority***/organisation/institution***), responsible for implementing the requirements of this Directive.

Or. en

Justification

In order to maintain the successful and approved organisational Member State structures Art. 18 should allow for the instalment of one or more competent bodies within the existing framework. It is indispensable that the wording clarifies explicitly that it can be any institution, organisation or authority as long as it is a non profit body, as laid down in the new definition in Art. 3, Amendment 9. [In Germany for example donation and allocation are organised by private non-profit organisations that report to the ministry of health as foreseen by the German Transplantation Act from 1997].

Amendment 40

Proposal for a directive
Article 18 – paragraph 2 - point d

Text proposed by the Commission	*Amendment*
(d) put in place a reporting system and a system for ***the recall of organs*** as provided for in Article 11(1) and (2);	(d) put in place a reporting ***and management*** system and a system for ***severe adverse events and/or reactions*** as provided for in Article 11(1) and (2);

Or. en

Justification

The measures to adopt for a severe adverse event or reaction do not include necessarily the recall of organs, as defined in this directive. Occasionally, the events or the reactions appear when the organ has already been transplanted and, in that case, the transplantectomy for the recall of the organ may not be the most appropriate measure to adopt. Besides, the management of a particular safety problem would also include the revision and assessment of the procedures and results, in order to introduce corrective or preventive measures.

Amendment 41

Proposal for a directive
Article 18 – paragraph 2 - point e

Text proposed by the Commission	*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;	(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*;**

Or. en

Justification

The transplant process does not end when the patient has received an organ in the transplant operation. The post-transplantation recovery period, and treatment with anti-rejection therapies, are also imperative to the success, or not, of a transplanted organ for the patient. This fact should not be neglected as it is a vital part of whether the patient has undergone a successful transplant and is ultimately able to improve their health. The National Transplant Centre must therefore look at guiding medical facilities in transplant care.

Amendment 42

Proposal for a directive
Article 18 - paragraph 2 - point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) collect relevant post-transplantation outcome data in order to allow comparable assessment of quality and safety of organ transplantation, which will serve to further improve the transplantation process at the European level.

Or. en

Justification

Although almost all European countries have already developed a registry that collects information on all aspects of the transplantation process, comparisons between the European registries is hampered by the lack in harmonization of definitions of terms used in organ transplantation, procedures for the collection of data on transplantation activity, and techniques for the evaluation of post-transplant outcome. This amendment calls on more cooperation.

Amendment 43

Proposal for a directive
Article 18 - paragraph 3 (new)

Text proposed by the Commission	*Amendment*
	The competent authorities of each Member State may delegate the implementation of the measures referred to in the second paragraph to recognised organisations dedicated to carrying out such measures.

Or. en

Justification

This paragraph might be of help for MS using those types of organizations.

Amendment 44

Proposal for a directive
Article 21 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that all exchanges of organs from or to third countries, are authorised by the competent authority.	1. Member States shall ensure that all exchanges of organs from or to third countries, are authorised by the competent authority***/organisation/institution. The competent authority shall consult with the national Data Protection Authority for developing a framework for the transfer of data relating to the exchange of organs to and from third countries. The specific regime for the transfer of personal data to third countries as laid down in Articles 25 and 26 of Directive 95/46/EC shall apply.***

Or. en

Justification

A specific regime for transfer of personal data to third countries is laid down in Articles 25 and 26 of Directive 95/46/EC. Article 21 or the relevant Recital 15 of the proposal could state

that the competent authority will consult with the national Data Protection Authority in order to develop the necessary framework for secure, but also fast and efficient transfer of organs' data to and from the third countries.

Amendment 45

Proposal for a directive
Article 21 - paragraph 2 - point b

Text proposed by the Commission	*Amendment*
(b) meet quality and safety requirements equivalent to the ones laid down in this Directive.	(b) meet quality and safety ***as well as donor and recipient protection*** requirements equivalent to the ones laid down in this Directive.

