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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8.12.2008  
COM(2008) 818 final

2008/0238 (COD)

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) 819 final}  
{SEC(2008)2956}  
{SEC(2008)2957}

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### INTRODUCTION

1. Organ transplantation is the therapeutic use of human organs involving the substitution of a non-functional organ by an organ from a donor. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such the liver, lung and heart, it is the only available treatment.
2. The use of organs in therapy poses a risk of transmission of diseases to the recipient; infectious or cancerous diseases could be transmitted. While most Member States have adopted legislation on the ethical aspects of organ transplantation, many have yet to agree on rules covering quality and safety. In 2003, the Commission carried out a survey of legal requirements relating to organ transplantation in the EU which showed discrepancies in quality and safety requirements between Member States<sup>1</sup>.
3. The exchange of organs between Member States in an effort to achieve better quality in the allocation process is already common practice. There are, however, large differences between the number of organs exchanged across borders between Member States that have set up bodies and laid down rules for the international exchange of organs such as Eurotransplant and Scandiatransplant and the other Member States.
4. The shortage of organs is a major factor affecting transplantation programmes. Nearly 56.000 patients are now on waiting lists<sup>2</sup>. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. Donation rates and availability of organs varies considerably across Europe with achievable good practice delivering far greater benefits in some Member States than in others.
5. One of the potential consequences of the scarcity of organs is the trafficking of human organs by organised criminal groups. Trafficking in human organs can be linked with trafficking in human beings 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. It is recognised that the best way of fighting organ trafficking is increasing the number of available organs and securing their quality and safety. 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.
6. Since 1999, Article 152 of the EC Treaty, as introduced by the Treaty of Amsterdam, has enabled the European Parliament and the Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted directives, on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004.

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<sup>1</sup> [http://ec.europa.eu/health/ph\\_threats/human\\_substance/documents/organ\\_survey.pdf](http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf)

<sup>2</sup> Council of Europe (2007).

7. There are important differences between organ transplantation and the use of other human substances such as blood, tissues and cells. Given the current shortage of organs, two factors have to be balanced: the need for organs' transplantation that is usually a matter of life and death with the need to ensure high standards of quality and safety.
8. The Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union was held on 17-18 September 2003 under the Italian presidency. The conclusions of the expert conference organised by the Italian government during its Presidency of the EU Council listed the shortage of organs as the main priority in this area and stressed the importance of addressing the quality and safety aspects given the current situation regarding the supply and demand for organs.
9. When adopting the Tissues and cells Directive on 31 March 2004, the Commission committed itself to conducting a thorough scientific review of the situation regarding organ transplantation. On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation<sup>3</sup> based on that analysis. This Communication proposes what activities the EU should undertake in the field of organ transplantation. The Communication concludes that a flexible European legal framework establishing quality and safety standards would be the right Community response to meeting the mandate provided in Article 152 (4) (a) of the Treaty.
10. On 6 December 2007, the Council adopted conclusions on organ donation and transplantation. The Council recognises the importance of having high standards with respect to the quality and safety of organs for transplantation, so as to ensure a high level of protection for patients throughout Europe and called on the Commission to consult the Member States, and continue its examination of the need for an EU framework on quality and safety for human organs.
11. The European Parliament resolution adopted on 22 April 2008 recognised that it is vitally important to improve the quality and safety of organ donation and transplantation to reduce transplant risks. Hence, the resolution looks forward to the Commission's proposal for a directive stipulating requirements to ensure the quality and safety of organ donation across the EU.

#### **SCOPE AND OBJECTIVES**

12. This proposal for a Directive covers human organs, that are used for transplantation, during all the phases of the process – donation, procurement, testing, preservation, transport and use – and aims to ensure their quality and safety and hence a high level of health protection.
13. The proposal excludes blood and blood components, human tissues and cells and organs or tissues and cells of animal origin. Blood and blood products are currently covered by Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC,

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<sup>3</sup> Communication from the Commission to the European Parliament and the Council - Organ donation and transplantation: Policy actions at EU level, Brussels - COM(2007) 275, 30.5.2007.

whereas Human Tissues and Cells are regulated by Directive 2004/23/EC, 2006/17/EC and 2006/86/EC.

14. This Directive does not intend to cover research using human organs, for purposes other than transplantation. However, organs that are transplanted into the human body in clinical trials should comply with the quality and safety standards laid down in this Directive.
15. This proposal aims to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements. In this way, the Directive will facilitate their exchange between Member States.

