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**(Ordinary legislative procedure: second reading)**

*The European Parliament,*

- having regard to the Council position at first reading (16627/1/2009 – C7-0051/2010),
  - having regard to the Commission proposal to Parliament and the Council (COM(2009)0067),
  - having regard to Article 251(2) and Article 63, first paragraph, point (2)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0070/2009),
  - having regard to its position at first reading<sup>1</sup>,
  - having regard to the Commission Communication to 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(7) and Article 78(2) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 72 of its Rules of Procedure,
  - having regard to the recommendation for second reading of the Committee on Civil Liberties, Justice and Home Affairs (A7-0117/2010),
1. Approves the Council's position;
  2. Notes that the act is adopted in accordance with the position;
  3. Instructs its President to sign the act with the President of the Council pursuant to Article 297(1) of the Treaty on the Functioning of the European Union;
  4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the Official Journal of the European Union;

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<sup>1</sup> Texts adopted, 7.5.2009, P6\_TA(2009)0375.

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

**Labelling and standard product information of the consumption of energy and other resources by energy-related products (recast) \*\*\*II**

**European Parliament legislative resolution of 19 May 2010 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products (recast) (05247/1/2010 – C7-0094/2010 – 2008/0222(COD))**

**(Ordinary legislative procedure: second reading)**

*The European Parliament,*

- having regard to the Council position at first reading (05247/1/2010 – C7-0094/2010),
- having regard to the Commission proposal to Parliament and the Council (COM(2008)0778),
- having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0412/2008),
- having regard to the Commission Communication to 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) and the addendum thereto (COM(2010)0147),
- having regard to Article 294(7) and Article 194(2) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
- having regard to its position at first reading<sup>1</sup>,
- having regard to the opinion of the European Economic and Social Committee of 24 March 2009<sup>2</sup>,
- after consulting the Committee of the Regions,
- having regard to Rules 72 and 37 of its Rules of Procedure,
- having regard to the recommendation for second reading of the Committee on Industry, Research and Energy (A7-0128/2010),

1. Approves the Council position;
2. Approves the joint statement by Parliament, the Council and the Commission annexed to

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<sup>1</sup> Texts adopted, 5.5.2009, P6\_TA(2009)0345.

<sup>2</sup> OJ C 228, 22.9.2009, p. 90.

this resolution;

3. Takes note of the Commission statements annexed to this resolution;
4. Notes that the act is adopted in accordance with the Council position;
5. Instructs its President to sign the act with the President of the Council pursuant to Article 297(1) of the Treaty on the Functioning of the European Union;
6. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed and, in agreement with the Secretary-General of the Council, to arrange for its publication in the Official Journal of the European Union;
7. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

## Statements

### **concerning Directive 2010/30/EU of the European Parliament and of the Council of 19 May 2010 on the indication by labelling and standard product information of the consumption of energy and other resources by energy-related products (recast)**

#### **Statement by the European Parliament, the Council and the Commission on Article 290 TFEU**

"The European Parliament, the Council and the Commission declare that the provisions of Directive 2010/30/EU shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions."

#### **Commission statements on certain provisions of Directive 2010/30/EU**

##### **Art. 1 (2)**

"When setting out the priority list of energy-related products referred to in Recital 7, the Commission will give due attention also to energy-related construction products, taking into account in particular the potential energy savings that could be achieved through the labelling of some of those products, given that buildings account for 40 % of total energy consumption in the EU."

##### **Art. 10**

"When preparing delegated acts under Directive 2010/30/EU, the Commission shall ensure that overlapping legislation is avoided and that overall consistency in the EU-legislation on products is maintained."

##### **Art. 10 (4)(d)**

Significant proportion of products for the review of label classification

"The Commission considers that the proportion of products in the two highest energy efficiency classes is considered to be significant when it can be estimated that

- either the number of models available on the internal market which achieve class A+++ or A++ is about one third or more of the total number of relevant models available,
- or the share of the annual sales of products in the internal market which achieve class A+++ or A++ is about one third or more,
- or both."

#### **Commission statement on consumer information**

"The Commission supports the use of Union instruments such as the Intelligent Energy-Europe Programme to contribute to:

- initiatives that raise end-users' awareness on the benefits of energy labelling
- initiatives that monitor the market evolution and the technological development leading to more energy efficient products, in particular by identifying the best performing models in the various product groups and making the information available to all interested parties, such as

consumer organisations, industry and environmental NGOs with the view of large dissemination towards consumers.

Such monitoring could also serve as an indicator for the review of Labelling and/or Ecodesign measures under Directives 2010/30/EU and 2009/125/EC."

**Commission statement on recess periods**

"The European Commission takes note that except in cases where the legislative act provides for an urgency procedure, the European Parliament and the Council consider that the notification of delegated acts shall take into account the periods of recess of the institutions (winter, summer and European elections), in order to ensure that the European Parliament and the Council are able to exercise their prerogatives within the time limits laid down in the relevant legislative acts, and is ready to act accordingly."

## **P7\_TA-PROV(2010)0179**

### **Amending budget No 1/2010: Section I - Parliament**

#### **European Parliament resolution of 19 May 2010 on the Council's position on Draft amending budget No 1/2010 of the European Union for the financial year 2010, Section I – European Parliament (09807/2010 – C7-0125/2010 – 2010/2045(BUD))**

*The European Parliament,*

- having regard to the Treaty on the Functioning of the European Union and in particular Article 314 thereof,
  - having regard to Council Decision 2007/436/EC, Euratom of 7 June 2007 on the system of the European Communities' own resources<sup>1</sup>,
  - having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>2</sup>,
  - having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management<sup>3</sup>, and in particular the Multiannual Financial Framework (MFF) provided for in Part I thereof and set out in Annex I thereto,
  - having regard to the general budget of the European Union for the financial year 2010, as finally adopted on 17 December 2009<sup>4</sup>,
  - having regard to the draft estimates adopted by Parliament on 25 February 2010<sup>5</sup>,
  - having regard to Draft amending budget No 1/2010 drawn up by the Commission on 19 March 2010 (COM(2010)0107),
  - having regard to the Council's position on Draft amending budget No 1/2010 established on 18 May 2010 (09807/2010),
  - having regard to Rules 75b and 75e of its Rules of Procedure,
  - having regard to the report of the Committee on Budgets (A7-0158/2010),
- A. whereas it was agreed, during the 2010 budget procedure, that any expenditure related specifically to the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community would be dealt with, if necessary, through existing budgetary instruments, such as an amending budget, after the adoption of the original 2010 budget,

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<sup>1</sup> OJ L 163, 23.6.2007, p. 17.

<sup>2</sup> OJ L 248, 16.9.2002, p. 1.

<sup>3</sup> OJ C 139, 14.6.2006, p. 1.

<sup>4</sup> OJ L 64, 12.3.2010.

<sup>5</sup> P7\_TA(2010)0038.

- B. whereas it was emphasised that, in such a case and to the fullest possible extent, reorganisation of existing resources should be fully examined before any call for additional resources was made,
- C. whereas it was particularly stressed that the adopted original level of its budget amounting to 19,87 % of the authorised expenditure under heading 5 (administrative appropriations) of the MFF did not include any adaptations in the light of the Treaty of Lisbon, particularly in the legislative area,
- D. whereas, at the same time, it was acknowledged that, due to the limited margins available, further savings and redeployment would be required to enable additional requirements to be fulfilled,
1. Welcomes the Commission's Draft amending budget No 1/2010, drawn up in full conformity with the Parliament's estimates of 25 February 2010;
  2. Notes the Council's position of 18 May 2010, approving the proposal without amendment, in full respect of the Gentlemen's Agreement;
  3. Emphasises that an extensive political debate and analysis of the measures put forward already took place during the estimates stage in January and February 2010;
  4. Approves Council's position on Draft amending budget No 1/2010 without amendment and instructs its President to declare that Amending budget No 1/2010 has been definitely adopted and arrange for its publication in the Official Journal of the European Union;
  5. Instructs its President to forward this resolution to the Council and the Commission.

## P7\_TA-PROV(2010)0180

### 2008 discharge: Council

#### European Parliament decision of 19 May 2010 on discharge in respect of the implementation of the European Union general budget for the financial year 2008, Section II – Council (C7-0174/2009 – 2009/2070(DEC))

*The European Parliament,*

- having regard to the European Union general budget for the financial year 2008<sup>1</sup>,
- having regard to the final annual accounts of the European Communities for the financial year 2008 – Volume I (C7-0174/2009)<sup>2</sup>,
- having regard to the Council's annual report to the discharge authority on internal audits carried out in 2008,
- having regard to the Annual Report of the Court of Auditors on the implementation of the budget concerning the financial year 2008, together with the institutions' replies<sup>3</sup>,
- having regard to the statement of assurance as to the reliability of the accounts and the legality and regularity of the underlying transactions provided by the Court of Auditors pursuant to Article 248 of the EC Treaty<sup>4</sup>,
- having regard to Article 272(10) and Articles 274, 275 and 276 of the EC Treaty and Article 314(10) and Articles 317, 318 and 319 of the Treaty on the Functioning of the European Union,
- having regard to Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>5</sup>, and in particular Articles 50, 86, 145, 146 and 147 thereof,
- having regard to Decision No 190/2003 of the Secretary-General of the Council/High-Representative for the Common Foreign and Security Policy concerning reimbursement of travel expenses of delegates of Council Members<sup>6</sup>,
- having regard to the Interinstitutional Agreement between the European Parliament, the Council and the Commission, of 17 May 2006, on budgetary discipline and sound financial management<sup>7</sup>,
- having regard to Rule 77 of, and Annex VI to, its Rules of Procedure,

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<sup>1</sup> OJ L 71, 14.3.2008.

<sup>2</sup> OJ C 273, 13.11.2009, p. 1.

<sup>3</sup> OJ C 269, 10.11.2009, p. 1.

<sup>4</sup> OJ C 273, 13.11.2009, p. 122.

<sup>5</sup> OJ L 248, 16.9.2002, p. 1.

<sup>6</sup> Decision stemming from the Rules of Procedure of the Council of 22 July 2002 (OJ L 230, 28.8.2002, p. 7).

<sup>7</sup> OJ C 139, 14.6.2006, p. 1.

- having regard to the report of the Committee on Budgetary Control (A7-0096/2010),
- 1. Grants discharge to the Secretary-General of the Council in respect of the implementation of the Council's budget for the financial year 2008;
- 2. Sets out its observations in the resolution <sup>\*</sup> that forms an integral part of its Decision on discharge in respect of the implementation of the European Union general budget for the financial year 2008, Section II – Council;
- 3. Instructs its President to forward this Decision and the resolution that forms an integral part of it to the Council, the Commission, the Court of Justice of the European Union, the Court of Auditors, the European Ombudsman and the European Data Protection Supervisor, and to arrange for their publication in the Official Journal of the European Union (L series).

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<sup>\*</sup> In accordance with Article 5(3) of Annex VI to the Rules of Procedure, Parliament's vote on the resolution with observations is postponed to a later date.

## **P7\_TA-PROV(2010)0181**

### **Standards of quality and safety of human organs intended for transplantation \*\*\*I**

**European Parliament legislative resolution of 19 May 2010 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 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 Commission Communication to 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 the opinion of 10 June 2009 of the European Economic and Social Committee<sup>1</sup>,
  - after consulting the Committee of Regions,
  - 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 (A7-0106/2009),
1. Adopts the position at first reading hereinafter set out;
  2. Approves the statement of the European Parliament, the Council and the Commission and takes note of the Commission statement annexed hereto, which will be published in the *Official Journal of the European Union* together with the final legislative act;
  3. 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;
  4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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<sup>1</sup> OJ C 306, 16.12.2009, p. 64.

