CPME/AD/EC/030210/017_Final/EN

On 3 February 2010, CPME Executive Committee adopted the following statement “CPME Response to the Proposal for a "Directive of the European Parliament and of the Council of 8 December 2008 on standards of quality and safety of human organs intended for transplantation [COM (2008) 818]” (CPME 2010/017 Final EN)

Proposal for a "Directive of the European Parliament and of the Council of 8 December 2008 on standards of quality and safety of human organs intended for transplantation [COM (2008) 818]

PRELIMINARY REMARKS

With the draft Directive of the European Parliament and of the Council of 8 December 2008 on standards of quality and safety of human organs intended for transplantation [COM (2008) 818, final; Status: 08/12/2008) the European Parliament and Council aims to integrate harmonised regulations for the fields of "blood, blood products, cells, tissue and organs of human origin". In that respect, the present draft directive is to be evaluated in the context of the directives already existing, in particular the tissue directive 2004/23/EC and its implementing directives.

Against this background, the scope of validity of the present draft directive is of considerable significance. Since, in Article 2(2)(c), the tissue directive 2004/23/EC excludes from its scope of validity "organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body", consequently corresponding regulations concerning this field should be integrated into the draft directive, so that no loophole emerges, in particular in regard 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 for so-called complex tissue". Organs, parts of organs and complex tissue of human origin which are intended for transplant in a human being should therefore be subsumed under the term "organs" in the definitions of Article 3 of the draft directive.

Furthermore, when comparing it to the tissue directive 2004/23/EC it is noticeable that here the terms "procurement, processing and preservation" have been defined, whereas the present draft directive only defines the terms "procurement and preservation". Thus, considerable intermediate steps, such as the preparation, handling, packaging and transport of human organs are not defined, and, as a result, no regulation is applied. In order to close this loophole it is proposed to add the following to Art. 3(i) in the definition of "procurement": "accordingly the term … 'procurement' designates a co-ordinated process, by means of which organs are

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donated and made available", and supplement it with the following definition: "Making available [is] the preparation, handling, preservation, packaging and transport of human organs".

In delimiting the contents of the provision of the directive, the principle of subsidiarity pursuant to Art. 168(7) TFEU (Art. 152(5) EC, old) must be observed. The latter is in fact partially accounted for by the recital (19), in which it is established that: "However, depending especially on the repartition of 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." However, this principle of subsidiarity is only conditionally taken into account in the individual articles of the draft directive. According to the principle of subsidiarity, the definitions of Article 3 of the draft directive are, for example, to be adapted. For instance, it is defined in Article 3 that the "competent authority/authorities is/are one or more public or private non-profit-making competent office(s)/organisation(s)/institution(s) which is/are particularly concerned with implementing this directive". Furthermore, it is to be added that "procurement organisations" are one or more public or private non-profit-making office(s)/organisation(s)/institution(s) which is/are particularly concerned with the co-ordinated process of procuring and making available human organs". Corresponding follow-up amendments, for example in Article 18, are to be taken into consideration.

In light of the communalism of transplantation medicine successfully established over many years in some member states, these amendments are of crucial significance; retaining the previous formulations of the draft directive would, in some countries, have unnecessarily resulted in abandoning the proven and tested organisational structures.

Furthermore, the partially inappropriate provisions of Article 4 to the Standard Operation Procedures construed in detail also appear to cause concern: For instance, according to the specifications of Article 4 e) in conjunction with Article 8, it is to be feared that, for example, due to the enormous bureaucratic hurdles, the currently prevalent practice of transporting organs for transplantation purposes through airlines in scheduled flights can no longer be maintained. Consequently, a significant increase in the transportation costs, and thus the transplantation costs, is to be expected, without any substantial gain in quality and safety being discernible. To that extent, it is to be examined for which regulatory contents and in what degree of detail Standard Operation Procedures are necessary.

In addition, a precise translations of the (original) English text of the directive into other languages with conformity of all official language versions is being requested. When comparing key terms in different official translations, for example the tissue directive 2004/23/EC, it is noticeable that individual terms in the present draft directive have been translated with different technical terms; this leads to unnecessary ambiguities and difficulties in interpreting the legal concepts.