## **THE ADDED VALUE OF THE DIRECTIVE**

### **Ensuring quality and safety for patients at EU level**

16. There are significant risks to using organs in therapy, but these can be effectively offset through the application of quality and safety procedures. A well-regulated donation and transplantation system is essential if organs are to be delivered on time, with accurate information and without any unnecessary risk of transmitting disease to the recipient.
17. This Directive sets out the basic quality and safety requirements needed in every transplant system. A sound infrastructure and responsible institutions for organ procurement and transplantation have been identified as the main features of a successful transplantation system. The proposed Directive provides for the creation or designation of a competent national authority in each Member State. These Competent authorities will ensure compliance with the requirements of the Directive. The Directive also establishes a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria<sup>4</sup>. This system would provide a complete list of authorised centres throughout the European Union, accessible to the public and professionals alike.
18. Procurement, evaluation and selection of the donor are the first and decisive steps in the transplantation chain. The proposed Directive will establish common quality and safety standards for the processes of evaluating donors and human organs, thus ensuring the health of recipients.
19. Of equal importance is to ensure the quality of the processes performed by the various organisations in the field. To improve these processes, the Directive proposes the introduction of national quality programmes to ensure continuous monitoring of performance and improvement and learning. Specific standards for the procurement and transport of human organs and training of professionals will be part of the national quality programmes.
20. Establishment of a system to ensure that all organs can be traced from donation to reception and vice versa is a key factor to ensure safety but also in order to prevent

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<sup>4</sup> Council of Europe Recommendation Rec(2004)19 of the Committee of Ministers to Member States on criteria for the authorisation of organ transplantation facilities.

remuneration, trade and trafficking in organs. The proposed Directive will ensure that Member States put in place organ traceability systems. The Commission will adopt procedures for guaranteeing full traceability of organs exchanged between Member States. Traceability does not mean that the organ receiver will learn the names and further details of the donor, or vice versa. Traceability therefore aims at safeguarding the health of donors and recipients and serves no other purpose than guaranteeing the quality and safety of the organs. The anonymity of both the donor and the recipient remains a cornerstone for their protection. But the relevant competent authorities should keep the necessary documentation and records, e.g. where the organ originated from, who supplied it and under which circumstances.

21. As organ donors are often also tissue and cell donors, it is additionally important that information about adverse events and infections can be quickly traced to a donation and immediately relayed to the tissue vigilance system provided for by the Tissue and Cell Directive 2004/23/EC. Currently such a system does not exist.
22. In addition, the proposal includes measures to capture serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation which may be connected to the procurement, testing and transport of the organ in the European Union. The Commission will adopt procedures for ensuring interoperability between the reporting systems on adverse events and reactions.

### **Ensuring the protection of donors**

23. The use of human organs should be under conditions protecting the rights and health of donors. As a matter of principle, organ transplantation programmes should be based on the principle of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor, the living donor (when relevant) and the recipient(s) and the protection of personal data. They should comply with the Charter of Fundamental Rights of the European Union, and take the principles of the Convention of Human Rights and Biomedicine of the Council of Europe fully into account.
24. Consent for procurement is as a general rule regulated by Member States in very different ways; ranging from presumed consent systems to systems where the consent of relatives is required. The Commission believes that this is a very sensitive field and that it raises a number of ethical concerns that falls within the competence of the Member States and should not be dealt with in this Directive.
25. The use of living donors is an increasing alternative given the failure to meet the growing need for organs with cadaver donation. The increase in living organ donation can be attributed to multiple factors, including pressure created by the shortage of deceased donors, surgical advances, and strong evidence of favourable transplant outcome and low donor risk.
26. The proposed Directive contains a number of measures to protect living donors. These include correct evaluation of the health of the donor and comprehensive information about the risks prior to donation, the introduction of registers for living donors to follow up their health and measures to ensure the altruistic and voluntary donation of organs by living donors.

## **Facilitating cooperation between Member States and cross-border exchanges**

27. The current proposal seeks to ensure a high level of quality and safety throughout the ‘organ transplantation chain’ in all Member States, bearing in mind the freedom of movement of citizens and the need to enhance the cross-border exchange of organs within the European Union. The establishment of quality and safety standards will help to reassure the public that human organs derived from donation in another Member State carry nonetheless the same guarantees as those in their own country.
28. The cross-border exchange of organs has clear benefits. Given that donor and recipient have to be matched, a large donor pool is important to cover the needs of all the patients on the waiting lists. If there is no exchange of organs between Member States, recipients in need of a rare match will have very low prospects of finding an organ, while at the same time donors will not be considered because there are no compatible recipients on the waiting lists. This holds particularly true for difficult to treat patients (paediatric, urgent or hypersensitised patients that require very specific matching) and small Member States.
29. The Directive will put in place the quality and safety conditions needed to facilitate cross-border exchanges. It will standardise the collection of the relevant information on the characteristics of the organ needed to make a proper risk assessment. It will also establish a mechanism for transmission of the information. Transplant teams in all Member States will be reassured that they will receive the appropriate and complete information required regardless of the country of origin of the organ. This will minimise the risks to the recipient and optimise the allocation of the organs across the EU level.
30. In addition the Directive will provide for the necessary mechanisms to be put in place for cross-border exchanges of organs to ensure traceability of the organ and pre-empt serious adverse reporting.
31. The establishment of competent authorities in all Member States and the organisation of regular meetings between them will help to promote European cooperation in this field as shown in the cases of blood and tissues and cells. Coordination between these authorities would make for a more efficient allocation of organs (especially helpful for smaller Member States and for urgent and difficult-to-treat patients). As more people move across borders information will need to move with them to optimise donation and transplantation while maintaining citizens’ confidence in the system in the country they are visiting.