Or. en

Justification

Protection of organ donors and organ recipients in third countries is strictly connected to the effective protection of organ donors and organ recipients within the European Union. Hence, an authorisation for the exchange of organs shall only be granted when all requirements of the new Directive are met also by the organ donation in the third country . The current wording is ambiguous.

Amendment 46

Proposal for a directive
Article 23

Text proposed by the Commission	*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.	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.
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	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.	this Directive. [*] ***2 years after the entry into force of this Directive.*** [**] ***3 years after the entry into force of this Directive.***

Or. en

Amendment 47

Proposal for a directive
Article 24

Text proposed by the Commission	*Amendment*
Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ***[…]*** and shall notify it without delay of any subsequent amendments affecting them.	Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by***** and shall notify it without delay of any subsequent amendments affecting them. [*] ***2 years after the entry into force of this Directive.***

Or. en

Amendment 48

Proposal for a directive
Article 25 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Detailed rules for the following measures shall be adopted in accordance with the procedure referred to in Article 26(3): ***(a) rules for the updating and transmission of information on human***	***deleted***

organs characterisation as detailed in the Annex;

(b) procedures for ensuring the full traceability of organs, including labelling requirements;

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

Or. en

Amendment 49

Proposal for a directive
Article 25 - paragraph 2

Text proposed by the Commission	*Amendment*
2. ***Detailed*** rules for the uniform implementation of this Directive, and in particular for the following measures, shall be adopted in accordance with the procedure referred to in Article 26(2):	2. ***Appropriate*** rules for the uniform implementation of this Directive, and in particular for the following measures, shall be adopted in accordance with the procedure referred to in Article 26(2):

Or. en

Amendment 50

Proposal for a directive
Article 25 a (new)

Text proposed by the Commission	*Amendment*
	Article 25a
	Delegated acts
	In order to achieve the objectives of this Directive, the Commission shall lay down by means of delegated acts in accordance with Articles 26a, 26b and 26c:
	(a) rules for the updating and transmission of information on human organs characterisation as detailed in the Annex;

(b) procedures for ensuring the full traceability of organs, including labelling requirements;

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

Or. en

Amendment 51

Proposal for a directive
Article 26 - paragraph 3

Text proposed by the Commission	*Amendment*
3. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.	***deleted***

Or. en

Amendment 52

Proposal for a directive
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Exercise of the delegation
	1. The powers to adopt the delegated acts referred to in Article 25a shall be conferred on the Commission until...*. The Commission shall make a report in respect of the delegated powers at the latest...**, accompanied, where relevant, by a legislative proposal to extend the duration of the delegation of powers.
	2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the

Council.

3. The power to adopt delegated acts shall be conferred on the Commission subject to the conditions laid down in Articles 26b and 26c.

**** OJ; please insert the date 3 years after the entry into force of this Directive.***

***** OJ; please insert the date 30 months after the entry into force of this Directive.***

Or. en

Amendment 53

Proposal for a directive
Article 26 b (new)

Text proposed by the Commission	*Amendment*
	Article 26b
	Revocation of the delegation
	1. The delegation of power referred to in Article 25a may be revoked by the European Parliament or by the Council.
	2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission stating the delegated powers which could be subject to revocation.
	3. The decision of revocation shall state the reasons for the revocation and shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Or. en

Amendment 54

Proposal for a directive
Article 26 c (new)

Text proposed by the Commission	*Amendment*
	Article 26c
	Objections to delegated acts
	1. The European Parliament and/or the Council may object to the delegated act within a period of two months from the date of notification. At the initiative of the European Parliament or the Council this period shall be extended by one month.
	2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, the delegated act shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.
	3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Or. en

Amendment 55

Proposal for a directive
Article 27 - paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ***[...]***at the latest. They shall forthwith communicate to the Commission the text of those provisions ***and a correlation table between those provisions and this Directive.***	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ...***** at the latest. They shall forthwith communicate to the Commission the text of those provisions.
	**** 2 years after the entry into force of this Directive.***

Or. en

Amendment 56

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.