Amendment 1

Proposal for a Directive – Amending Act
Recital 2

Commission Proposal	*Proposed 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.

Grounds

The proposed directive determines the substantial requirements concerning the quality and safety of organ transplantation; the adjective "extensive" is out of place in the context. In addition, the meaning is not clear in relation to the risks associated with organ transplantation.

Amendment 2

Proposal for a Directive – Amending Act
Recital 6

Commission Proposal	*Proposed Amendment*
(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.	(6) There is therefore a need for common quality and safety standards for the procurement, transport and use of human organs at Community level, ***while adhering to the principle of subsidiarity pursuant to Art. 168(7) TFEU (Art. 152(5) EC, old)***. 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 ***acknowledged*** 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.

Grounds

Art. 168(7) TFEU determines that it is part of the Union's remit that the responsibility of the Member States for regulating its health policy, as well as for the organisation of the public health sector and health care, is maintained. Steps to lay down high quality and safety standards for organs do not affect regulations of the individual States concerning donation or the medical use of organs. As the terms "procurement" and "donation" partly overlap, it is absolutely necessary to point out the subsidiarity principle. Only recognised quality and safety standards reflect the status of medical science.

Amendment 3

Proposal for a Directive – Amending Act
Recital 7

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

Amendment 4

Proposal for a Directive – Amending Act
Recital 8

Commission Proposal	*Proposed Amendment*
(8) The conditions of procurement should be supervised by the Competent Authorities through the authorisation of identified procurement organisations. The authorization should assume that proper organisation, qualified staff and adequate facilities and material are in place.	(8) The ***conditions of procurement of human organs*** should be supervised by the ***competent offices/institutions/organisations*** **by** ***appointing suitable institutions***. ***In that respect, it should be ensured that a suitable institution with qualified personnel is appointed.***

Grounds

This formulation accommodates the structure established in some member states, and thus the principle of subsidiarity.

Amendment 5

Proposal for a Directive – Amending Act
Recital 11

Commission Proposal	*Proposed Amendment*
(11) Effective rules for the transportation of organs should be provided which minimises ischemic times and prevents organ damage. While maintaining medical confidentiality, the organ container should be clearly labelled and contain the necessary documentation.	(11) Effective rules ~~***for the transportation of organs***~~ should be provided ~~***minimises ischemic times and prevents organ damage***~~ ***in order to transport the organ with the necessary care***. While ~~***maintaining medical confidentiality***~~ ***observing data protection***, the organ container should be clearly labelled and contain the necessary documentation.

Grounds

The proposed formulation relies on necessary care in transportation, taking into account data protection, and thus contains a general principle which is to be observed when transporting organs.

Amendment 6

Proposal for a Directive – Amending Act
Recital 13

Commission Proposal	*Proposed 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. 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.	(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.***~~ ***Should the organ donor simultaneously be a tissue donor, it must be ensured that any unexpected serious reactions experienced*** ~~***An unexpected adverse reaction in by***~~ a~~***n organ***~~ donor or recipient ***of an organ*** should be traced by the competent authority and reported in the tissue vigilance system as provided for in that Directive.

Grounds

Recital 13 relies upon an organ donor who is simultaneously a tissue donor. In this case, the retracing system in accordance with Art. 10 of this proposal is to be harmonised with Art. 8 of the tissue directive 2004/23/EC in regard to the tissue vigilance system.

Amendment 7

Proposal for a Directive – Amending Act
Art. 1

Commission Proposal	*Proposed Amendment*

Subject Matter	***Aim***
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.	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.

Grounds

Article 1 regulates the aim, before Article 2 paraphrases the objective scope of validity in further detail.