Proposal for a

**DIRECTIVE 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 establishing the European Community, and in particular Article 152 (4) (a) thereof,

Having regard to the proposal from the Commission<sup>5</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>6</sup>,

Having regard to the opinion of the Committee of the Regions<sup>7</sup>,

After consulting the European Data Protection Supervisor<sup>8</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>9</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.
- (3) In addition the availability of organs of human origin used for therapeutic purposes is dependent on Community citizens being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

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<sup>5</sup> OJ C , , p. .

<sup>6</sup> OJ C , , p. .

<sup>7</sup> OJ C , , p. .

<sup>8</sup> OJ C , , p. .

<sup>9</sup> OJ C , , p. .



- (4) Every year organs are exchanged between Member States. The exchange of organs is an important way of expanding the pool of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplant. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitised patients or paediatric patients. Available organs should be able to cross borders without unnecessary problems and delays.
- (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 Community level. These standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Community legislation should ensure that human organs comply with acceptable standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.
- (7) In order to reduce the risks and maximise the benefits of the transplantation process. Member States need to operate an effective national quality programme. This programme should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The national quality programme should include auditing where necessary. Member States should be able to delegate, through written agreements, the responsibility for parts of this programme to European organ exchange organisations.
- (8) The conditions of procurement should be supervised by the Competent Authorities through the authorisation of identified procurement organisations. The authorisation should assume that proper organisation, qualified staff and adequate facilities and material are in place.
- (9) The risk-benefit ratio is a fundamental approach to organ transplantation. Owing to the shortage of organs and the inherent life threatening nature 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 stipulates the information required to make this assessment.
- (10) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. This evaluation must provide enough information for the transplant centre to undertake a proper risk-benefit analysis. The risks and characteristics of the organ must be identified and documented to allow allocation to a suitable recipient. Information should be collected for complete characterisation of the organ and the donor.
- (11) Effective rules for the transportation of organs should be provided which minimises ischemic times and prevents organ damage. While maintaining medical

confidentiality, the organ container should be clearly labelled and contain the necessary documentation.

- (12) 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.
- (13) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Community system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells<sup>10</sup>. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported in the tissue vigilance system as provided for in that Directive.
- (14) Personnel directly involved in the donation, procurement, testing, preservation, transport and transplantation of human organs should be suitable qualified and trained.
- (15) As a general principle, exchange of organs from/to third countries should be supervised by the Competent Authority. Authorisation should be granted only if standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account. (16) This Directive should respect the fundamental rights and observe the principles recognised in particular by the Charter of Fundamental Rights of the European Union<sup>11</sup>. In line with that charter and to take account of, as appropriate the Convention on human rights and biomedicine<sup>12</sup>, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s).
- (17) Article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>13</sup> prohibits in principle the processing of data concerning health. Limited exemptions to this prohibition principle are laid down. Directive 95/46/EC also requires the controller to implement appropriate technical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing.

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<sup>10</sup> Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

<sup>11</sup> OJ C 364 18.12.2000 , p. 1.

<sup>12</sup> Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine of the Council Of Europe.

<sup>13</sup> OJ L 281, 23.11.1995, p. 31.

- (18) Living donor should undertake an adequate evaluation 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>14</sup> and should be informed in advance as to the purpose and nature of the donation, the consequences and risks, as established in the additional protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin of the Council of Europe. This will contribute to assess the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves.
- (19) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation. As emphasised by the Recommendation of the Committee of Ministers to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO) of the Council of Europe<sup>15</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.
- (20) 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.
- (21) The measures needed to implement this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>16</sup>.
- (22) In particular, power should be conferred on the Commission to lay down, where the organs concerned are to be exchanged between Member States, the procedures for the transmission to transplantation centres of the information on the characteristics of the organs, the procedures needed to ensure the traceability of the organs, including labelling requirements, and the procedures for the reporting of serious adverse events or reactions. Since these measures are of general scope and are designed to amend non-essential elements of this Directive, or to supplement this Directive with new non-

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<sup>14</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.