**Position of the European Parliament adopted at first reading on 19 May 2010 with a view to the adoption of Directive 2010/.../EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

After consulting the Committee of the Regions,

Having regard to the opinion of the European Data Protection Supervisor<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure<sup>3</sup>,

Whereas:

- (1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.
- (2) Risks however are associated with the use of organs in transplantation. The extensive therapeutic use of human organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. ***Well organized national and international transplant systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs in patients.***
- (3) In addition the availability of organs of human origin used for therapeutic purposes is dependent on ■ citizens ***of the Union*** being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.
- (4) Every year organs are exchanged between Member States. The exchange of organs is an important way of expanding the pool of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients

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<sup>1</sup> OJ C 306, 16.12.2009, p. 64.

<sup>2</sup> OJ C 192, 15.8.2009, p. 6.

<sup>3</sup> Position of the European Parliament of 19 May 2010.

requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.

- (5) However, the transplantation process is carried out by hospitals or professionals falling under different jurisdictions and there are significant differences in quality and safety requirements between Member States.
- (6) There is therefore a need for common quality and safety standards for the procurement, transport and use of human organs at **Union** 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. **Union** legislation should ensure that human organs comply with **recognised** standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.
- (7) *Unacceptable practices in organ donation and transplantation include trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs, which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This Directive, although having as its first objective the safety and quality of organs, will indirectly contribute to combating organ trafficking through the establishment of competent authorities, the authorisation of transplantation centres, the establishment of conditions of procurement and systems of traceability.*
- (8) *According to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the measures adopted under paragraph 4(a) of the same Article shall not affect national provisions on the medical use of organs and therefore the surgical act of transplantation itself. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include in the scope of this Directive certain provisions concerning the transplantation process and, in particular, provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.*
- (9) In order to reduce the risks and maximise the benefits of the transplantation process, Member States need to operate an effective **framework for quality and safety**. This **framework** should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the **health care** personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The **framework for quality and safety** should include auditing where necessary. Member States should be able to delegate **the performance of activities provided for under the framework for quality and safety to specific bodies deemed appropriate under national provisions, including** European organ exchange organisations.
- (10) The conditions of procurement should be supervised by the Competent Authorities through the authorisation of identified procurement organisations. The authorisation should assume that proper organisation, qualified **or trained and competent** staff and adequate facilities and material are in place.
- (11) The risk-benefit ratio is a fundamental approach to organ transplantation. Owing to the shortage of organs and the inherent life threatening nature **of diseases leading to the need** of organ transplants, the overall benefits of organ transplantation are high and more risks

are accepted than with blood or most tissues and cell-based treatments. The clinician plays an important role in this context by deciding whether or not organs are suitable for transplantation; therefore this Directive *sets out* the information required to make this assessment.

- (12) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient. Information *from medical history, physical examination, and complementary tests* should be collected for *the adequate* characterisation of the organ and the donor. *To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, whenever necessary and appropriate, with the relatives of the deceased donor. This is due to the time constraints of the process of deceased donation which reduce the ability of ruling out potentially serious transmissible diseases. During this interview, the medical team should properly inform them on the potential risks and consequences of donation and transplantation.*
- (13) *The shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation makes it necessary to take into account those situations in which the transplantation team lacks some of the information required for donor and organ characterisation as set out in Part A of the Annex, which specifies a minimum mandatory data set of information. In those particular cases, the medical team shall assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Therefore, if a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, such organ may be considered for transplantation where the non-transplantation may pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set of information, will allow performing a more detailed organ and donor characterisation.*
- (14) Effective rules for the transportation of organs should be provided which *optimises* ischemic times and *reduces* organ damage. While maintaining medical confidentiality, the organ container should be clearly labelled and contain the necessary documentation.
- (15) The transplant system must ensure traceability of organs from donation to reception. The system must have the capacity to raise the alert if there is any unexpected complication. A system should therefore be put in place to detect and investigate serious adverse events or reactions, for the protection of vital interest of the individuals concerned.
- (16) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing *Union* system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>1</sup>. *This does not necessarily mean that both systems should be electronically linked.* 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.

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<sup>1</sup> OJ L 102, 7.4.2004, p. 48.

- (17) **Healthcare** personnel directly involved in the donation, testing, **characterisation, procurement**, preservation, transport and transplantation of human organs should be **suitably qualified or trained and competent**. **The importance of donor coordinators, being appointed at hospital level, has been acknowledged by the Council of Europe. The role of the donor coordinator or coordination team should be recognised as a key figure for improving, not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted.**
- (18) As a general principle, exchange of organs from/to third countries should be supervised by the Competent Authority. Authorisation should be granted only if standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account.
- (19) **Altruism is an important factor in organ donations. To ensure organs quality and safety**, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation. **This is essential, since the violation of these principles might be associated with unacceptable risks. When donation is not voluntary and/or foresees financial gain, the quality of the process of donation can be jeopardised, since improving the quality of life or saving the life of a person is not the main and /or the unique objective to be achieved. Even if the process is developed in accordance with appropriate quality standards, the clinical history obtained either from the potential living donor or the relatives of the potential deceased donor might not be accurate enough in terms of conditions and/or diseases potentially transmissible from donor to recipient when the former are seeking financial gain or are subjected to any kind of coercion. This would imply a safety problem for potential recipients since the medical team would have a limited capability for performing an appropriate risk assessment. The Charter of Fundamental Rights of the European Union should be recalled, notably its Article 3.2, third indent. This principle is also enshrined in Article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which many Member States have ratified. It is also reflected in the World Health Organization Guiding Principles, whereby the human body and its parts cannot be the subject of commercial transactions.**
- (20) **Other internationally recognized principles guiding practices in organ donation and transplantation include, inter alia, the certification or the confirmation of death according to national provisions before the procurement of organs from deceased persons and the allocation of organs based on transparent, non-discriminatory and scientific criteria. They should be recalled and be taken into account in the context of the Action Plan on Organ Donation and Transplantation.**
- (21) **Several models of consent to donation coexist in the Union, including opting-in systems in which consent to organ donation has to be explicitly obtained, and opting-out systems in which donation can take place if there is no evidence of any objection to donate. In order to express the individual decision in this regard, some Member States have developed specific registries where citizens record their wishes about donation. This Directive is without prejudice of the broad diversity of the systems of consent already in place in the Member States. In addition, by means of its Action plan on Organ Donation and Transplantation the Commission aims to increase public**

*awareness of organ donation and in particular to develop mechanisms to facilitate the identification of organ donors across Europe.*

- (22) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>1</sup> prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. ***In line with Directive 95/46/EC, it should be ensured that strict confidentiality rules and security measures are in place for the protection of the donors' and the recipients' personal data. Moreover, the competent authority may also consult with the national Data Protection Authority in relation to developing a framework for the transfer of organs data to and from third countries. As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa, without prejudice to legislation in force in Member States which, under specific conditions, might allow such information to be made available to donor or donors' families and organ recipients.***
- (23) ***Living donation coexists with deceased donation in most Member States. Living donation has been evolving along the years in a way that good results can be obtained even when there is no genetic relationship between donor and recipient.*** Living donor should ***be adequately evaluated*** to determine their suitability for donation in order to minimise the risk of transmission of diseases to the recipient. In addition living donors of organs face risks linked both to testing to ascertain their suitability as a donor and to the procedure to obtain the organ. Complications may be medical, surgical, social, financial or psychological. The level of risk very much depends on the type of organ to be donated. Therefore, living donations needs to be performed in a manner that minimizes the physical, psychological and social risk to the individual donor and the recipient and does not jeopardise the public's trust in the healthcare community. The potential living donor must be able to take an independent decision on the basis of all the relevant information<sup>2</sup> and should be informed in advance as to the purpose and nature of the donation, the consequences and risks. ***In this context, and to guarantee the respect for the principles governing donation, the highest possible protection of living donors should be ensured. It should also be noted that some Member States are signatories to the Convention on Human Rights and Biomedicine, and the additional protocol on Transplantation of Organs and Tissues of Human Origin of the Council of Europe. A complete information, a proper evaluation and an adequate follow-up are internationally recognised measures aimed to protect the living donors and they also contribute to ensure the quality and safety of the organs.***
- (24) 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 in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting***

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<sup>1</sup> OJ L 281, 23.11.1995, p. 31.

<sup>2</sup> Consensus Statement of the Amsterdam Forum on the care of living kidney donor and the Vancouver Forum, on the care of the non kidney living donor.

*serious adverse events and reactions, the collection of relevant post transplantation data would be needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such information between Member States would further allow improving the donation and transplantation process at European level.* 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<sup>1</sup>, 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 together to co-ordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, co-operation and efficiency.

- (25) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that these penalties are implemented. Those penalties must be effective, proportionate and dissuasive.

(26) *The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to adapt the Annex. The Commission should supplement or amend the minimum data set specified in Part A of the Annex in those exceptional situations where it is justified by a serious risk to human health and supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.*

(27) *The exchange of organs between Member States requires that uniform conditions on the procedures for the transmission of information on the organs and on characterisation of the donor, as well as for ensuring the traceability of the organs and reporting of serious adverse events and reactions, should be adopted by the Commission, in order to ensure the highest standards of quality and safety of the organs exchanged. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>2</sup> continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.*

(28) Since the objectives of this Directive, namely laying down quality and safety standards for human organs intended for transplantation, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at **Union** level, the **Union** may adopt measures, in accordance with the principle of

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<sup>1</sup> Rec(2006)15.

<sup>2</sup> *OJ L 184, 17.7.1999, p. 23.*

subsidiarity as set out in Article 5 of the Treaty *on European Union*. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER I SUBJECT MATTER, SCOPE AND DEFINITIONS

### Article 1 Subject Matter

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

### Article 2 Scope

1. This Directive applies to the donation, **■** testing, characterization, *procurement*, preservation, transport and transplantation of organs of human origin intended for transplantation.
2. **■** Where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.

### Article 3 Definitions

For the purposes of this Directive, the following definitions apply:

- (a) "authorisation" means authorisation, accreditation, designation, licensing *or registration*, depending *on* the concepts used *and the practices in place* in each Member State;
- (b) "*competent authority*" means *one (or more than one) authority, body, organisation and/or institution responsible for implementing the requirements of this Directive*;
- (c) "disposal" means the final placement of an organ when it is not used for transplantation;
- (d) "donor" means every *person who donates one or several* organs, whether *donation occurred during lifetime or after death*;
- (e) "donation" means donating human organs for transplantation;
- (f) "donor characterisation" means the collection of the relevant information on the characteristics of the donor needed *to evaluate his/her suitability for organ donation, in order* to undertake a proper risk assessment *and* minimize the risks for the recipient, and **■** optimize organ allocation;

- (g) "European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated **■** to ***national and*** cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the ***Union***;
- (h) "organ" means a differentiated **■** part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy. ***A part of an organ is also considered under this definition if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;***
- (i) "organ characterisation" means the collection of the relevant information on the characteristics of the organ needed ***to evaluate its suitability, in order*** to undertake a proper risk assessment ***and*** minimise the risks for the recipient, and **■** optimise organ allocation;
- (j) "procurement" means a process by which the donated organs become available;
- (k) "procurement organisation" means a healthcare establishment, a team or a unit of a hospital, ***a person, or any other*** body which ***undertakes or coordinates the procurement of human organs, and*** is authorised ***to do so*** by the competent authority ***under the regulatory framework used in that Member State;***
- (l) "preservation" means the use of chemical agents, alterations in environmental conditions or other means **■** to prevent or retard biological or physical deterioration of human organs from the procurement until the transplantation;
- (m) "recipient": means a person who receives a transplant of an organ;
- (n) "serious adverse event" means any ***undesired and*** 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;
- (o) "serious adverse reaction" means an unintended response, including a communicable disease, in the ***living*** donor or in the recipient ***that might be*** associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;
- (p) "**■** procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end ***outcome;***
- (q) "transplantation" means the process ***intended to restore*** certain functions of the human body by transferring ***an organ from a donor*** to a recipient;
- (r) "transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which ***undertakes the transplantation of human organs, and*** is authorised ***to do so*** by the competent authority ***under the regulatory framework used in that Member State;***
- (s) "traceability" means the ability **■** to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, ***including the ability*** 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.