Amendment 8

Proposal for a Directive – Amending Act
Art. 2

Commission Proposal	*Proposed Amendment*
Scope	**Scope**
1. This Directive applies to the donation, procurement, testing, characterisation, preservation, transport and transplantation of organs of human origin intended for transplantation. 2. However, where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.	1. This Directive applies to the donation, procurement, testing, characterisation, preservation, transport and transplantation of organs of human origin intended for transplantation. ***2. It also applies to parts of organs if they are supposed to be used for the same purpose as the whole organ in the human body, and to complex tissue.*** ***3***. However, where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.

Grounds

The reformulation supplements the scope of validity in Clause 2 in regard to Art. 2(2)(c) of the tissue directive and in addition takes complex tissue into consideration (e.g. the transplant of a

face or of limbs, such as hands or arms).

Amendment 9

Proposal for a Directive – Amending Act
Art. 3 (a)

Commission Proposal	*Proposed 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***~~, ***accreditation, authorisation, licensing or certification***, depending of the ***regulatory*** concepts used in each Member State;

Grounds

The reformulation is geared towards the concepts of the tissue directive 2004/23/EC and takes into consideration the various national regulatory concepts.

Amendment 10

Proposal for a Directive – Amending Act
Art. 3 (c)

Commission Proposal	*Proposed Amendment*
(c) 'donor' means every human source of organs, whether living or deceased ;	(c) 'donor' means every ~~**human source of organs**~~ ***person who functions as the source of human organs***, whether living or deceased ;

Grounds

With the reformulation, the "donor" is defined without resorting again to the term "organ donor". The definition is especially relevant in differentiating it from the term "procurement".

Amendment 11

Proposal for a Directive – Amending Act
Art. 3 (d)

Commission Proposal	*Proposed Amendment*
(d) 'donation' means donating human organs for transplantation;	(d) 'donation' means ~~***donating human organs for transplantation***~~ ***the provision of human organs intended for use with people***

Grounds

The proposed formulation defines the term "donation" without resorting again to this word.

Proposal for a Directive – Amending Act
Art. 3 (g)

Commission Proposal	*Proposed Amendment*
(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;	(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; ***as well as parts of organs, if they are supposed to be used for the same purpose as the whole organ in the human body, as well as complex tissue***;

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Grounds

With the draft Directive of the European Parliament and of the Council of 8 December 2008 on standards of quality and safety of human organs intended for transplantation [COM (2008) 818 final; Status: 08/12/2008) the European Parliament and Council aims to integrate harmonised regulations for the fields of "blood, blood products, cells, tissue and organs of human origin". Against this background, the scope of validity of the present draft directive is of considerable significance in the context of the rules and regulations already existing. Since, in Article 2(2)(c), the tissue directive 2004/23/EC excludes from its scope of validity "organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body", consequently corresponding regulations for this field should be integrated into the draft directive, so that no loophole emerges, in particular in regard 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 for so-called complex tissue", such as, for example, when transplanting a face or complete limbs, e.g. arms.

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Amendment 12

Proposal for a Directive – Amending Act
Art. 3 (i)

Commission Proposal	*Proposed Amendment*
(i) 'procurement' means a process by which the donated organs become available;	(i) 'procurement' means a ***coordinated*** process by which the donated organs become available; **(ii)** '***Becoming available*' *shall mean the preparation, handling, preservation, packaging and transport of human organs;***

Grounds

When comparing it to the tissue directive 2004/23/EC it is noticeable that here the terms "procurement, processing and preservation" have been defined, whereas the present draft directive only defines the terms "procurement and preservation". Thus, considerable intermediate steps, such as the preparation, handling, packaging and transport of human organs are not defined, and, as a result, no regulation is applied. In particular the procurement and preservation of human organs are defined through the definitions. These can be made available for transplantation, however only if they are allocated in the sense of the above-mentioned supplementary definition of "making available".