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

<sup>16</sup> OJ L 184, 17.7.1999, p. 23, Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

- (23) 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 Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. 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 high standards of quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure a high level of human health protection.

#### *Article 2* *Scope*

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

#### *Article 3* *Definitions*

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

- (a) 'authorisation' means authorisation, accreditation, designation or licensing, depending of the concepts used in each Member State;
- (b) 'disposal' means the final placement of an organ when it is not used for transplantation;
- (c) 'donor' means every human source of organs, whether living or deceased ;

- (d) 'donation' means donating human organs for transplantation;
- (e) 'donor characterisation' means the collection of the relevant information on the characteristics of the donor needed to undertake a proper risk assessment in order to minimise the risks for the recipient and to optimise organ allocation;
- (f) 'European organ exchange organisation' means a non-profit organisation, whether public or private, dedicated especially to cross-border organ exchange; the countries members of such an organisation are in their majority Member States of the Community;
- (g) 'organ' means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy;
- (h) 'organ characterisation' means the collection of the relevant information on the characteristics of the organ needed to undertake a proper risk assessment in order to minimise the risks for the recipient and to optimise organ allocation;
- (i) 'procurement' means a process by which the donated organs become available;
- (j) "procurement organisation" means a health care establishment, a team or a unit of a hospital or another body which is authorised by the competent authority to undertakes procurement of human organs;
- (k) 'preservation' means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of human organs from the procurement until the transplantation;
- (l) 'recipient': means a person who receives a transplant of an organ;
- (m) 'serious adverse event' means any unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling, or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;
- (n) 'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;
- (o) 'standard operating procedures' means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;
- (p) 'transplantation' means the process of restoring certain functions of the human body by transferring equivalent organs to a recipient.;

- (q) ‘transplantation centre’ means a health care establishment, a team or a unit of a hospital or any other body which is authorised by the competent authority to undertake transplantation of human organs;
- (r) ‘traceability’ means the ability for a competent authority to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, which under specified circumstances in this Directive is authorised to :
  - identify the donor and the procurement organisation
  - identify the recipient(s) at the transplantation centre(s)
  - locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;

## CHAPTER II

### THE QUALITY AND SAFETY OF ORGANS

#### *Article 4*

#### *National quality programmes*

1. Member States shall ensure that a national quality programme is established to cover all stages of the chain from donation to transplantation or disposal, in order to ensure compliance with the rules laid down in this Directive.
2. The national quality programmes shall provide for the adoption and implementation of:
  - (a) standard operating procedures for the verification of donor identity;
  - (b) standard operating procedures for the verification of the details of donor or donor family consent or authorisation in accordance with national rules;
  - (c) standard operating procedures for the verification of the completion of the organ and donor characterisation in accordance with Article 7 and with the model set out in the Annex;
  - (d) procedures for the procurement, preservation packaging and labelling of organs, in accordance with Article 5, 6 and 8 ;
  - (e) rules for the transportation of human organs in accordance with Article 8.
3. The national quality programmes shall
  - (a) lay down rules to ensure the traceability of organs at all stages of the chain from donation to transplantation or disposal, in accordance with Article 10, including

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

(b) establish the standard operating procedures for:

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

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

#### *Article 5*

#### ***Procurement organisations***

1. Member States shall ensure that the procurement takes place in procurement organisations that comply with the rules laid down in this Directive.
2. The organisational structure and operational procedures of procurement organisations shall include:
  - (a) an organisational chart which clearly defines job descriptions, accountability and reporting relationships;
  - (b) standard operating procedures as specified in national quality programmes .
3. 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, are performed under the advice and the supervision of a medical doctor as defined in Directive 2005/36/EC.
2. Member States shall ensure that procurement takes place in dedicated facilities, which are designed, constructed, maintained and operated so as to comply with the requirements laid down in this Directive and which allow minimising bacterial or

other contamination of procured human organs in accordance with best medical practices.

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

- (a) Restricted access;
  - (b) personnel that are appropriately dressed for sterile operations, wearing sterile gloves, hats and facemasks.
3. Member States shall ensure that procurement material and equipment are managed in accordance with relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for procurement.

#### *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 and data listed in the organ characterisation form in the Annex. The tests required for organ characterisation shall be carried out by a qualified laboratory.
2. Member States shall ensure that organisations, bodies and qualified laboratories involved in organ and donor characterisation have appropriate standard operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in time.

#### *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 standard operating procedures in place to ensure the integrity of the organ during transport and that transport time is minimised.
  - (b) the shipping containers used for transporting organs are labelled with the following information:
    - identification of the procurement organisation, including its address and telephone number;
    - identification of the transplantation centre of destination, including address and telephone number;
    - a statement that the package contains a human organ and marked **HANDLE WITH CARE**;



- recommended transport conditions, including instructions for keeping the container at a certain temperature and in a certain position
- safety instructions and method of cooling (when applicable).