## CHAPTER II THE QUALITY AND SAFETY OF ORGANS

### Article 4

#### *Framework for quality and safety*

1. Member States shall ensure that a *framework for quality and safety* is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive.
2. The *framework for quality and safety* shall provide for the adoption and implementation of:
  - (a) procedures for the verification of donor identity;
  - (b) procedures for the verification of the details of *the consent, authorisation or absence of any objection of the donor or donor family*, in accordance with national rules applying *where donation and procurement take place*;
  - (c) procedures for the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex;
  - (d) procedures for the procurement, preservation packaging and labelling of organs, in accordance with Articles 5, 6 and 8;
  - (e) *procedures* for the transportation of human organs in accordance with Article 8;
  - (f) *procedures needed* to ensure traceability, *in accordance with Article 10, guaranteeing compliance with* the legal requirements on the protection of personal data and confidentiality;
  - (g) *procedures for* the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1);
  - (h) *procedures for the management of serious adverse events and reactions* as referred in Article 11(2).

*The procedures referred to in points (f), (g) and (h) shall specify inter alia the responsibilities of procurement organizations, European organ exchange organisations and transplantation centres in this respect.*
3. *In addition*, the *framework for quality and safety* shall *ensure that the healthcare* personnel involved at all stages of the chain from donation to transplantation or disposal

*is suitably qualified or trained and competent*, and *shall* develop specific training programmes for *such* personnel ■ .

#### Article 5 Procurement organisations

1. Member States shall ensure that the procurement takes place in *or is carried out by* procurement organisations that comply with the rules laid down in this Directive.  
■
2. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

#### Article 6 Organ procurement

1. Member States shall ensure that medical activities in procurement organisations, such as donor selection *and evaluation*, are performed under the advice and the *guidance* of a medical doctor as defined in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications<sup>1</sup>.
2. Member States shall ensure that procurement takes place in *operating theatres*, which are designed, constructed, maintained and operated *in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured*.  
■
3. Member States shall ensure that procurement material and equipment are managed in accordance with relevant *Union, international and national regulations*, standards and guidelines covering the sterilisation ■ and medical devices. ■

#### Article 7 Organ and donor characterisation

1. Member States shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of the information *set out* in the Annex. ■

*Information specified in Part A of the Annex contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Annex contains a set of complementary information to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.*

2. *Notwithstanding paragraph 1, if according to a risk-benefit analysis in a particular case, including life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available.*

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<sup>1</sup> OJ L 255, 30.9.2005, p. 22.

3. *In order to meet the quality and safety requirements laid down in this Directive, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need to understand the consequences of donation. In the case of deceased donation, whenever possible and appropriate, the medical team shall endeavour to obtain such information from relatives or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of this information.*
4. The tests required for organ *and donor* characterisation shall be carried out by *laboratories having qualified or trained and competent personnel and adequate facilities and equipment.*
5. Member States shall ensure that organisations, bodies and ▯ laboratories involved in organ and donor characterisation have appropriate ▯ procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in *due* time.
6. *Where organs are exchanged between Member States, they shall ensure that the information on organ and donor characterisation, as detailed in the Annex, is transmitted to the other Member State with which the organ is exchanged in conformity with the procedures established by the Commission in accordance with Article 29.*

#### Article 8 Transport of organs

1. Member States shall ensure that the following requirements are met:
  - (a) the organisations, bodies or companies involved in the transportation of organs have appropriate ▯ procedures in place to ensure the integrity of the organs during transport and *a suitable* transport time ▯ ;
  - (b) the shipping containers used for transporting organs are labelled with the following information:
    - identification of the procurement organisation *and the donor's hospital*, including *their addresses* and telephone *numbers*,
    - identification of the transplantation centre of destination, including address and telephone number,
    - a statement that the package contains a human organ, *specifying the type of organ and its left or right location when applicable* and marked HANDLE WITH CARE,
    - recommended transport conditions, including instructions for keeping the container at *an appropriate* temperature and ▯ position.

▯  
However point (b) *need* not apply where the transportation is carried out within the same establishment;

- (c) *the organs transported are accompanied by the report on the donor and organ characterization.*

#### Article 9 Transplantation centres

1. Member States shall ensure that transplantation takes place in *or is carried out by* transplantation centres that comply with the rules laid down in this Directive.
2. The competent authority shall indicate in the ■ authorisation ■ which activities the transplantation centre concerned may undertake.
3. Transplantation centres shall verify before proceeding to transplantation that:
  - (a) the organ and donor characterisation is completed *and recorded* in accordance with *Article 7 and* the Annex ■ ;
  - (b) the ■ conditions of *preservation and* transport of shipped human organs have been maintained.
4. Member States shall, upon the request of the Commission or another Member State , provide information on the national requirements for the authorisation of transplantation centres.

#### Article 10 Traceability

1. Member States shall ensure that all organs procured, allocated *and transplanted* on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.
2. Member States shall ensure the implementation of a donor *and recipient* identification system that can identify each donation and each of the organs *and recipients* associated with it. *With regard to such system*, Member States shall ensure that *confidentiality and data security measures are in place in compliance with Union and national rules, as referred to in Article 16 of this Directive.*
3. Member States shall ensure that:
  - (a) the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal *and the information on organ and donor characterisation as set out in the Annex*, in accordance with the *framework for quality and safety*;
  - (b) data required for full traceability is kept for a minimum of 30 years after donation. Such data storage may be ■ in electronic form.
4. *Where organs are exchanged between Member States, they shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission in accordance with Article 29.*

## Article 11

### Reporting systems *and management* 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 ■ that may influence the quality and safety of human organs and which may be attributed to the ■ testing, *characterisation, procurement, preservation* and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.
2. Member States shall ensure that a procedure is in place *for the management of* serious adverse *events and reactions* as specified in the *framework for quality and safety*.
3. *In particular, and with regards to paragraphs 1 and 2, Member States shall ensure that procedures are in place for:*
  - (a) *the notification of any serious adverse event and reaction to the competent authority and to the concerned procurement or transplantation organisation in due time;*
  - (b) *the notification of the management measures with regards to serious adverse events and reactions to the competent authority in due time.*
4. *Where organs are exchanged between Member States, they shall ensure the reporting of serious adverse events and reactions in conformity with the procedures established by the Commission in accordance with Article 29.*
5. 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.

## Article 12

### Personnel

Member States shall ensure that *healthcare* personnel directly involved in the chain from donation to the transplantation or disposal of organs are *suitably qualified or trained and competent* to perform their tasks and are provided with the relevant training, as specified in the *framework for quality and safety*.

## CHAPTER III

### DONOR AND RECIPIENT PROTECTION *AND DONOR SELECTION AND EVALUATION*

## Article 13

### Principles governing organ donation

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

2. *The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of incomes related to the donation. For such cases, Member States shall define the conditions under which compensation may be granted, while avoiding any financial incentives or benefit for a potential donor.*
3. 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.
4. Member States shall ensure that the procurement of organs is carried out on a non-profit basis.

Article 14  
Consent requirements

*The procurement of human organs shall only be carried out after all consent or authorization requirements or requirements related to absence of any objection in force in the Member State concerned have been met.*

Article 15  
*Quality and safety aspects of living donation*

1. Member States shall take all necessary measures to ensure *the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.*
2. Member States shall ensure that living donors are selected on the basis of their health and medical history, by qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks.
3. Member States shall ensure that a register or record of the living donors is kept, in line with provisions on the protection of the personal data and statistical confidentiality.
4. *Member States shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report, and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.*

Article 16  
Protection of personal data, confidentiality and security of processing.

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

- (a) *the data processed are kept confidential and secure in accordance with Article 16 and 17 of Directive 95/46/EC. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible should be penalized according to Article 23 of this Directive;*
- (b) *donors and recipients whose data are being processed within the scope of this Directive are not identifiable, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identifications of donors or recipients possible with a view to tracing donors or recipients other than the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and national provisions implementing that Directive should be penalized according to Article 23 of this Directive;*
- (c) *the principles relating to data quality, as set out in Article 6 of Directive 95/46/EC are met.*



## CHAPTER IV OBLIGATIONS OF THE COMPETENT AUTHORITIES AND EXCHANGES OF INFORMATION

### Article 17

#### Designation and tasks of competent authorities

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

*Member States may delegate, or may allow a competent authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist a competent authority in carrying out its functions.*

The competent authorities shall, in particular, take the following measures:

- (a) put in place and keep updated a *framework for quality and safety* in accordance with Article 4;
- (b) ensure that procurement organisations and transplantations centres are controlled *or* audited on a regular basis to ascertain compliance with the requirements of this Directive;
- (c) grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres *or prohibit procurement organisations or transplantation centres to carry out their activities* if control measures demonstrate that such organisations or centres do not comply with the requirements of this Directive;
- (d) put in place a reporting *and management* system for *serious adverse events and/or reactions* as provided for in Article 11(1) and (2);

- (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, **which may include guidance for the collection of relevant post-transplant information to evaluate the quality and safety of the organs transplanted**;
- (f) participate **whenever possible**, in the **Union** network referred to in Article 19 and coordinate at national level input to the activities of the network;
- (g) supervise the exchanges of organs with other Member States and with third countries **as provided for in Article 20(1)**;
- (h) ensure **■** that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with **Union** provisions on the protection of personal data, in particular Directive 95/46/EC.

#### Article 18

#### **Records** 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 **■** 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 **an updated record** of procurement organisations and transplantation centres.
2. Member States shall, upon the request of the Commission or another Member State, provide information on the **record** of procurement organisations and transplantation centres.

#### Article 19

#### 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.
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.

### CHAPTER V EXCHANGES OF ORGANS WITH THIRD COUNTRIES AND EUROPEAN ORGAN EXCHANGE ORGANISATIONS

Article 20  
Exchange of organs with third countries

1. Member States shall ensure that **█** exchanges from or to third countries are *supervised* by the competent authority. *For this purpose, the competent authority and European organ exchange organisations may establish agreements with counterparts in third countries.*
2. *The supervision of organ exchanges with third countries may be delegated by the Member States to European organ exchange organisations.*
3. **█** Exchanges of organs, as referred to in paragraph 1, shall only be *allowed* 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.

Article 21  
European organ exchange organisations

Member States may establish *or may allow a competent authority to establish* agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in this Directive, delegating to them, *inter alia*:

- (a) the performance of activities provided for under the *framework for quality and safety*;
- (b) **█** specific tasks in relation to the exchanges of organs to and from Member States and third countries.

CHAPTER VI  
GENERAL PROVISIONS

Article 22  
Reports concerning this Directive

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 this Directive

Article 23  
Penalties

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

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

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 ...<sup>\*\*\*</sup> and shall notify it without delay of any subsequent amendments affecting them.

#### **Article 24** **Adaptation of the Annex**

*The Commission may adopt delegated acts in accordance with Article 25 and subject to the conditions of Article 26, 27 and 28 in order to:*

- (a) supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health considered as such on the basis of the scientific progress;*
- (b) supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation.*

#### **Article 25** **Exercise of the delegation**

- 1. The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of five years following ...<sup>\*\*\*\*</sup>. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 26.*
- 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 is conferred on the Commission subject to the conditions laid down in Articles 26 and 27.*
- 4. Where, in the case of the emergence of new serious risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 28 shall apply to delegated acts adopted pursuant to point (a) of Article 24.*

#### **Article 26** **Revocation of the delegation**

- 1. The delegation of powers referred to in Article 24 may be revoked at any time 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 powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the*

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<sup>\*\*\*</sup> Two years after the entry into force of this Directive.