Amendment 13

Proposal for a Directive – Amending Act
Art. 3 (j)

Commission Proposal	*Proposed Amendment*
(j) "procurement organisation" means a health care establishment, a team or a unit	***(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;	~~***of a hospital or another body which is authorised by the competent authority to undertakes procurement of***~~ ***one or more public or private non-profit-making office(s)/organisation(s)/institution(s) which is/are in particular involved with the coordinated process of procuring and making available*** human organs ***the following new definition shall be added after (j):*** ***"(j1)*** '***competent authority***' ***shall mean one or more public or private non-profit-making competent office(s)/organisation(s)/institution(s) which is/are particularly concerned with implementing this directive;"***

Grounds

In delimiting the contents of the provision of the directive, the principle of subsidiarity pursuant to Art. 168(7) TFEU (Art. 152(5) EC, old) must be observed. The latter is in fact partially accounted for by Recital (19): "However, depending especially on the repartition of 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." According to this orientation, the definitions of Article 3 of the draft directive are to be adapted. Follow-up amendments, for example in Article 18, are to be taken into consideration.

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COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Amendment 14

Proposal for a Directive – Amending Act
Art. 3 (k)

Commission Proposal	*Proposed Amendment*
(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;	*(k)* 'preservation' means the use of chemical agents, alterations in environmental conditions or other means during ***~~processing~~ the time that they are made available*** to prevent or retard biological or physical deterioration of human organs from the procurement until the transplantation;

Grounds

The addition is a follow-up regulation based on the supplemented definition of "making available" (cf. amendment to Art. 3(i)).

Amendment 15

Proposal for a Directive – Amending Act
Art. 3 (m)

Commission Proposal	*Proposed Amendment*
(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;	(m) 'serious adverse event' means any ***undesired and*** unexpected occurrence associated with ***~~any stage of the chain from donation to transplantation~~ the procurement, preservation and making available of organs*** that might lead to the ***~~transmission of a communicable disease~~ the transmission of an infectious disease,*** to death, or ***~~life-threatening~~ a life-threatening condition, or a*** disabling condition ***~~or incapacitating conditions for patients or which results in, or prolongs,~~***

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	~~hospitalisation or morbidity;~~for donors or recipients, making a stay in hospital necessary or lead to any other illness, in so far as it is not side effects of immunosuppression that are concerned;

Grounds

The definition of the serious unexpected incident is construed to the extent that a cumulation of messages would inevitably occur, without their being relevant to quality or safety. Therefore, the definition in the above sense should define the term somewhat more narrowly.

Amendment 16

Proposal for a Directive – Amending Act
Art. 3 (n)

Commission Proposal	*Proposed Amendment*
(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;	*(n)* 'serious adverse reaction' means an unintended ***serious*** response, including a communicable disease, in the donor or in the recipient associated with ***~~any~~*** ***~~stage of the chain from donation~~ the donation, procurement, preservation or making available of an organ*** to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or **unexpected** morbidity; ***excepted therefrom shall be side effects of immunosuppression****;*

Grounds

The definition of the serious undesired reaction is construed to the extent that a cumulation of messages would inevitably occur, without their being relevant to quality or safety. Therefore, the definition in the above sense should define the term somewhat more narrowly.

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Amendment 17

Proposal for a Directive – Amending Act
Art. 3 (p)

Commission Proposal	*Proposed Amendment*
(p) 'transplantation' means the process of restoring certain functions of the human body by transferring equivalent organs to a recipient.;	(p) 'transplantation' means the process of restoring certain functions of the human body by transferring ~~***equivalent***~~ ***human*** organs to a recipient.;

Grounds

Clarification of the term "transplantation".

Amendment 18

Proposal for a Directive – Amending Act
Art. 3 (r)

Commission Proposal	*Proposed 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	(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;	~~***transplantation centre(s)***~~ ~~***– locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;***~~

Grounds

The reformulation contains a clear proposal for the term "traceability" and abandons specification of the regulation in the directive (Art. 10).

Amendment 19

Proposal for a Directive – Amending Act
Art. 5 par. 1

Commission Proposal	*Proposed Amendment*
Member States shall ensure that the procurement takes place in procurement organisations that comply with the rules laid down in this Directive.	Member States shall ensure that the procurement ***and making available*** takes place in ~~***procurement***~~ ~~***organisations***~~ ***one or more public or private non-profit-making competent office(s)/organisation(s)/institution(s)*** that comply with the rules laid down in this Directive.