However point (b) shall not apply where the transportation is carried out within the same establishment

#### *Article 9* ***Transplantation centres***

1. Member States shall ensure that transplantation takes place in transplantation centres that comply with the rules laid down in this Directive.
2. The Competent authority shall indicate in the accreditation, designation, authorisation or licence 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 in accordance with the model set out in the Annex and that records are kept of the information contained in that form ;
  - b) the indicated storage temperature and other conditions of 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 and allocated 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 identification system that can identify each donation and each of the organs associated with it. Member States shall ensure that this donor identification system are designed and selected in accordance with the aim of collecting, processing or using no personal data or as little personal data as possible. In particular, use is to be made of the possibilities for pseudonymisation or rendering individuals anonymous.
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 in accordance with the national quality programmes.

- b) Data required for full traceability is kept for a minimum of 30 years after donation. Such data storage may be stored in electronic form.

#### *Article 11*

#### ***Reporting systems for serious adverse events and reactions***

1. Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events and reactions that may influence the quality and safety of human organs and which may be attributed to the procurement, testing, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.
2. Member States shall ensure that a procedure is in place to enable the rapid recall of any organ which may be related to a serious adverse event or reaction as specified in the national quality programme.
3. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the reporting system established in accordance with Article 11 of Directive 2004/23/EC.

#### *Article 12*

#### ***Personnel***

Member States shall ensure that personnel directly involved in the chain from donation to the transplantation or disposal of organs are qualified to perform their tasks and are provided with the relevant training, as specified in the national quality programmes.

### **CHAPTER III**

## **DONOR AND RECIPIENT PROTECTION**

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

*Article 14*  
***Consent and authorisation requirements prior to procurement***

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

*Article 15*  
***Protection of the living donor***

1. Member States shall take all necessary measures to ensure that potential living donors are provided with all the information necessary, as to the purpose and nature of the donation, the consequences and risks, and on alternative therapies for the potential recipient to enable them to make an informed decision. . The information shall be supplied in advance of the donation.
2. Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified and trained professionals. Such assessments may provide for the exclusion of persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or a serious risk to themselves.
3. Member States shall ensure that the competent authority keeps a register of the living donors after the donation, in line with provisions on the protection of the personal data and statistical confidentiality, and collects information on their follow up and, and specifically, on complications related to their donation that might appear in the short, mid and long term.

*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 transplantation activities, in conformity with Community provisions on the protection of personal data, such as Directive 95/46/EC, and in particular Articles 8 (3), 16, 17 and 28 (2) of that Directive.

*Article 17*  
***Anonymisation of donors and recipients***

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

## CHAPTER IV

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

#### *Article 18*

##### *Designation and tasks of competent authorities*

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

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

- (a) put in place and keep updated a national quality programme in accordance with Article 4;
- (b) ensure that procurement organisations and transplantations centres are controlled and audited on a regular basis to ascertain compliance with the requirements of this Directive;
- (c) grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres if control measures demonstrate that such organisations or centres do not comply with the requirements of this Directive;
- (d) put in place a reporting system and a system for the recall of organs 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;
- (f) participate in the Community network referred to in Article 20 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;
- (f) ensure, in cooperation with the supervisory authority established in compliance with Article 28 of Directive 95/46/EC, that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Community provisions on the protection of personal data, in particular Directive 95/46/EC.

#### *Article 19*

##### *Registers and reports concerning procurement organisations and transplantation centres*

1. Member States shall ensure that the competent authority:

- (a) keeps a record of the activities of procurement organisations and transplantation centres, including aggregated and anonymised numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in line with provisions on the protection of personal data and statistical confidentiality;
  - (b) draws up and makes publicly accessible an annual report on those activities;
  - (c) establishes and maintains a register of procurement organisations and transplantation centres.
2. Member States shall, upon the request of the Commission or another Member State, provide information on the register of procurement organisations and transplantation centres .

*Article 20*  
***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 21*  
***Exchange of organs with third countries***

1. Member States shall ensure that all exchanges of organs from or to third countries, are authorised by the competent authority.
2. Authorisations for exchanges of organs, as referred to in paragraph 1, shall only be granted if the organs:
  - (a) can be traced from the donor to the recipient and vice versa;
  - (b) meet quality and safety requirements equivalent to the ones laid down in this Directive.

*Article 22*  
***European organ exchange organisations***

Member States may establish written agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in this Directive, delegating to them:

- (a) the performance of activities provided for under the national quality programmes;
- (b) the granting of authorisation and specific tasks in relation to the exchanges of organs to and from Member States and third countries.