<sup>\*\*\*\*</sup> The entry into force of this Directive.

*delegated powers which could be subject to revocation and possible reasons for a revocation.*

- 3. The decision of revocation 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.*

#### *Article 27*

##### *Objection to delegated acts*

- 1. The European Parliament or the Council may object to a 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 two months.*

- 2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and shall enter into force on the date stated therein.*

*The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.*

- 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.*

#### *Article 28*

##### *Urgency procedure*

- 1. Delegated acts adopted under the urgency procedure shall enter into force without delay and apply as long as no objection is expressed in accordance with paragraph 2. The notification of the act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.*
- 2. The European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 27(1). In such a case, the act shall cease to be applicable. The institution which objects shall state the reasons for objecting to the delegated act.*

#### *Article 29*

##### *Implementing measures*

*The Commission shall adopt, where organs are exchanged between Member States, detailed rules for the uniform implementation of this Directive in accordance with the procedure referred to in Article 30(2):*

- (a) procedures for the transmission of information on organ and donor characterisation as detailed in the Annex, in accordance with Article 7(6);*

- (b) procedures for *the transmission of the necessary information to ensure the traceability of the organs in accordance with Article 10(4)*;
- (c) procedures for ensuring the reporting of serious adverse events and reactions *in accordance with Article 11(4)*.

Article 30  
Committee


1. The Commission shall be assisted by the Committee on organ transplantation, hereinafter referred to as "the Committee."
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down to in Article 5(6) of Decision 1999/468/EC shall be set at three months.



Article 31  
Transposition

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 *inform* the Commission *thereof*.

When *they are adopted* by Member States, *those measures* shall contain a reference to this Directive or *shall* be accompanied by such reference on the occasion of their official publication. *The methods of making* such reference *shall be laid down by Member States*.

2. *This Directive shall not prevent Member States from maintaining or introducing more stringent rules, provided that they comply with the provisions of the Treaty.*
3. 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.

CHAPTER VII  
FINAL PROVISIONS

Article 32  
Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 33  
Addresses

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

This Directive is addressed to the Member States.

Done at

For the European Parliament

The President

For the Council

The President

ANNEX  
ORGAN AND DONOR CHARACTERISATION

**PART A**  
**MINIMUM DATA SET**

*Minimum data - information for the characterisation of organs and donors, which has to be collected for each donation in accordance with second subparagraph of Article 7(1) and without prejudice to Article 7(2).*

**MINIMUM DATA SET**

*Procurement centre and other general data*

*Type of donor*

*Blood group*

*Gender*

*Cause of death*

*Date of death*

*Date of birth or estimated age*

*Weight*

*Height*

*Past or present history of IV drug abuse*

*Past or present history of malignant neoplasia*

*Present history of other transmissible disease*

*HIV; HCV; HBV tests*

*Basic information to evaluate the function of the donated organ*

**PART B**  
**COMPLEMENTARY DATA SET**

*Complementary data - information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case, in accordance with the second subparagraph of Article 7(1).*

**COMPLEMENTARY DATA SET**

**GENERAL DATA**

*Contact details of procurement centre/organisation necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.*

#### **DONOR DATA**

*Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.*

#### **DONOR MEDICAL HISTORY**

*Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.*

#### **PHYSICAL AND CLINICAL DATA**

*Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.*

#### **LABORATORY PARAMETERS**

*Data needed for the assessment of the functional characterization of the organs and for the detection of potentially transmissible diseases and of possible contraindications to organ donation.*

#### **IMAGE TESTS**

*Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.*

#### **THERAPY**

*Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.*

Statement of the European Parliament, the Council and the Commission on Article 290 TFEU

The European Parliament, the Council and the Commission declare that the provisions of this Directive shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions.

Statement of the European Commission (Urgency)

The European Commission undertakes to keep the European Parliament and the Council fully informed on the possibility of a delegated act being adopted under the urgency procedure. As soon as the Commission's services foresee that a delegated act might be adopted under the urgency procedure, they will informally warn the secretariats of the European Parliament and of the Council.

**Food additives other than colours and sweeteners**

**European Parliament resolution of 19 May 2010 on the draft Commission directive amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC**

*The European Parliament,*

- having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives<sup>1</sup>, and in particular Articles 31 and 28(4) thereof,
  - having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>2</sup>,
  - having regard to Directives 95/2/EC of the European Parliament and Council of 20 February 1995 on food additives other than colours and sweeteners<sup>3</sup> and Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption<sup>4</sup> which have been repealed and replaced by the above-mentioned Regulation (EC) No 1333/2008,
  - having regard to the draft Commission directive amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC,
  - having regard to Article 5a(3)(b) of the Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>5</sup>,
  - having regard to Rule 88(2) and (4)(b) of its Rules of Procedure,
- A. whereas, under Article 31 of Regulation (EC) No 1333/2008, the Commission may, until the establishment of the Community lists of food additives provided for in Article 30 of that Regulation, adopt measures to amend the Annexes to, inter alia, Directive 95/2/EC,
- B. whereas Annex IV to Directive 95/2/EC contains a list of food additives that may be used in the European Union and prescribes the conditions for their use,
- C. whereas, in addition, the general criteria for the use of food additives were laid down in Annex II to Directive 89/107/EEC and since that Directive has been repealed and replaced

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 31, 1.2.2002, p. 1.

<sup>3</sup> OJ L 61, 18.3.1995, p. 1.

<sup>4</sup> OJ L 40, 11.2.1989, p. 27.

<sup>5</sup> OJ L 184, 17.7.1999, p. 23.

by Regulation (EC) No 1333/2008, the relevant criteria are now to be found, inter alia, in Article 6 of that Regulation, which concerns general conditions for inclusion and use of food additives in Community lists,

- D. whereas Article 6 of that Regulation provides that a food additive may be permitted for use in the EU only if it meets certain conditions including, under paragraph 1(c), that it does not mislead the consumer, and under paragraph 2, that it has advantages and benefits for consumers,
- E. whereas Article 6 of that Regulation also provides, in paragraph (1)(a), that a food additive may only be permitted for use if it does not pose a safety concern to the health of the consumer,
- F. whereas furthermore, Regulation (EC) No 178/2002 (which is known as “the General Food Law Regulation”) and in particular Article 8 thereof, provides inter alia that food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume, and that it shall aim at the prevention of practices which may mislead the consumer,
- G. whereas the draft Commission Directive, and in particular recital 25 and point (3)(h) of the Annex thereto, provides for the inclusion in Annex IV to Directive 95/2/EC of an enzyme preparation based on thrombin with fibrinogen as a food additive for reconstituting food,
- H. whereas thrombin, whilst derived from the edible parts of animals, has the character of a “meat-glue” and its purpose as a food additive is to bind together separate meat pieces in order to produce a single meat product,
- I. whereas the purpose of the use of thrombin therefore is to present pieces of meat to consumers as a single meat product, and therefore the risk of misleading the consumer is obvious,
- J. whereas recital 25 of the draft Commission Directive itself recognises that the use of thrombin with fibrinogen as a food additive could mislead the consumer as to the state of the final food,
- K. whereas point (3)(h) of the Annex to the draft Commission Directive provides for the inclusion of bovine and/or porcine thrombin in the list of permitted food additives under Annex IV to Directive 95/2/EC in pre-packed meat preparations and pre-packed meat products for the final consumer to a maximum of 1mg/kg, to be used together with fibrinogen and under the condition that the food shall bear the information “combined meat parts” in the proximity of its sales name,
- L. whereas, whilst the draft Commission Directive would not permit the use of thrombin as a food additive in meat products served in restaurants or other public establishments serving food, there is however, a clear risk that meat containing thrombin would find its way into meat products served in restaurants or other public establishments serving food, given the higher prices that can be obtained for pieces of meat served as a single meat product,
- M. whereas it is therefore not clear that the prohibition against the use of thrombin in meat products served in restaurants or other public establishments serving food, would result in the prevention in practice of such meat products being used in restaurants or other public

establishments serving food, and sold to consumers as single-meat products,

- N. whereas the above-mentioned labelling conditions contained in the draft Commission Directive would fail to guard against the creation of a false and misleading impression to consumers as to the existence of a single-meat product, and therefore there is a risk that consumers would be misled and prevented from making an informed choice in relation to the consumption of meat products containing thrombin,
  - O. whereas the advantages and benefits for consumers of thrombin have not been demonstrated,
  - P. whereas the process of binding together many separate pieces of meat significantly increases the surface area that may be infected by pathogenic bacteria (such as clostridium and salmonella) which, in such a process, can survive and be reproduced without oxygen,
  - Q. whereas the risk of infection by pathogenic bacteria is particularly serious since the binding process can be undertaken by way of cold bonding without the addition of salt and without any subsequent heating process, and as a result the safety of the final product cannot be guaranteed,
  - R. whereas the draft Commission Directive therefore fails in these respects to comply with the criteria for the inclusion of food additives in Annex IV to Directive 95/2/EC,
1. Considers that the draft Commission directive is not compatible with the aim and content of Regulation (EC) No 1333/2008;
  2. Opposes the adoption of the draft Commission Directive amending the Annexes to European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners and repealing Decision 2004/374/EC;
  3. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

**Commission communication "Action plan on organ donation and transplantation (2009-2015): Strengthened cooperation between Member States"**

**European Parliament resolution of 19 May 2010 on the Commission Communication: Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (2009/2104(INI))**

*The European Parliament,*

- having regard to Article 184 of the Treaty on the Functioning of the European Union,
  - having regard to the Charter on Fundamental Rights of the European Union,
  - having regard to 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),
  - having regard to the Commission Communication entitled ‘Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States’ (COM(2008)0819),
  - having regard to Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>1</sup>,
  - having regard to the World Health Organization's Guiding Principles on Human Organ Transplantation,
  - having regard to the Council of Europe Convention on Human Rights and Biomedicine, and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin,
  - having regard to the Conference on Safety and Quality in Organ Donation and Transplantation in the European Union held in Venice on 17-18 September 2003,
  - having regard to Rule 48 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 (A7-0103/2010),
- A. whereas there are currently 56 000 patients waiting for a suitable organ donor in the EU, and it is estimated that every day 12 people die while waiting for a solid organ transplant,
- B. whereas the needs of patients for transplantation in Europe are not being met owing to the limited number of organs available from both deceased and altruistic living donors,
- C. whereas there are wide variations between Member States in deceased organ donation rates,

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<sup>1</sup> OJ L 102, 7.4.2004, p.48.

ranging from 34.2 donors per million population (pmp) in Spain to 1.1 pmp in Bulgaria, and the shortage of organs is a major factor affecting transplantation programmes,