Grounds

It concerns a follow-up regulation in regard to the official term and the making available of organs.

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Amendment 20

Proposal for a Directive – Amending Act
Art. 6 par. 2

Commission Proposal	*Proposed Amendment*
Member States shall ensure that procurement takes place in dedicated facilities,	Member States shall ensure that ***~~procurement~~ the donation*** takes place ***~~in dedicated~~ at suitable*** facilities,
which are designed, constructed, maintained and operated so as to comply with the	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	requirements laid down in this Directive and which allow minimising bacterial or
other contamination of procured human organs in accordance with best medical	other contamination of procured human organs in accordance with best medical
practices.	practices. ***These institutions shall satisfy the required standard for operating theatres.***

Grounds

Clarifying formulation.

Amendment 21

Proposal for a Directive – Amending Act
Art. 8

Commission Proposal	*Proposed Amendment*
Member States shall ensure that the following requirements are met:	Member States shall ensure that the following requirements are met:
(a) the organisations, bodies or companies involved in the transportation of organs	(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	***~~have appropriate standard operating procedures in place to ensure the integrity of the~~***

organ during transport and that transport time is minimised. (b)the shipping containers used for transporting organs are labelled with the following information: – identification of the procurement organisation, including its address and telephone number; – identification of the transplantation centre of destination, including address and telephone number; – a statement that the package contains a human organ and marked HANDLE WITH CARE; – recommended transport conditions, including instructions for keeping the container at a certain temperature and in a certain position – safety instructions and method of cooling (when applicable). However point (b) shall not apply where the transportation is carried out within the same establishment	~~***organ during transport and that transport time is minimised.***~~ ***shall ensure that the organ is transported with the necessary care;*** (b)the shipping containers used for transporting organs are labelled with the following information: – identification of the procurement organisation, ***and of the donating hospital*** including its address and telephone number; – identification of the transplantation centre of destination, including address and telephone number; – a statement that the package contains a human organ and marked HANDLE WITH CARE; ~~***– recommended transport conditions, including instructions for keeping***~~ ~~***the container at a certain temperature and in a certain position***~~ ~~***– safety instructions and method of cooling (when applicable).***~~ ~~***However point (b) shall not apply where the transportation is carried out within the same***~~ ~~***establishment***~~

Grounds

The proposed amendments accommodate the quality and safety requirements and take the specific requirements concerning organ transplantation into consideration.

Amendment 22

Proposal for a Directive – Amending Act
Art. 9 par. 2

Commission Proposal	*Proposed Amendment*
The Competent authority shall indicate in the accreditation, designation, authorisation or licence which activities the transplantation centre concerned may undertake.	The Competent authority shall indicate in the ***~~accreditation, designation~~***, authorisation ***~~or licence~~*** which activities the transplantation centre concerned may undertake.

Grounds

Follow-up amendment to the proposal concerning Art. 3(a).

Amendment 23

Proposal for a Directive – Amending Act
Art. 11

Commission Proposal	*Proposed Amendment*
Reporting systems for serious adverse events and reactions 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. 2. Member States shall ensure that a procedure is in place to enable the rapid recall of	**Reporting systems for *unexpected* serious adverse events and reactions** 1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning ***unexpected*** 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. 2. Member States shall ensure that a procedure is in place to enable ***~~the rapid recall of~~ immediately informing the***

any organ which may be related to a serious adverse event or reaction as specified in the national quality programme. 3. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the reporting system established in accordance with Article 11 of Directive 2004/23/EC.	***recipient of*** any organ which may be related to a serious adverse event or reaction as specified in the national quality programme. 3. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the reporting system established in accordance with Article 11 of Directive 2004/23/EC.

Grounds

The proposed amendments accommodate the quality and safety requirements and take the specific requirements concerning organ transplantation into consideration; this in particular concerns the use of the term "recalling".