**CHAPTER VI**  
**GENERAL PROVISIONS**

*Article 23*  
***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 24*  
***Penalties***

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

*Article 25*  
***Implementing measures***

1. Detailed rules for the following measures shall be adopted in accordance with the procedure referred to in Article 26(3):
  - (a) rules for the updating and transmission of information on human organs characterisation as detailed in the Annex;
  - (b) procedures for ensuring the full traceability of organs, including labelling requirements;

- (c) procedures for ensuring the reporting of serious adverse events and reactions.
2. Detailed rules for the uniform implementation of this Directive, and in particular for the following measures, shall be adopted in accordance with the procedure referred to in Article 26(2):
- (a) the interconnection between the reporting systems on adverse events and reactions referred to in Article 11 (3);
  - (b) the establishment and functioning of the network of the competent authorities referred to in Article 20.

*Article 26*  
**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.
3. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 27*  
**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 communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

## CHAPTER VII FINAL PROVISIONS

### *Article 28* *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 29* *Addresses*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*



## ANNEX

### ORGAN AND DONOR CHARACTERISATION

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

CATEGORY	SUB-CATEGORY	ITEM	ACRONYM
GENERAL DATA		Donor identification	
		hospital	
		local coordinator/contact person	
DONOR DATA		donor type*	
		date of birth	
		age	
		gender	
		weight	
		height	
		chest perimeter (if required)	
		abdomen perimeter (if required)	
		ABO group	
		HLA (if required)	
		Cause of death	
		Date of death	
ICU ADMISSION		Date and time of ICU (intensive care units)	
		Date and time of intubation	
DONOR MEDICAL HISTORY (general description)		neoplasia	
		Indicate all relevant nephro-, hepato- cardio-, pneumo-, pancreato- and neuropathology as well as relevant previous operations, traumata or parasitic diseases	
		diabetes	

		Hypertension	
		alcohol	
		smoking	
		drugs	
PHYSICAL / CLINICAL DATA		Blood pressure	
		Hypotension (duration)	
		Body temperature	
		Diuresis (last 24 hours)	
		Diuresis last hour	
		Cardiorespiratory reanimation (if relevant) (duration)	
		Heart rate	
LABORATORY		Date time values	
	HEMATOLOGY	Prothrombine	PT
		White blood cell count	WBC
		platelettes	
		haemoglobin	Hb
		Haematocrit	PCV
	BIOCHEMISTRY	Na+	
		K+	
		Alk. Phos. (liver)	AP
		Glucose	
		Bilirubine Tot_Dir (liver)	
		Amylase or Lipase(Pancreas)	
		Glut oxalacetic trans(GOT).	AST
		Glut pyruvic trans (GPT).	ALT
		Gamma glutamil trans(GGT). (liver)	GGT
		Creatinine	

		Troponine (Heart)	
		Urea (For Kidney transplantation)	BUN
		LDH	
		TOTAL Protein (highly recommended)	
		Albumin (highly recommended)	
	MICROBIOLOGY  (This information could be available after transplantation)	blood culture (highly recommended at the time of procurement)	
		urine culture (highly recommended at the time of procurement)	
		tracheal secretions (highly recommended at the time of procurement)	
	SEROLOGY	HIV 1-2	
		HBsAg	
		AntiHbc (highly recommended)	
		HCV	
		Anti CMV IgG (recommended)	
		Anti CMV IgM (recommended)	
		Syphilis	
		HTLV I II (for donors living in, or originating from high incidence areas, or with risk factors of been exposed to the virus)	
	URINE	Glucose (yes/no)	
		Protein (yes/no)	
DIAGNOSTICS		Abdominal echography (if required)	
		Chest X Ray	
		ECG	
		Cardiac ECHO (heart)	

BLOOD GAS AND VENTILATION		FiO2 %	
		PEEP	
		PaO2 (with indicated FiO2)	
		PaCO2 (with indicated FiO2)	
		PH	
		HCO3	
		Sat O2	
		FiO2 1,0 / PEEP 5 (lung)	
		PaO2 (lung) with FiO2 1,0 / PEEP 5 (lung)	
		PaCO2 (lung) with FiO2 1,0 / PEEP 5 (lung)	
THERAPY (general description)		Antibiotics	
		Diuretics	
		Inotropic support (Adrenaline, Noradrenaline, Dobutamine, Dopamine...)	
		Blood transfusion	
		Other medication	

**LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS HAVING A  
BUDGETARY IMPACT EXCLUSIVELY LIMITED TO THE REVENUE SIDE**

**1. NAME OF THE PROPOSAL:**

Proposal for a Directive setting standards of quality and safety of human organs intended for transplantation.