- D. whereas national policies and the regulatory framework for donations and transplantation vary substantially between Member States according to different legal, cultural, administrative and organisational factors,
- E. whereas organ donation and transplantation are sensitive and complex issues, with an important ethical dimension, which require the full participation of society for their development and the involvement of all relevant stakeholders,
- F. whereas organ transplantation provides the possibility of saving lives, offers a better quality of life and (in the case of kidney transplantation) has the best cost/benefit ratio when compared with other replacement therapies as well as increasing the possibilities for patients to participate in social and working life,
- G. whereas the exchange of organs between Member States is already common practice, although there are wide differences in the number of organs exchanged across borders between Member States; and whereas the exchange of organs between Member States has been facilitated by international exchange organisations such as Eurotransplant and Scandi transplant,
- H. whereas at present there is neither a database covering the whole of the European Union which contains information about organs intended for donation and transplantation or on living or deceased donors, nor, moreover, a pan-European certification system which provides proof that human organs and tissues have been legally obtained,
- I. whereas only Spain and few other Member States have succeeded in increasing significantly the number of deceased donations, and it has been proven that such increases are linked to the introduction of certain organisational practices that allow the systems to identify potential donors and maximise the number of deceased persons becoming actual donors,
- J. whereas Directive 2004/23/EC will provide a clear legal framework for organ donation and transplantation in the European Union, with the result that in every Member State a national competent authority will be created or designated to ensure compliance with EU quality and safety standards,
- K. whereas the trafficking of organs and of human beings for the purpose of removing organs constitutes a severe violation of human rights,
- L. whereas there is a strong link between illegal organ trafficking and the trafficking of persons for the purpose of removing organs on the one hand and the legal system of organ donation on the other because, firstly, the non-availability of organs in the legal system acts as an incentive for illegal activities, and, secondly, illegal activities severely undermine the credibility of the legal system of organ donation,
- M. whereas rates of refusal of organ donation vary widely within Europe, and such variability could be explained by the level of training and expertise of professionals in terms of communication and family care, the different legislative approaches to consent to organ donation and their practical implementation, and other important cultural, economic or social factors that influence society's perception of the benefits of donation and

transplantation,

- N. whereas living donation can be a helpful additional measure for patients who cannot get the organ they need via post-mortem transplantation, but whereas it needs to be emphasised that living donation can only be considered if any illegal activity and payment for the donation has been ruled out,
  - O. whereas a healthcare intervention may only be carried out after the person concerned has given free and informed consent to it; whereas that person should be given appropriate information beforehand as to the purpose and nature of the intervention as well as on its consequences and risks; and whereas the person concerned may freely withdraw consent at any time,
  - P. whereas Member States must ensure that organs intended for transplantation are not removed from a deceased person unless that person has been certified dead in accordance with national law,
  - Q. whereas living donation should be complementary to deceased donation,
  - R. whereas the use of organs in therapy entails a risk of transmission of infectious and other diseases,
  - S. whereas the fact that people are living longer is serving to reduce the quality of available organs, which in turn is leading in many cases to a reduction in the number of transplants, including in those Member States where the number of donors is increasing,
  - T. whereas public awareness and opinion play a very important role in increasing organ donation rates,
  - U. whereas work carried out by charities and other voluntary organisations in Member States increases awareness of organ donation, and whereas their efforts ultimately contribute to an increase in the numbers of people on organ donor registers,
1. Welcomes the Action Plan on Organ Donation and Transplantation (2009-2015) adopted by the Commission in December 2008, which sets out a cooperative approach between Member States in the form of a set of priority actions based on the identification and development of common objectives and the evaluation of donation and transplantation activities through agreed indicators that might help to identify benchmarks and best practices;
  2. Expresses its concern over the insufficiency of available human organs for transplantation to meet patients' needs; acknowledges that the severe shortage of organ donors remains a major obstacle preventing the full development of transplant services and the main challenge that the Member States face with regard to organ transplantation;
  3. Notes the success of schemes whereby citizens are given the option of directly joining an organ-donor register when completing certain administrative procedures, such as applying for a passport or driving licence; urges the Member States to look into adopting such schemes with a view to increasing the numbers of people on donor registers;
  4. Considers that, to ensure that organs available for therapy are not wasted, it is important that

there is a clearly defined legal framework regarding their use and that society trusts the donation and transplantation system;

5. Notes the importance of organisational aspects of organ procurement and stresses that the exchanging of information and best practice among Member States will help countries with low organ availability to improve their donation rates, as demonstrated, for example, by the implementation of elements of the Spanish Model in different countries both within and outside the EU which have succeeded in increasing organ donation rates;
6. Stresses the importance of donor coordinators, and the importance to appoint donor coordinators at hospital level. The role of the donor coordinator should be recognised as a key figure for improving, not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted;
7. Emphasises that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates;
8. Emphasises that the identification of potential donors has been considered one of the key steps in the process of deceased donation; stresses that the appointment of a key donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme and optimise the entire process of organ donation, is the most important step towards improving donor detection and organ donation rates;
9. Takes note of the importance of the cross-border exchange of organs, given the need to match donors with recipients and the consequent importance of a large donor pool to cover the needs of all the patients on the waiting lists; considers that if there is no exchange of organs between Member States, then recipients that need a rare match will have very low chances of receiving an organ, while at the same time specific donors will not be considered because there is not a suitable recipient on the waiting lists;
10. Welcomes the activities of Eurotransplant and Scanditransplant, but notes that exchanges of organs outside these systems and between these systems can be significantly improved, especially for the benefit of patients in small countries;
11. Stresses that the establishment of common binding standards of quality and safety will be the only mechanism that can ensure a high level of health protection throughout the EU;
12. Stresses that donation should be voluntary and unpaid, and take place in clearly defined legal and ethical contexts;
13. Calls on Member States to ensure that organs are allocated to recipients according to transparent, non-discriminatory and scientific criteria;
14. Calls on Member States to ensure that a legal basis for ensuring valid consent or objection to organ donation by a deceased person or his/her relatives is clearly defined and to ensure that organs are not removed from a deceased person unless that person has been certified dead in accordance with national law;
15. Endorses measures which aim at protecting living donors and ensuring that organ donation is made altruistically and voluntarily, without any payment other than compensation which

is strictly limited to making good the expenses incurred in donating an organ, such as travel expenses, childminding costs, loss of earnings or recovery costs, prohibiting any financial incentives or disadvantages for a potential donor; urges Member States to define the conditions under which compensation may be granted;

16. Calls on the Commission to evaluate the possibility to ensure that living donors are legally insured in all Member States; calls on the Commission to analyse the different health care coverage of living donors in all Member States in order to identify best practices across the EU;
17. Stresses that Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified or trained and competent professionals;
18. Stresses that the establishment of well-structured operational systems and the promotion of successful models at a national level are of the utmost importance; suggests that operational systems should comprise an adequate legal framework, technical and logistic infrastructure, and organisational support coupled with an effective allocation system;
19. Calls on Member States to promote the development of quality improvement programmes for organ donation in every hospital where there is potential for organ donation, as a first step, on the basis of a self-evaluation of the entire process of organ donation by specialists in intensive care and the transplant coordinator of every hospital, but seeking complementarity with external audits to the centres, if necessary and feasible;
20. Stresses that continuous education should form an essential part of all Member States' communication strategies on the issue; in particular, suggests that people should be better informed and encouraged to speak about organ donation and to communicate their wishes about donation to their relatives; notes that only 41% of European citizens seem to have discussed organ donation within their families;
21. Encourages the Member States to make it easier for living persons to make explicit statements of willingness to donate organs by offering on-line enrolment in a national and/or European donors' register with a view to speeding up procedures for verifying consent to donate organs;
22. Calls on 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;
23. Calls on Member States to ensure the accomplishment of systems and related registers which are easily accessible for the purposes of recording the wishes of future donors;
24. Calls, further, on the Member States to take steps to facilitate the inclusion, on national identity cards or driving licences, of references or symbols which identify the holder as an organ donor;
25. Calls, consequently, on Member States to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation; calls on the Commission, the Member States and civil society organisations to take part in this effort to

raise public awareness of the possibility of organ donation whilst taking into account the cultural particularities of each Member State;

26. Calls on Member States to reach the full potential of deceased donation by establishing efficient systems for identifying organ donors and by promoting transplant donor coordinators in hospitals across Europe; asks Member States to evaluate and make more frequent use of organs from 'expanded' criteria donors (i.e. older donors or those who have certain diseases), maintaining the highest quality and safety standards by exploiting, in particular, recent biotechnological advances which limit the risk of transplanted organs being rejected;
27. Believes it is necessary to ensure that a suitable balance is struck between, on the one hand, the protection of the donor in terms of anonymity and confidentiality and, on the other hand, the ability to trace organ donations for medical purposes, in order to prevent the remuneration of organ donation and trading and trafficking in organs;
28. Stresses that living donors should be treated in accordance with the highest medical standards and without any financial burden for themselves when medical problems such as hypertension, renal failure and their consequences occur which are potentially caused by the transplantation process, and any loss of earning as consequence of the transplantation or any medical problem should be avoided; the donors should be protected against discrimination in the social system;
29. Considers that all transplant system rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled, with a view to avoiding any unjustified discrimination in terms of access to transplant waiting lists and/or therapeutic procedures;
30. Notes that, although several Member States have introduced compulsory registration of transplant procedures and some voluntary registries also exist, no comprehensive system exists to collect data on the different types of transplantation and their outcomes;
31. Strongly supports, in consequence, the creation of national and EU-wide registers as well as the establishment of a methodology to compare the results of existing post-transplant follow-up registers of organ recipients in compliance with the existing European legal framework on the protection of personal data;
32. Supports the creation of special EU-wide protocols to provide procedures for operative and post-operative stages under the responsibility of the respective operating teams, specialist pathologists and specialists in other necessary fields;
33. Supports the creation of national and EU-wide registers on the follow-up of living donors, with the purpose of better ensuring their health protection;
34. Emphasises that any commercial exploitation of organs that denies equitable access to transplantation is unethical, is inconsistent with the most basic human values, contravenes Article 21 of the Convention on Human Rights and Biomedicine and is prohibited under Article 3(2) of the EU Charter on Fundamental Rights;
35. Points out that the organ shortage is linked in two ways to organ trafficking and trafficking in persons for the purpose of the removal of organs: firstly, increased organ availability in

the Member States would contribute to better monitoring of these practices, by obviating any need for EU citizens to consider seeking an organ outside the EU, and, secondly, illegal activity seriously undermines the credibility of the legal organ donation system:

36. Repeats the recommendations on the fight against the organ trade made in the Adamou report on organ donation and transplantation<sup>1</sup> and takes the view that these should be taken fully into account by the Commission when drafting the action plan; insists that awareness of the problem within the Commission and Europol needs to be increased;
37. Emphasises the importance of the World Health Assembly to be held in May 2010 and urges the Commission and the Council to fight strongly at WHO level for the principle of voluntary and unpaid donation;
38. Welcomes the joint Council of Europe/United Nations study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs;
39. Notes the report of David Matas and David Kilgour about the killing of members of Falun Gong for their organs, and asks the Commission to present a report on these allegations, along with other such cases, to the European Parliament and to the Council;
40. Urges Member States to establish mechanisms to avoid a situation where healthcare professionals, institutions or insurance companies encourage citizens of the Union to acquire an organ in third countries through practices involving trafficking in organs or in persons for the purpose of the removal of organs; urges Member States to monitor cases of this nature occurring within their territories; urges Member States to evaluate the introduction of legislative measures, including sanctions, applicable to persons promoting and / or participating in such activities;
41. Strongly rejects the behaviour of some health insurance organisations in encouraging patients to participate in transplant tourism and asks the Member States to monitor strictly and punish such behaviour;
42. Emphasises that patients who have received an organ under illegal circumstances cannot be excluded from healthcare in the European Union; points out that as in any other case a distinction should be drawn between the punishment for illegal activity and the need for treatment;
43. Stresses that the Member States should intensify their cooperation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively;
44. Recognises that it is vitally important to improve the quality and safety of organ donation and transplantation; points out that this will have an impact on reducing transplant risks and will consequently reduce adverse effects; acknowledges that actions on quality and safety could have an effect on organ availability and vice versa; asks the Commission to help Member States to develop their capacity in creating and developing regulatory frameworks to enhance quality and safety;

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<sup>1</sup> European Parliament resolution of 22 April 2008 on organ donation and transplantation: Policy actions at EU level (Texts adopted of that date, P6\_TA(2008)0130).

45. Emphasises that good cooperation between health professionals and national authorities or other legitimised organisations is necessary and provides added value;
46. Recognises the important role of post-transplantation care, including the appropriate use of anti-rejection therapies, in the success of transplants; acknowledges that optimum use of anti-rejection therapies can lead to improved long-term health for patients, graft survival and, hence, wider availability of organs owing to the reduced need for retransplantation, and asserts that Member States should ensure that patients have access to the best available therapies;
47. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.