EXPLANATORY STATEMENT

Organ transplantation has been transformed from an extraordinary exercise in immunobiology to the most practical way of rehabilitating patients with a wide variety of illnesses resulting in fatal kidney, liver, heart, lung and pancreas diseases. Over past five decades, it has become an established and efficient worldwide practice which tremendously improves quality of life and extents life expectancy. Moreover, organ donation is a gift and supports expression of altruism and solidarity in the society.

Nonetheless, the need for organ transplantation in the European Union has increased steadily and more rapidly than the number of organs donated. Significant number of patients dies as result of the chronic shortage of organs. Serious imbalance between need and availability of organs might lead to the cases of commercialization and illegal organ trafficking which violates fundamental human rights. Meanwhile shortage of organs remains the most important challenge, there are many more with regard to the different transplantation systems applied in Member States. Since enhanced cooperation and cross border exchange between Member States has an impressive potential to increase number of transplantations, it requires the adoption of common quality and safety standards.

In order to ensure high level of health protection throughout the European Union, the proposed Directive establishes common binding standards of quality and safety of human organs intended for transplantation. After adoption of the directive on quality and safety of human blood and blood components (2003), followed by the directive on quality and safety of human tissues and cells (2004), this directive seeks to encompass human organs to complete the legislation based on the Article 152 of the EC Treaty. A need for common action at European level was clearly acknowledged in the Resolution on organ donation and transplantation adopted in the European Parliament by huge majority in April 2008.

Proposed 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 the process of donation, procurement, testing, characterization, preservation, transport and transplantation. It introduces national quality programmes specifying rules and practice of the transplantation process in Member States. It further elaborates more on process of the procurement and involved subjects including reporting system. Special attention is paid to the traceability and protection of donor and recipient. With regard to the implementation, there are provisions on designation and tasks of competent national authorities, European organ exchange organizations and exchange of organs with third countries.

The rapporteur welcomes this proposal and highly appreciates its three principal aims: ensuring quality and safety for patients at EU level, ensuring protection of donors and facilitating cooperation between Member States. Generally, in the European Union there is broad societal consensus on organ donation for the purpose of transplantation. However, due to different cultural, traditional or organizational system background, there are differences between Member States in approach to this issue. While maintaining or striving for harmonization of the quality and safety measures, rapporteur stresses that the directive must not create an additional administrative burden for Member States and must leave enough flexibility without jeopardizing current good practices.

The rapporteur agrees with Commission's view, that as matter of principle, organ transplantation programmes are based on the principle of voluntary and unpaid donation since this principle was anchored already in the previous legislation on substances of human origin. Organ donation must be always a free gift and protected from any linkage to possible commercialization. Moreover, donation and transplantation systems are based on altruism. To foster the quality of transplantation process, rapporteur proposes some amendments related to the human dignity. Coming to the issue of consent, the freedom of choice as whether or not to donate an organ needs to be respected and protected as well, therefore its adjustment falls in the competence of Member States.

Introducing the compensation to the living donors should be seen strictly as making good the expenses directly related to the donation such as for example traveling fees, avoiding any financial incentives for potential donors. Moreover, the person who has suffered undue damage resulting from an intervention is entitled to fair compensation.
Traceability of organ from the donor to the recipient and vice versa represents one of the major safety concerns, for that reason concept of anonymity needs to be replaced by confidentiality in order to avoid any contradiction in terms. Rapporteur supported inclusion of the notion of sound data protection measures of donor and recipient into the proposal.
Sharing of best practices, models and expertise across the European Union has already proved useful in increasing organ donor rates. Cooperation should be fostered in order to identify successful elements of different transplantation systems and promote them on the European level, thus leading to the improvements in provision of high quality and safety of organ donation and transplantation.

Finally, the rapporteur proposes proportionate number of amendments reflecting concerns with regard to the definition of donor, competent authorities, post transplantation period and more precise wording in certain articles to improve the text. Rapporteur decided as well to include almost all proposals by JURI committee.

The draft report does not contain amendments to Article 25 and 26 of the proposal in order to align them to the system of implementing acts as introduced by the Treaty of Lisbon. These amendments will be tabled at a later stage.