Amendment 24

Proposal for a Directive – Amending Act
Art. 13

Commission Proposal	*Proposed Amendment*
Principles governing organ donation	**Principles governing organ donation**
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.
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.	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.~~ shall prohibit the offering or making available of human organs for the purpose of financial gain or offering or achieving comparable benefits.***
3. Member States shall ensure that the procurement of organs is carried out on a nonprofit basis.	3. Member States shall ensure that the procurement of organs is ***~~carried out on a nonprofit basis~~***. ***not procured***

	commercially.

Grounds

The proposals shall eliminate any trading with organs and ensure altruism when donating organs.

Amendment 25

Proposal for a Directive – Amending Act
Art. 15 par. 2

Commission Proposal	*Proposed Amendment*
Member States shall ensure that living donors are selected on the basis of their health	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	and medical history, including a psychological evaluation if deemed necessary, by
qualified and trained professionals. Such assessments may provide for the exclusion	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	of persons whose donation could present a health risk to others, such as the
possibility of transmitting diseases, or a serious risk to themselves.	possibility of transmitting diseases, or a serious risk to themselves. ***The Member States shall also guarantee that the live donor is secured by insurance.***

Grounds

The live donor is especially protected by insurance being secured. Through the altruistic donation, a live donor is exposed to a considerable health risk, which should also be limited by such a measure.

Amendment 26

Proposal for a Directive – Amending Act
Art. 17

Commission Proposal	*Proposed Amendment*
Anonymisation of donors and recipients	***~~Anonymisation~~ Data protection and confidentiality* of donors and recipients**
Member States shall take all necessary measures to ensure that all personal data of donors and	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.	recipients ***~~processed within the scope of this Directive~~ recorded and processed within the scope of this directive to which third parties have access*** are rendered anonymous ***~~so that neither~~*** ***~~donors nor recipients remain identifiable.~~ or pseudonymised, so that the protection of the donor and recipient are ensured***.

Grounds

The terms "traceability" and "anonymisation" used in the proposal contradict one another. In this respect it is recommended to amend the formulations to conform to the relevant data protection guidelines; to that extent, we make reference to the response of the European Data Protection Supervisor concerning the proposed directive (Official Journal of the EU of 15/08/2009, C 192, p. 6 et seq.).

Amendment 27

Proposal for a Directive – Amending Act
Art. 18 (before (a))

Commission Proposal	*Proposed Amendment*
Designation and tasks of competent authorities	**Designation and tasks of competent authorities**
Member States shall designate the competent authority, or authorities (hereafter competent authority), responsible for implementing the requirements of this Directive. The competent authorities shall, in particular, take the following measures**:**[…]	Member States shall designate the ***~~competent authority, or authorities~~ public or private non-profit-making competent office(s)/organisation(s)/institution(s) which is/are particularly concerned with implementing the provisions of this directive as ~~(hereafter competent authority)~~***, responsible for implementing the requirements of this Directive. The competent ***authority/authorities and institution(s)*** shall, in particular, take the following measures**:**[…]

Grounds

Follow-up regulations; concerning the further grounds, cf. in particular Amendments to Recital 8 and Art. 3 (new).

Amendment 28

Proposal for a Directive – Amending Act
Art. 19

Commission Proposal	*Proposed Amendment*
Registers and reports concerning procurement organisations and transplantation centres	**Registers and reports concerning procurement organisations and transplantation centres**
1. Member States shall ensure that the competent authority: (a) keeps a record of the activities of procurement organisations and transplantation centres, including aggregated and anonymised numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in line with provisions on the protection of personal data and statistical confidentiality; (b) draws up and makes publicly accessible an annual report on those activities; (c) establishes and maintains a register of procurement organisations and transplantation centres.	1. Member States shall ensure that the competent ***~~authority~~ office(s), organisation(s) and/or institution(s)*** : (a) keeps a record of the activities of procurement organisations and transplantation centres, including aggregated and anonymised numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in line with provisions on the protection of personal data and statistical confidentiality; (b) draws up and makes publicly accessible an annual report on those activities; (c) establishes and maintains a register of ***~~procurement organisations~~ public health institutions, teams or hospital departments or any other institutions which are approved for the procurement of human organs*** and transplantation centres.
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 .	2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of ***~~procurement organizations~~ public health institutions, teams or hospital departments or any other institutions which are approved for the procurement of human organs***

	and transplantation centers .