**Institutional aspects of accession by the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms**

**European Parliament resolution of 19 May 2010 on the institutional aspects of the accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms (2009/2241(INI))**

*The European Parliament,*

- having regard to Article 6(2) of the Treaty on European Union, Articles 216(2), 218(6), 218(8) and 218(10) of the Treaty on the Functioning of the European Union and the Protocol on Article 6(2) of the Treaty on European Union concerning the accession of the Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms (hereafter referred to as the ECHR),
  - having regard to the decision of the Conference of Presidents of 14 January 2010 authorising the application of Rule 50 of the Rules of Procedure (procedure with associated committees)<sup>1</sup>,
  - having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Constitutional Affairs and the opinions of the Committee on Civil Liberties, Justice and Home Affairs and the Committee on Foreign Affairs (A7-0144/2010),
- A. whereas, in case law which has remained consistent since the judgments in Case 11-70 Internationale Handelsgesellschaft mbH [1970] ECR<sup>2</sup> and in Case 4-73 Nold [1974] ECR<sup>3</sup>, the Court of Justice of the European Union has held that fundamental rights form an integral part of the general legal principles which the Court enforces,
- B. whereas in so doing the Court of Justice of the European Union draws its inspiration from the constitutional traditions common to the Member States and from international instruments concerning the protection of human rights to which the Member States have acceded, such as the ECHR,
- C. whereas the essence of this case law was incorporated into primary law by the Maastricht Treaty on European Union of 1993,
- D. whereas the Court of Justice of the European Union devotes particular attention to the development of the case law of the European Court of Human Rights, as demonstrated by the growing number of judgments which refer to provisions of the ECHR,
- E. whereas in principle the European Court of Human Rights makes a ‘presumption of compatibility’ of the conduct of a Member State of the Union with the ECHR when the

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<sup>1</sup> Minutes of the meeting of the Conference of Presidents, PE432.390/CPG, point 9.1.

<sup>2</sup> ECR 1970, p. 1125.

<sup>3</sup> ECR 1974, p. 491.

State is merely implementing Union law,

- F. whereas, in an opinion of 28 March 1996, the Court of Justice of the European Union found that the European Community could not accede to the ECHR without a previous amendment to the Treaty because the Community did not have an explicit or implicit competence to do so,
- G. whereas the limits set by the Lisbon Treaty and the Protocols thereto must be upheld at the time of accession and, more specifically, Article 6(2) of the Treaty on European Union and Protocol No 8 to the Lisbon Treaty; whereas these provisions do not merely constitute an option allowing the Union to accede but require the Union institutions to act accordingly, and whereas the agreement on the accession of the Union to the ECHR must reflect the need to retain the specific features of the Union and of Union law,
- H. whereas, due to the conclusion of Protocol No 14 amending the ECHR, it is now possible for the Union to accede on behalf of the signatory states to the ECHR and whereas the accession terms and conditions must be agreed at the time of accession between the Union, of the one part, and the signatory states to the ECHR of the other part,
- I. whereas such an agreement should also deal with administrative and technical issues, such as the principle of a contribution from the Union to the operating costs of the European Court of Human Rights; whereas in that context plans should be made to establish an autonomous budget for the European Court of Human Rights to facilitate assessment of the various contributions,
- J. whereas, as a result of acceding to the ECHR, the Union will be integrated into its fundamental rights protection system and, in addition to the internal protection of these rights by the case law of the Court of Justice of the European Union, will have the benefit of an external protection body which is international in character,
- K. whereas the ECHR has been developed not only through the additional Protocols, but also through other Conventions, Charters and Agreements, resulting into a continuously evolving system of protection of Human Rights and Fundamental Freedoms
1. Stresses the main arguments in favour of accession of the Union to the ECHR, which may be summarised as follows:
- accession constitutes a move forward in the process of European integration and involves one further step towards political Union
  - while the Union's system for the protection of fundamental rights will be supplemented and enhanced by the incorporation of the Charter of Fundamental Rights into its primary law, its accession to the ECHR will send a strong signal concerning the coherence between the Union and the countries belonging to the Council of Europe and its pan-European human rights system; this accession will also enhance the credibility of the Union in the eyes of third countries which it regularly calls upon in its bilateral reports to respect the ECHR,
  - accession to the ECHR will afford citizens protection against the action of the Union similar to that which they already enjoy against action by all the Member States; this is all the more relevant because the Member States have transferred substantial powers to

the Union,

- legislative and case law harmonisation in the field of human rights of the rule of law of the EU and the ECHR will contribute to the harmonious development of the two European courts in the field of human rights, particularly because of the increased need for dialogue and cooperation, and thus will create an integral system, in which the two courts will function in synchrony,
  - accession will also compensate to some extent for the fact that the scope of the Court of Justice of the European Union is somewhat constrained in the matters of foreign and security policy and police and security policy by providing useful external judicial supervision of all EU activities,
  - accession will not in any way call into question the principle of the autonomy of the Union's law, as the Court of Justice of the European Union will remain the sole supreme court adjudicating on issues relating to EU law and the validity of the Union's acts, as the European Court of Human Rights must be regarded not only as a superior authority but rather as a specialised court exercising external supervision over the Union's compliance with obligations under international law arising from its accession to the ECHR; the relationship between the two European courts shall not be hierarchical but rather a relationship of specialisation; thus the Court of Justice of the European Union will have a status analogous to that currently enjoyed by the supreme courts of the Member States in relation to the European Court of Human Rights;
2. Recalls that, pursuant to Article 6 of the Treaty on European Union and Protocol No 8, accession does not entail any extension of the powers of the Union and in particular does not create a general human rights competence for the Union, and that, pursuant to Article 4(2) and Article 6(3) of the Treaty on European Union, the Member States' traditions and constitutional identities must be respected;
  3. Notes that, pursuant to Article 2 of Protocol No 8 to the Lisbon Treaty, the agreement on the accession of the Union to the ECHR must ensure that accession will not affect the particular internal situation of the Member States in relation to the ECHR and its protocols in general and with regard to any derogations and reservations made by Member States in particular, and that such circumstances should not influence the position taken by the Union in relation to the ECHR;
  4. Observes that the ECHR system has been supplemented by a series of additional protocols concerning the protection of rights which are not covered by the ECHR and recommends that the Commission be mandated also to negotiate accession to all the protocols concerning rights corresponding to the Charter of Fundamental Rights, regardless of whether they have been ratified by the Member States of the Union;
  5. Stresses that, as the accession of EU to the ECHR is an accession of a non-State Party to a legal instrument created for States, it should be completed without altering the features of the ECHR and modifications to its judicial system should be kept to a minimum; considers it important, in the interests of those in both the Union and third countries who are seeking justice, to give preference to accession arrangements that will have the least impact on the workload of the European Court of Human Rights;
  6. Emphasises that, in tandem with the necessary political commitment, it is of the utmost

importance that adequate answers and solutions be found to the main technical questions in order to enable the EU's accession to the ECHR to be used for the benefit of citizens; points out that unresolved and unclear details may create confusion and endanger the very purpose of the accession; stresses, however, that technical impediments should not be allowed to delay the process;

7. Stresses that accession to the ECHR does not make the Union a member of the Council of Europe but that a degree of participation by the Union in the ECHR bodies is necessary in order to ensure proper integration of the Union into the ECHR system and that, therefore, the Union should have certain rights in this domain, particularly:
  - the right to submit a list of three candidates for the post of judge, one of whom is elected by the Parliamentary Assembly of the Council of Europe on behalf of the Union and participates in the work of the Court on a footing of equality with the other judges, pursuant to Article 27(2) of the ECHR; the European Parliament being involved either in drawing up the list of candidates in line with a procedure similar to that provided for in Article 255 of the Treaty on the Functioning of the European Union for candidates for the position of judge at the Court of Justice of the European Union,
  - the right to attend via the European Commission, with voting rights on behalf of the EU, meetings of the Committee of Ministers when it performs its task of monitoring the execution of judgments given by the European Court of Human Rights or when it decides on the desirability of seeking an opinion from the Court and the right to be represented on the Steering Committee for Human Rights (a subsidiary body of the Committee of Ministers),
  - the right of the European Parliament to appoint/send a certain number of representatives to the Parliamentary Assembly of the Council of Europe when the latter elects judges to the European Court of Human Rights;
8. Considers that the Member States should undertake, at the time of accession to the ECHR, with respect to one another and in their mutual relations with the Union, not to bring interstate applications concerning an alleged failure of compliance pursuant to Article 33 of the ECHR when the act or omission in dispute falls within the scope of Union law, as this would be contrary to Article 344 of the Treaty on the Functioning of the European Union;
9. Considers that the principal added value of the accession of the EU to the ECHR lies in recourse for individuals against acts by means of which the law of the Union is implemented by its institutions or the Member States and that consequently any application by a natural or legal person concerning an act or failure to act by an institution or body of the Union should be directed solely against the latter and that similarly any application concerning a measure by means of which a Member State implements the law of the Union should be directed solely against the Member State, without prejudice to the principle that, where there might be any doubt about the way in which responsibility is shared, an application may be brought simultaneously against the Union and the Member State;
10. Considers that for the purposes of complying with the requirement set out in Article 35 ECHR for domestic remedies to have been exhausted, the applicant shall have exhausted the judicial remedies of the State concerned including a reference for a preliminary ruling to the Court in Luxembourg; the latter procedure shall be regarded as having been complied with where following a request to that end by the applicant the national court does not consider it

appropriate for a reference for a preliminary ruling to be made;

11. Notes that, following the EU's accession to the ECHR, it might occur that both the European Court of Human Rights and the Court of Justice of the European Union have jurisdiction in certain cases, and points out that simultaneous referrals to the two Courts will not be admissible;
12. Considers it appropriate that, in the interests of the proper administration of justice and without prejudice to Article 36(2) of the ECHR, in any case brought against a Member State before the European Court of Human Rights which may raise an issue concerning the law of the Union, the Union may be permitted to intervene as a co-defendant, and that in any case brought against the Union subject to the same conditions any Member State may be permitted to intervene as a co-defendant; this possibility must be defined in the provisions of the accession treaty in a manner which is both clear and sufficiently broad;
13. Considers that the adoption of the institution of co-defendant does not impede other indirect options provided by the ECHR (Article 36, I), such as the right of the Union to intervene as a third party in any application by an EU citizen;
14. Considers that, as the European Court of Human Rights has acknowledged the extra-territorial applicability of the ECHR, the Union must aim to respect this obligation fully in its external relations and activities;
15. Considers that it would be unwise to formalise relations between the Court of Justice of the European Union and the European Court of Human Rights by establishing a preliminary ruling procedure before the latter or by creating a body or panel which would take decisions when one of the two courts intended to adopt an interpretation of the ECHR which differed from that adopted by the other; recalls in this context Declaration No 2 concerning Article 6(2) of the Treaty on European Union, which notes the existence of a regular dialogue between the Court of Justice of the European Union and the European Court of Human Rights, which should be reinforced when the Union accedes to the ECHR;
16. Is clearly aware of the fact that the European Court of Human Rights may find a violation in a case that has already been decided by the Court of Justice of the European Union and stresses that this would in no way cast a doubt on the credibility of the Court of Justice of the European Union as an ultimate umpire in the EU judicial system;
17. Stresses that, following the accession, the ECHR will constitute the minimum standard of protection for human rights and fundamental freedoms in Europe and will be crucial, in particular, in cases where the protection granted by the EU is inferior to that provided under the ECHR; points out that the ECHR reinforces protection of the rights recognised by the Charter of Fundamental Rights that come within its scope and that the Charter also recognises other rights and principles, which are not contained in the ECHR, but in the additional protocols and in instruments related to the ECHR;
18. Recalls that promotion of respect of human rights, a core value of the EU as enshrined in its founding treaty, constitutes common ground for its relations with third countries; takes the view, therefore, that accession will further enhance the confidence of citizens in the European Union and the EU's credibility in talks on human rights with non-member States; stresses, furthermore, that the uniform and full application of the Charter of Fundamental Rights at EU level is equally essential to ensure the Union's credibility in this dialogue:

19. Notes that the ECHR has an important function in connection with the interpretation of the Charter of Fundamental Rights, as rights guaranteed by the Charter which correspond to rights recognised by the ECHR must be interpreted in accordance with the Convention and as, by virtue of Article 6(3) of the Treaty on European Union, the ECHR constitutes a source of inspiration for the Court of Justice of the European Union in the formulation of general principles of Union law; notes likewise that, pursuant to Article 53 of the ECHR, the Convention cannot be interpreted as limiting or adversely affecting the rights recognised by the Charter of Fundamental Rights, so that the latter retains its full legal force;
20. Emphasises the significance of the ECHR and the case law of the European Court of Human Rights in providing a legal framework and guiding principles for current and future EU action in the domain of civil liberties, justice and home affairs, especially in the light of the new forms of integration and harmonisation in civil liberties, justice and home affairs initiated by the entry into force of the Treaty of Lisbon and the adoption of the Stockholm Programme;
21. Stresses that the accession will, first and foremost, contribute to a more coherent human rights system within the EU; takes the view that the accession will strengthen the EU's credibility in the eyes of its own citizens in the field of human rights protection, ensuring full and effective respect for fundamental rights whenever EU law is in play;
22. Underlines that, after the accession, the competence of the European Court of Human Rights when judging matters coming under the ECHR may not be contested on the basis of the internal structure of EU law; underlines also that the competence of the European Court of Human Rights must not be limited to European citizens or to the geographical area of the European Union (for example in the case of missions or delegations);
23. Notes that EU accession to the ECHR will provide an additional mechanism for enforcing human rights, namely the possibility of lodging a complaint with the European Court of Human Rights in relation to an act, or a failure to act, by an EU institution or a Member State implementing EU law and falling within the remit of the ECHR; stresses, however, that this does not alter the present system of jurisdiction of the Court of Justice of the European Union nor that of the European Court of Human Rights, and that the requirement that all domestic judicial remedies should have been exhausted will remain the condition for the admissibility of any application; calls for applications and complaints to be dealt with in a reasonable period of time; encourages the Commission to provide some guidance, in consultation with the Court of Justice of the European Union and the European Court of Human Rights, on what constitutes the appropriate domestic remedy within the Union and on preliminary rulings under EU law; stresses, in this context, that it will be necessary to ensure that Member State courts refer cases to the Court of Justice of the European Union when there is arguably a fundamental rights issue at hand;
24. Stresses that, at the same time, the accession will require enhanced cooperation between national courts, the Court of Justice of the European Union and the European Court of Human Rights in protecting fundamental rights; points out that cooperation between the two European courts will further the development of a coherent case-law system in the field of human rights;
25. Welcomes, further, the fact that Article 1 of the ECHR would not only guarantee protection to EU citizens and other individuals within Union territory, but also outside Union territory to any individuals who come under its jurisdiction;

26. Is aware that accession as such will not resolve the extremely serious problems facing the ECHR system, namely on the one hand the excessive workload due to an exponential increase in the number of individual requests and on the other hand the reform of the structure and functioning of the Court to cope with it; notes that the European Court of Human Rights recognises that it operates in a complex legal and political environment, and notes that the entry into force of Protocol No 14 on 1 June 2010 will certainly help to reduce the number of uncompleted procedures but will not eliminate them; stresses, in the context of the reform of the European Court of Human Rights, the importance of the Interlaken Declaration, with particular reference to paragraph 4 thereof, which rightly calls for a uniform and rigorous application of the criteria concerning admissibility and the Court's jurisdiction;
27. Considers it essential to maintain the independence of the European Court of Human Rights in terms of personnel and budgetary policy;
28. Draws attention to the fact that, in view of the constitutional importance of accession by the Union to the ECHR, the Treaty on the Functioning of the European Union lays down stringent conditions for this, the Council being required to adopt the decision concluding the agreement unanimously after approval has been given by the European Parliament, and the agreement entering into force only after its approval by the Member States in accordance with their respective constitutional rules;
29. Encourages the national parliaments of the EU Member States to clearly express their will and readiness to facilitate the accession process by involving their national courts and ministries of justice;
30. Notes that accession by the Union to the ECHR signifies the recognition by the EU of the entire system of protection of human rights, as developed and codified in numerous documents and bodies of the Council of Europe; in this sense, accession by the Union to the ECHR constitutes an essential first step which should subsequently be complemented by accession by the Union to, inter alia, the European Social Charter, signed in Turin on 18 October 1961 and revised in Strasbourg on 3 May 1996, which would be consistent with the progress already enshrined in the Charter of Fundamental Rights and in the social legislation of the Union;
31. Calls, further, for the Union to accede to Council of Europe bodies such as the Committee on the Prevention of Torture (CPT), the European Commission against Racism and Intolerance (ECRI) and the European Commission on the Efficiency of Justice (CEPEJ); stresses also the need for the Union to be involved in the work of the Commissioner for Human Rights, the European Committee of Social Rights (ECSR), the Governmental Social Committee and the European Committee on Migration, and asks to be duly informed of the conclusions and decisions of these bodies;
32. Takes the view that, for the benefit of citizens, democracy and human rights in Europe and the EU, and to guarantee respect for and the safeguarding of human rights, cooperation between the institutions of the European Union and the specialised bodies of the Council of Europe should be strengthened in order to help bring about greater consistency and greater complementarity in the sphere of human rights at pan-European level;
33. Suggests that, in order to raise awareness of the added value of the accession to citizens, the Council of Europe and the EU should develop guidelines with clear explanations of all the

implications and effects of accession; maintains that the Commission and Member States should provide EU citizens with information ensuring that they are fully aware of what the additional mechanism means and how to use it adequately;

34. Stresses that it is important to have an informal body in order to coordinate information sharing between the European Parliament and the Parliamentary Assembly of the Council of Europe;
35. Stresses that, as accession to the ECHR affects not only the EU institutions, but also the Union's citizens, the European Parliament must be consulted and involved throughout the negotiation process, and must be associated and immediately and fully informed at all stages of the negotiations, as provided for in Article 218(10) of the Treaty on European Union;
36. Welcomes the commitment shown by the current Spanish Presidency in treating the accession as a 'matter of urgency' and the positive and cooperative attitude of the Council of Europe in this respect; calls on the Belgian and Hungarian Presidencies to do their utmost to finalise the accession at the earliest suitable opportunity and in as simple and accessible a manner as possible, so that EU citizens may benefit as soon as possible from the Union's accession to the ECHR;
37. Insists, in view of the important role that the Lisbon Treaty confers on the European Parliament as regards conclusion of the accession agreement, that it be duly informed of the definition of the negotiating mandate for accession to the ECHR and that it be closely involved in the preliminary discussions and also in the conduct of negotiations on that text, in accordance with the provisions of Article 218 of the Treaty on the Functioning of the European Union;
38. Instructs its President to forward this resolution to the Council and the Commission.

## **P7\_TA-PROV(2010)0185**

### **First review Conference of the Rome Statute**

#### **European Parliament resolution of 19 May 2010 on the Review Conference on the Rome Statute of the International Criminal Court, in Kampala, Uganda**

*The European Parliament,*

- having regard to the decision of the Assembly of States Parties, adopted at its 8th plenary meeting, on 26 November 2009<sup>1</sup>, to convene the Review Conference on the Rome Statute of the International Criminal Court in Kampala, Uganda, from 31 May to 11 June 2010,
- having regard to previous resolutions and reports on the Review Conference, and in particular Resolution ICC-ASP/7/Res.2 on the procedure for the nomination and election of the judges, the prosecutor and the deputy prosecutors of the ICC,
- having regard to its previous resolutions on the International Criminal Court, in particular those of 19 November 1998<sup>2</sup>, 18 January 2001<sup>3</sup>, 28 February 2002<sup>4</sup>, 4 July 2002 on the draft American Service Members' Protection Act (ASPA)<sup>5</sup> and 26 September 2002<sup>6</sup>, and its resolution of 22 May 2008<sup>7</sup>,
- having regard to the Rome Statute of the International Criminal Court (ICC) and its entry into force on 1 July 2002,
- having regard to the declaration of 1 July 2002 on the International Criminal Court by the Council Presidency on behalf of the European Union,
- having regard to the importance accorded by both the ICC and the EU to the consolidation of the rule of law and respect for human rights and international humanitarian law, as well as the preservation of peace and the strengthening of international security, in accordance with the Charter of the United Nations and as provided for in Article 21(2)(b) of the Treaty on European Union,
- having regard to the fact that the Council of the EU adopted Common Position 2003/444/CFSP on the International Criminal Court on 16 June 2003<sup>8</sup>, stating that the serious crimes within the jurisdiction of the ICC are of concern to all Member States, which are determined to cooperate for the prevention of such crimes and to put an end to the impunity of the perpetrators thereof, and with the objective of supporting the effective functioning of the Court and advancing universal support for the Court by promoting the widest possible participation in the Statute,

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<sup>1</sup> Resolution ICC-ASP/8/Res.6.

<sup>2</sup> OJ C 379, 7.12.1998, p. 265.

<sup>3</sup> OJ C 262, 18.9.2001, p. 262.

<sup>4</sup> Texts adopted of that date, P5\_TA(2002)0082.

<sup>5</sup> Texts adopted of that date, P5\_TA(2002)0367.

<sup>6</sup> Texts adopted of that date, P5\_TA(2002)0449.

<sup>7</sup> Texts adopted of that date, P6\_TA(2008)0238.

<sup>8</sup> OJ L 150, 18.6.2003, p. 67.

- having regard to the action plan to follow-up the Common Position finalised by the EU on 4 February 2004<sup>1</sup> for the co-ordination of EU activities, the universality and integrity of the Rome Statute and the independence and effective functioning of the ICC,
  - having regard to the adoption by the EU of a set of ‘Guiding Principles’<sup>2</sup> that fix minimum benchmarks to be respected by ICC States Parties if entering into bilateral non-surrender agreements,
  - having regard to the several decisions<sup>3</sup> adopted by the Council of the EU in the field of justice, freedom and security with a view to strengthening cooperation among Member States in the investigation and prosecution of genocide, crimes against humanity and war crimes at national level,
  - having regard to the Stockholm Programme inviting the EU institutions to support and promote Union and Member States’ activity against impunity and to fight against crimes of genocide, crimes against humanity and war crimes, and ‘in that context [to] promote cooperation between Member States [...] and the ICC’,
  - having regard to the considerable progress made since the first ICC judges and prosecutor were elected and to the fact that the Court is currently conducting investigations in five countries (Kenya, DR Congo, Sudan/Darfur, Uganda and Central African Republic),
  - having regard to the fact that the ICC Review Conference is an opportune moment to reflect on the Court’s progress and its work for the deterrence and resolution of armed conflicts, with particular reference to UN Security Council Resolution 1325 on Women, Peace and Security,
  - having regard to the Rome Statute Explanatory Memorandum defining the jurisdiction of the ICC, which recognises rape, sexual slavery, enforced prostitution, forced pregnancy, enforced sterilisation, or ‘any other form of sexual violence of comparable gravity’ as crime against humanity,
  - having regard to the statements by the Council and Commission on the Review Conference on the Rome Statute of the International Criminal Court, in Kampala, Uganda,
  - having regard to Rule 110(2) of its Rules of Procedure,
- A. whereas the EU is a staunch supporter of the ICC and promotes the universality, and defends the integrity, of the Rome Statute with a view to protecting and enhancing the independence, legitimacy and effectiveness of the international judicial process,
- B. whereas achieving the widest possible ratification and implementation of the Rome Statute

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<sup>1</sup> Doc. 5742/04.