**2. ABM / ABB FRAMEWORK**

Public health

**3. BUDGET LINES**

**3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B.A lines)) including headings:**

XX0101: for the payment of the officials

XX010211: for the payment of the committee costs

**3.2. Duration of the action and of the financial impact:**

From 2009, duration not defined

This budget intends to cover the costs of the future Regulatory Committee (comitology) and Network (Competent Authorities meeting) on organ donation and transplantation that will be set up according to the provisions of the Directive after the adoption of that Directive by the Parliament and the Council:

2 FTE administrator valued at €122,000 each (according to the specific Guidelines), to support the transposition and comitology processes.

Costs of the plenary session (first CA meeting), with one participant from each of the 27 Member States. 3 meetings scheduled per year (first 2 years after adoption), valued at €20,000 each; this number will diminish from 3 meetings per/year to 2 and then to 1 per/year. Actual costs of the meetings and frequency of those meetings might need revision, depending on the final shape of the directive, after adoption by council and parliament, and the necessary comitology structures. Moreover 3 comitology meetings per year should be calculated at a cost of €20,000 each.

**3.3. Budgetary characteristics:**

Budget line	Type of expenditure	New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
-------------	---------------------	-----	-------------------	--	----------------------------------

XX 0101	Comp	Non-diff <sup>17</sup>	NO	NO	NO	5
XX 010211	Non com	Non-diff <sup>18</sup>	NO	NO	NO	5

#### 4. SUMMARY OF RESOURCES

##### 4.1. Financial Resources

##### 4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2009	2010	2011	2012	2013	Total 2009-2013	2014 and later
------------------	-------------	--	------	------	------	------	------	-----------------	----------------

##### Operational expenditure<sup>19</sup>

Commitment Appropriations (CA)	8.1.	a							
Payment Appropriations (PA)		b							

##### Administrative expenditure within reference amount<sup>20</sup>

Technical & administrative assistance (NDA)	8.2.4.	c							
---	--------	---	--	--	--	--	--	--	--

##### TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c							
Payment Appropriations		b+c							

##### Administrative expenditure not included in reference amount<sup>21</sup>

Human resources and associated expenditure (NDA)	8.2.5.	d	0.244	0.244	0.244	0.244	0.244	1.220	0.244
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0.120	0.120	0.100	0.100	0.080	0.420	0.080

<sup>17</sup> Non-differentiated appropriations hereafter referred to as NDA.  
<sup>18</sup> Non-differentiated appropriations hereafter referred to as NDA.  
<sup>19</sup> Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.  
<sup>20</sup> Expenditure within article xx 01 04 of Title xx.  
<sup>21</sup> Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

**Total indicative financial cost of intervention**

<b>TOTAL CA including cost of Human Resources</b>	a+c +d+ e	0.364	0.364	0.344	0.344	0.324	1.640	0.324
<b>TOTAL PA including cost of Human Resources</b>	b+c +d+ e	0.364	0.364	0.344	0.344	0.324	1.640	0.324

**Co-financing details: not applicable**

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

Co-financing body		Year 2009	2010	2011	2012	2013	Total 2009- 2013	2014 and later
.....	f							
<b>TOTAL CA including co-financing</b>	a+c +d+ e+f							

**4.1.2. Compatibility with Financial Programming**

- Proposal is compatible with existing financial programming.
- Proposal will entail reprogramming of the relevant heading in the financial perspective.
- Proposal may require application of the provisions of the Interinstitutional Agreement<sup>22</sup> (i.e. flexibility instrument or revision of the financial perspective).

**4.1.3. Financial impact on Revenue**

- Proposal has no financial implications on revenue
- Proposal has financial impact – the effect on revenue is as follows:

<sup>22</sup> See points 19 and 24 of the Interinstitutional agreement.

EUR million (to one decimal place)

		Prior to action [Year n-1]	Situation following action					
Budget line	Revenue		[Year 2009]	[+1]	[+2]	[+3]	[+4]	[+5] <sup>23</sup>
	<i>a) Revenue in absolute terms</i>							
	<i>b) Change in revenue</i>	$\Delta$						

**4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.**

**Annual requirements**

	Year 2009	2010	2011	2012	2013	2014 and later
Total number of human resources	2	2	2	2	2	2

**5. CHARACTERISTICS AND OBJECTIVES**

**5.1. Need to be met in the short or long term**

Not applicable.

**5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy**

Not applicable.

**5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework**

Not applicable.

**5.4. Method of Implementation (indicative)**

- Centralised Management*
  - directly by the Commission
  - indirectly by delegation to:
    - executive Agencies

<sup>23</sup> Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.



- bodies set up by the Communities as referred to in art. 185 of the Financial Regulation
- national public-sector bodies/bodies with public-service mission
- Shared or decentralised management
- with Member states
- with Third countries
- Joint management with international organisations (please specify)***

Relevant comments:

## **6. MONITORING AND EVALUATION**

### **6.1. Monitoring system**

Regular reporting of the working groups will be ensured and disseminated to the member States and Commission services.