Grounds

It concerns clarifying provisions, which take the various national organisational models of the public health sector into account.

Amendment 29

Proposal for a Directive – Amending Act
Art. 20

Commission Proposal	*Proposed Amendment*
Exchange of information	**Exchange of information**
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.	1. The Commission shall set up a network of the competent ***~~authorities~~ office(s), organisation(s) and/or institution(s)*** with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.
2. Where appropriate, experts on organ transplantation, representatives from European organ exchange organisations, as well as data protection supervisory authorities and other relevant parties may be associated to this network.	2. Where appropriate, experts on organ transplantation, representatives from European organ exchange organizations, as well as data protection supervisory authorities and other relevant parties may be associated to this network.

Grounds

Follow-up amendment concerning the amendment of Article 19(1).

Amendment 30

Proposal for a Directive – Amending Act
Art. 21

Commission Proposal	*Proposed Amendment*
Exchange of organs with third countries	**Exchange of organs with third countries**
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 authorized by the competent authority.
2. Authorisations for exchanges of organs, as referred to in paragraph 1, shall only be granted if the organs: (a) can be traced from the donor to the recipient and vice versa; (b) meet quality and safety requirements equivalent to the ones laid down in this Directive.	***2. The granting of the approval for the exchange of organs with non-EU countries may be transferred by the Member States to European organ exchange organisations.*** ***3***. Authorizations for exchanges of organs, as referred to in paragraph 1, shall only be granted if the organs: (a) can be traced from the donor to the recipient and vice versa; (b) meet quality and safety requirements equivalent to the ones laid down in this Directive.

Grounds

The existing organisational and proven and tested system of organ transplantation, which also stipulates an exchange of organs with non-EU countries, should be preserved. At the same time, not every exchange of organs with non-EU countries should be subject to official approval, but rather the exchange of organs with a particular non-EU country in general. This can, in individual cases, also be transferred to a European organ exchange organisation (Clause 2).

Amendment 31

Proposal for a Directive – Amending Act
Art. 25

Commission Proposal	*Proposed Amendment*
Implementing measures	**Implementing measures**
1. Detailed rules for the following measures shall be adopted in accordance with the procedure referred to in Article 26(3):	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 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. 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): (a) the interconnection between the reporting systems on adverse events and reactions referred to in Article 11 (3); (b) the establishment and functioning of the network of the competent authorities referred to in Article 20.	(a) rules for the updating and transmission of information on human organs ***and donors*** characterization as detailed in the Annex; (b) procedures for ensuring the full traceability of organs, including labeling requirements; (c) procedures for ensuring the reporting of ***unexpected*** serious adverse events and reactions. 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): (a) the interconnection between the reporting systems on ***unexpected*** adverse events and reactions referred to in Article 11 (3); (b) the establishment and ~~***functioning***~~ ***functional capability*** of the network of the competent authorities referred to in Article 20.

Grounds

The additions take into account the connection between the characterisation of human organs and donors (1a) as well as the definition pursuant to Art. 3(m) and (n) of the proposed directive (1c, 2a and b).

Amendment 32

Proposal for a Directive – Amending Act
On Annex 1

Commission Proposal	*Proposed Amendment*
ORGAN AND DONOR CHARACTERISATION 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	**ORGAN AND DONOR CHARACTERISATION** For the purpose of Article 7 the following information shall be gathered by the procurement organisation or procurement team ***while making an appraisal of all the individual circumstances*** on the

necessary and processed in line with the legal requirements on the protection of personal data and confidentiality:	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***. In the event of any data being missing, a decision is to be made on the transplant in accordance with an individual risk examination of the donor and the recipient.***

Grounds

The supplementary formulation takes into account that not all the information and data which is stipulated in accordance with the Appendix on organ and donor characterisation is always available or can be procured. This may, in individual cases, not lead to a transplant therefore not being possible. Should the addition not be taken into consideration, this would reduce the number of donor organs further.