<sup>2</sup> Guiding Principles concerning Arrangements between a State Party to the Rome Statute of the ICC and the United States regarding the Conditions to Surrender of Persons to the Court.

<sup>3</sup> Decision 2002/494/JHA of 13 June 2002 (OJ L 167, p. 1) setting up a European network of contact points in respect of persons responsible for genocide, crime against humanity and war crimes; Framework Decision 2002/584/JHA of 13 June 2002 (OJ L 190, p. 1) on the European arrest warrant and the surrender procedures between Member States; Decision 2003/335/JHA of 8 May 2003 (OJ L 118, p. 12) concerning the investigation and prosecution of genocide, crimes against humanity and war crimes.

has also been an EU objective during enlargement negotiations and in the process of accession by new EU Member States, and whereas the ratification and implementation of the Rome Statute should be also an important objective for the EU in its relations with other partners, in particular the United States, China, Russia and Israel,

- C. whereas the EU systematically pursues the inclusion of an ICC clause in negotiating mandates and in agreements with third countries,
- D. whereas respect for, and the promotion and safeguarding of, the universality of human rights is part of the Union's ethical and legal *acquis* and one of the cornerstones of European unity and integrity<sup>1</sup>,
- E. whereas the role of the EU as a global player has increased in recent decades,
- F. whereas its Special Representatives promote EU policies and interests in troubled regions and countries and play an active role in efforts to consolidate peace, stability and the rule of law,
- G. whereas, in April 2006, the EU became the first regional organisation to sign an agreement with the ICC on cooperation and assistance<sup>2</sup>,
- H. whereas the EU has provided more than EUR 40 million over 10 years under the EIDHR financial instrument for projects aimed at supporting the ICC and international criminal justice,
- I. whereas the ACP-EU Joint Parliamentary Assembly has been active in ensuring that international criminal justice is included in the revised ACP-EU Partnership Agreement (Cotonou Agreement) and has adopted several resolutions aimed at mainstreaming the fight against impunity in international development cooperation and relevant political dialogue,
- J. whereas this Review Conference represents a key opportunity for the States Parties, as well as non-State Parties, civil society and other stakeholders, strongly to reaffirm their commitment to justice and accountability,
- K. whereas States Parties have seized the opportunity of the Review Conference to go beyond the proposed amendments to the Rome Statute and to take stock of the ICC more than 10 years after its founding and evaluate more broadly the state of international criminal justice, focusing on four major themes, namely: complementarity, cooperation, the impact of the Rome Statute system on victims and affected communities, and peace and justice,
- L. whereas, with 111 States Parties to the ICC, some regions, such as the Middle East, North Africa and Asia, are still under-represented,
- M. whereas cooperation among states, international organisations and the ICC is essential for the effectiveness and success of the international criminal justice system, in particular in terms of law-enforcement capacity,
- N. whereas, on 19 April 2010, for the first time since the creation of the ICC, a request was submitted to it for a finding of non-cooperation by a state,

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<sup>1</sup> Articles 2, 3(5) and 6 of the Treaty on European Union.

<sup>2</sup> OJ L 115, 28.04.2006.

- O. whereas the premise underlying the principle of complementarity, on which the Rome Statute is founded, is that it is for the state itself to investigate and, where appropriate, to prosecute persons suspected of having committed crimes under international law,
- P. whereas in most conflict situations where justice has not been incorporated as part of the peacemaking process there has been a return to violence,
1. Reiterates its strong support for the ICC and its aims; stresses that the Rome Statute was ratified by all the EU Member States as an essential component of the democratic principles and values of the Union and calls, therefore, upon the Member States to comply fully with the Statute as part of the EU *acquis*;
  2. Highlights the importance of the choice of an African country, Uganda, to host this Review Conference, and expresses support for the Court's request to open a liaison office to the African Union in Addis Ababa, while recognising the universal dimension of the 'Rome Statute system';
  3. Underlines the importance of the principle of universality of the Rome Statute and calls on the Vice-President of the Commission/ High Representative of the Union for Foreign Affairs and Security Policy actively to promote accession to and ratification of the Statute;
  4. Reiterates its position that no immunity agreement should allow impunity of any individual accused of war crimes, crimes against humanity or genocide; welcomes the announcement of the US administration that no new immunity agreements will be concluded and calls on the USA and its partners to abandon the existing ones;
  5. Urges the Member States to participate in the Review Conference at the highest possible level, including Heads of State and Government, and to publicly reaffirm their commitment to the ICC;
  6. Encourages the Member States to make pledges reaffirming their commitment to the ICC and highlighting practical steps that they plan to take in support of it, by promising *inter alia* to implement the Rome Statute, ratify and implement the Agreement on Privileges and Immunities of the Court (APIC), work with other states that have fewer capabilities in order to promote universal acceptance of the Court, and affirm their contribution to strengthening the system of complementarity and cooperation, notably with regard to impact on victims and affected communities, as well as other areas of the Rome Statute;
  7. Firmly supports the inclusion in Article 5.1 of the Rome Statute of the crime of aggression within the ICC's material jurisdiction, regarding which the Special Working Group of the Assembly of States Parties to the Rome Statute has agreed that, for the purpose of the Statute, 'crime of aggression' means 'the planning, preparation, initiation or execution, by a person in a position effectively to exercise control over or to direct the political or military action of a State, of an act of aggression which, by its character, gravity and scale, constitutes a manifest violation of the Charter of the United Nations';
  8. Strongly affirms that any decision on the definition of a crime of aggression must be respectful of the Court's independence; recommends that states should adopt the proposal that does not require any jurisdictional filter to determine whether an act of aggression has been committed before the ICC prosecutor can proceed with an investigation; and that if the Review Conference decides that a jurisdictional filter must be established, they should

require that the determination of whether an act of aggression has been committed be conducted by the relevant Chamber in the course of the legal proceedings already set out in the Rome Statute;

9. Calls on the Member States to engage meaningfully in the stocktaking exercise by actively participating in the official panel discussions as well as the events organised by civil society (and other stakeholders) on the margins of the official conference;
10. Urges the Member States also to take the opportunity of the Review Conference to reaffirm their commitment to the Court through specific pledges on the four stocktaking themes and to honour those commitments;
11. Supports the ICC during this Review Conference in the process of stocktaking on every stage of the implementation and impact of the Rome Statute, bearing in mind the perspective of victims and affected communities;
12. Is concerned about the impact of the Rome Statute system on victims, individuals and communities affected by the crimes under the ICC's jurisdiction; considers it essential to ensure that victims and affected communities have access to information about, and understand the work of, the Court, and that victims' rights and interests should be a primary concern for the Rome Statute community, bearing in mind that the ICC is a judicial institution that complements the primary role of states in providing protection and facilitating access to justice and effective reparations for victims, whether individually or collectively; considers that the Member States should:
  - actively cooperate when a person is subject to an ICC arrest warrant, to facilitate the transfer of the person to the ICC for judgment;
  - acknowledge the innovative tools at the disposal of the ICC for the exercise of victims' right to justice, including the possibility for victims of participating in ICC proceedings and applying for reparations, taking into account the complementary role of the Trust Fund for Victims in the delivery of reparations and other assistance, including witness protection; ensure that victims, as well as their lawyers, benefit from adequate legal assistance and protection;
  - recognise the progress made by the Court to date in conducting outreach to affected communities and encourage it to develop that work further; and underscore the importance of ICC field operations in increasing the Court's impact among victims and affected communities;
  - pay particular attention to those groups who have been historically marginalised, such as children, women and indigenous people, in order to ensure that international criminal justice does not become a tool for perpetuating harm and stereotyping that may have been suffered;
  - announce a substantial financial contribution to the Trust Fund for Victims;
  - engage with civil society during the Review Conference to ensure that their views are adequately represented, including by participating in events at the People's Space being organised by the Human Rights Network;

13. Reiterates its call to the Member States to ensure full cooperation between States Parties, signatory states and the Court, in accordance with Article 86 of the Rome Statute, in order to respect the object and purpose under which, according to its Preamble, ‘the most serious crimes of concern to the international community as a whole must not go unpunished’, by the following means:
  - enacting national legislation on cooperation, in accordance with Part IX of the Rome Statute, if they have not yet done so;
  - reaffirming their commitment to provide the Court with all necessary cooperation and assistance without reservation;
  - considering concluding ad hoc agreements with the Court for the relocation of victims and witnesses and the enforcement of the Court’s sentences;
  - ensuring that cooperation becomes a standing item on the agenda of the Assembly of States Parties to the ICC, that the actual challenges and needs of the Court are discussed and that the progress made by states is measured;
14. Welcomes the revision and discussion of Article 124 (‘transitional provision’) of the Rome Statute, which allows states to choose not to have their nationals subject to the Court’s jurisdiction over war crimes for a seven-year period after ratification, and calls for its prompt deletion from the Statute so that the law is applied equally to all suspects of alleged war crimes committed in the territories of, or by nationals of, States Parties to the Statute;
15. Calls on the Member States to prioritise the inclusion as a war crime within the jurisdiction of the court of the use of certain weapons in the context of an armed conflict not of an international character, in accordance with the Belgian proposal for amendments to Article 8 of the Rome Statute, submitted to the 8th session of the Assembly of States Parties and extending criminalisation of the use of poison, poisoned weapons, asphyxiating, poisonous or other gases and all analogous liquids, materials or devices, as well as the use of bullets that expand or flatten in the body, to armed conflicts not of an international character;
16. Stresses the effectiveness of the principle of complementarity of the Court, which is the foundation of the comprehensive system of international criminal justice (the Rome Statute system) and under which the primary duty of States Parties to investigate and prosecute international crimes is clearly reinforced by the complementary (subsidiary) jurisdiction of the ICC;
17. Is deeply convinced that, during the discussions in Kampala, the Member States should:
  - reaffirm their primary obligation to investigate and prosecute war crimes, genocide and crimes against humanity, and commit to enacting in their legislation definitions of war crimes, genocide and crimes against humanity, in conformity with the Rome Statute;
  - engage in ‘positive complementarity’ by, *inter alia*, emphasising the necessity of effective national proceedings, including in countries where there is a high need for justice, such as ICC situation countries and countries under preliminary analysis by the ICC;

- stress the importance of initiating and implementing effective national proceedings and, in particular, address the issue of lack of political willingness on the part of states;
  - stress the vital importance of building the political will of states to fulfil their obligations under complementarity, and take steps to encourage states to stand on the side of justice and against impunity;
18. Urges all States Parties to the Rome Statute, especially the EU Member States, to enact or implement national legislation ensuring that they can cooperate fully with the ICC;
  19. Urges all States Parties to the Rome Statute to enter into agreements with the Court on victim and witness relocation and enforcement of sentences;
  20. Calls on the Union, the Member States and other international donors to support reform processes and national capacity-building efforts aimed at strengthening the independent judiciary, the law-enforcement sector and the penitentiary system in all developing countries directly affected by the commission of Rome Statute crimes, thus ensuring effective implementation of the principle of complementarity and also compliance by states with the decisions of the Court;
  21. Call on the States Parties to adopt a resolution, based on the discussions in Kampala, highlighting the importance of delivering effective justice to victims, in the context of fair and impartial trials;
  22. Calls on the EU Member States to renew their commitment to the ICC for the future;
  23. Supports the proposal made by high-level representatives of States Parties to the Rome Statute of the ICC to adopt the 17th of July, which is the day of the adoption of the Rome Statute in 1998, as the Day of International Criminal Justice;
  24. Instructs its President to forward this resolution to the Vice-President of the Commission/ High Representative of the Union for Foreign Affairs and Security Policy, the Council, the Commission and the governments and parliaments of the Member States and the candidate countries.