### **6.2. Evaluation**

#### *6.2.1. Ex-ante evaluation*

Not applicable.

#### *6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)*

Not applicable.

#### *6.2.3. Terms and frequency of future evaluation*

An evaluation of the running of the working group will be done after 5 years.

## **7. ANTI-FRAUD MEASURES**

Not applicable.

## 8. DETAILS OF RESOURCES

### 8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year 2009		Year 2010		Year 2011		Year 2012		Year 2013		Year 2014 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 <sup>24</sup> .....																
<b>Action 1:</b>																
- - Output	N° meetings															
- Output 2																
<b>Action 2</b> .....																
- Output 1																
Sub-total Objective 1																
OPERATIONAL OBJECTIVE No.2 <sup>1</sup> .....																
<b>Action 1</b> .....																

<sup>24</sup>

As described under Section 5.3.

- Output 1																
Sub-total Objective 2																
OPERATIONAL OBJECTIVE No.n 1																
Sub-total Objective n																
<b>TOTAL COST</b>																

## 8.2. Administrative Expenditure

### 8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources ( <b>number of posts/FTEs</b> )					
		Year 2009	Year 2010	Year 2011	Year 2012	Year 2013	Year 2014
Officials or temporary staff <sup>25</sup> (XX 01 01)	A*/AD	2	2	2	2	2	2
	B*, C*/AST						
Staff financed <sup>26</sup> by art. XX 01 02							
Other staff <sup>27</sup> financed by art. XX 01 04/05							
<b>TOTAL</b>		2	2	2	2	2	2

### 8.2.2. Description of tasks deriving from the action

2 FTE administrators valued at € 122,000 each (according to the specific Guidelines), to support the transposition and comitology processes. Running of Regulatory Committee and Network (CA meetings) established in accordance with Article 26 and 20 respectively of this Directive and its potential working groups that will work on the implementation of the Directive.

### 8.2.3. Sources of human resources (statutory)

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment)
- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

<sup>25</sup> Cost of which is NOT covered by the reference amount.

<sup>26</sup> Cost of which is NOT covered by the reference amount.

<sup>27</sup> Cost of which is included within the reference amount.

8.2.4. *Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)*

EUR million (to 3 decimal places)

Budget line (number and heading)	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013	Total 2009- 2013	2014 and later
<b>1 Technical and administrative assistance (including related staff costs)</b>							
Executive agencies <sup>28</sup>							
Other technical and administrative assistance							
- <i>intra muros</i>							
- <i>extra muros</i>							
<b>Total Technical and administrative assistance</b>							

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount*

EUR million (to 3 decimal places)

Type of human resources	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013	Year 2014 and later
Officials and temporary staff (XX 01 01)	0.244	0.244	0.244	0.244	0.244	0.244
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.)  (specify budget line)						
<b>Total cost of Human Resources and associated costs (NOT in reference amount)</b>	<b>0.244</b>	<b>0.244</b>	<b>0.244</b>	<b>0.244</b>	<b>0.244</b>	<b>0.244</b>

<sup>28</sup> Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

Calculation– *Officials and Temporary agents*

Rate of €122,000/ staff used to quantify the costs, as suggested in BUDG guidelines

Calculation– *Staff financed under art. XX 01 02*

[...]

8.2.6. *Other administrative expenditure not included in reference amount*

EUR million (to 3 decimal places)

	Year 2009	Year 2010	Year 2011	Year 2012	Year 2013	Total 2009- 2013	2014 and later
XX 01 02 11 01 – Missions							
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees <sup>29</sup>	0.120	0.120	0.100	0.100	0.080	0.420	0.080
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
<b>2 Total Other Management Expenditure (XX 01 02 11)</b>	0.120	0.120	0.100	0.100	0.080	0.420	0.080
<b>3 Other expenditure of an administrative nature</b> (specify including reference to budget line)							
<b>Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)</b>	0.120	0.120	0.100	0.100	0.080	0.420	0.080

<sup>29</sup> Specify the type of committee and the group to which it belongs.

Calculation - *Other administrative expenditure not included in reference amount*

Running of Regulatory Committee and Network (CA meetings) established in accordance with Article 23 and 19 respectively of this Directive and its potential working groups that will work on the implementation of the Directive

Costs of the plenary session (first CA meeting), with one participant from each of the 27 Member States. 3 meetings scheduled per year (first 2 years after adoption), valued at €20,000 each; this number will diminish from 3 meetings per/year to 2 and then to 1 per/year. Actual costs of the meetings and frequency of those meetings might need revision, depending on the final shape of the directive, after adoption by the Council and the Parliament. Moreover 3 comitology meeting per year should be calculated at a cost of €20,000.

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure in the light of budgetary constraints