

# **HUMAN ORGAN TRANSPLANTATION IN EUROPE: AN OVERVIEW**

**European Commission  
Directorate-General Health and Consumer Protection  
Public Health and Risk Assessment Directorate  
Unit C6 Health Measures**

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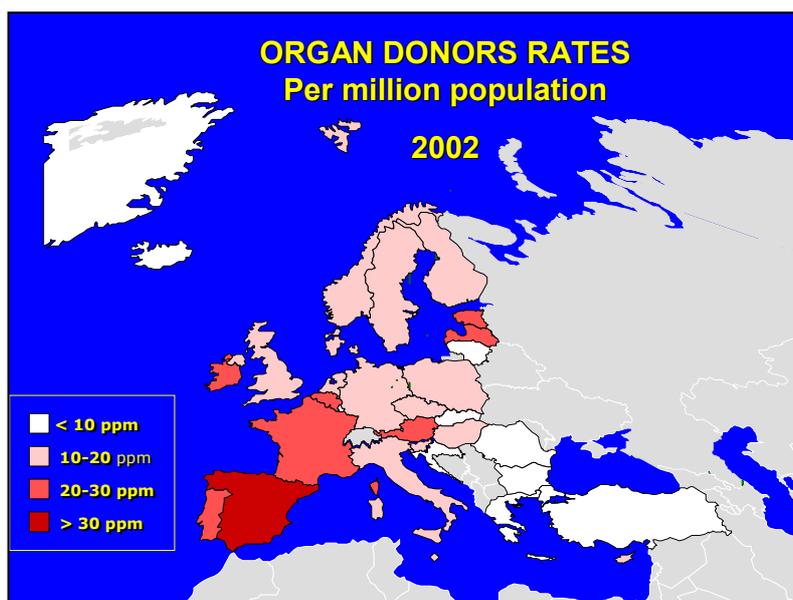
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## 1. INTRODUCTION AND METHODOLOGY

Human organ transplantation is the therapeutic use of human organs as a substitute for one that is non-functional. The organ may come from a deceased or a living donor. Today it is a common procedure used in medicine throughout the European Union. Transplantation not only provides the possibility of saving lives but also yields the best results in terms of quality of life for patients and the reduction of long-term health care costs. Transplantation in general has higher measurable quality indicators than other replacement therapies such as dialysis.

In spite of the fact that organ transplants have saved thousands of lives and greatly improved the quality of life of thousands more, regrettably many people will not benefit from this therapeutic procedure. The severe shortage of donors across all organ categories remains a major constraint facing the Member States in the European Union.

There are wide differences in the organ donor rate if we compare the European countries (fig 1). These differences cannot be explained by the differences in public attitude or mortality rates. Comparison of other causes especially in the legal field between EU Member States offers some insight into the differences.



To this end the European Commission conducted beginning in 2003 a survey on legal requirements related to organ transplantation in the 25 EU Member States as well as Bulgaria, Norway, Romania and Turkey. The survey was intended to collect information on the legal framework related to ethical, organisational and technical aspects in the field of organ transplantation. The results of this survey are presented in this report.

## 1.1. Methodology

In cooperation with a group of international experts, the Commission elaborated the survey questionnaire. The questionnaire, detailed instructions for its use and a third document with the purpose to invite any additional comment or clarification, were developed by the group.

The three documents were sent in June 2003 to the permanent rep health attachés in Brussels (acting as focal points) and to national experts (list attached).

The questionnaire covers:

- (1) General legal framework
  - Protection of the donor and the recipient
  - Living Donor
  - Deceased Donor
  - Authorisation for transplantation procedures
  
- (2) Legal Framework on organisational aspects
  - Characteristics of the organ exchange organisation
  - Organ allocation criteria
  - Waiting list organisation
  
- (3) Legal Framework in technical aspects
  - Donor Selection Criteria
  - Laboratory test required for donors
  - Tumours markets required
  - Regulation of the procedures

Three terms were defined to categorise the answers:

- (L) 'Legally binding' means that there is a legal obligation to comply with such provisions.
- (G) Guidelines or recommendations suggest good practice for professionals but are not a legal obligation.
- (N) Not regulated by law nor mentioned in guidelines or recommendations.

## 2. RESULTS

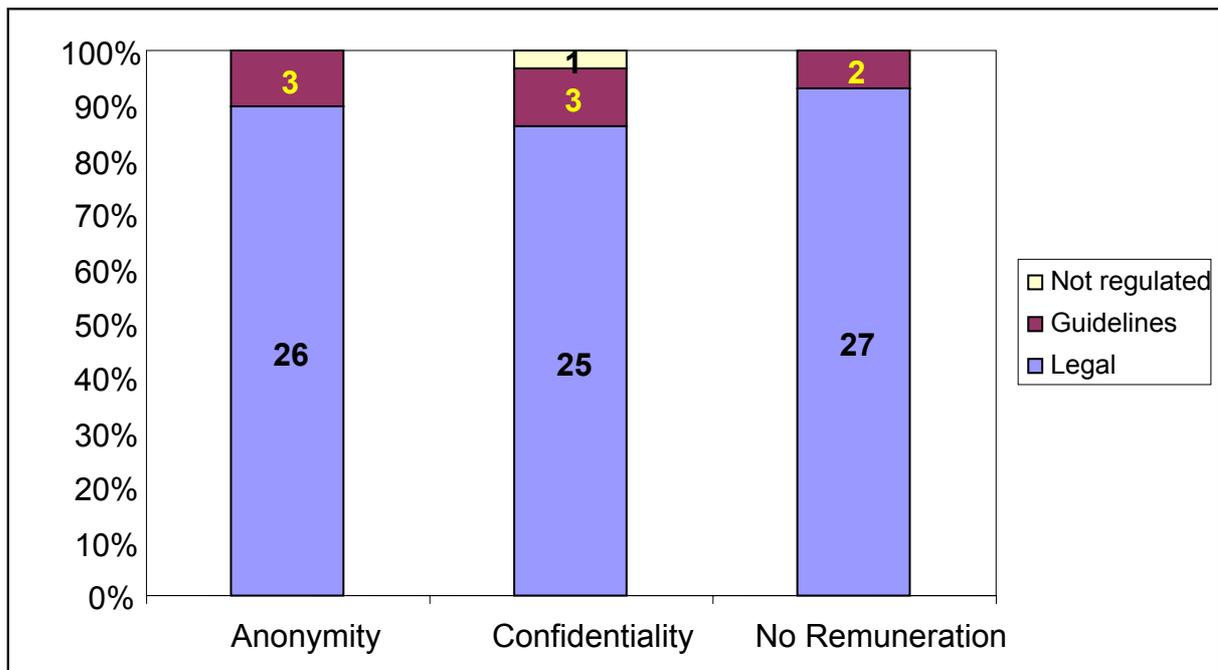
### 2.1. General legal framework

#### 2.1.1. Protection of the donor

Most of the Member States that responded have legislation to protect the donor in respect of: (figure 1)

- **anonymity** (measures ensuring that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa),
- **confidentiality** (measures ensuring that all data collated, including genetic information, have been rendered anonymous so that the donor and the recipient are no longer identifiable) and
- **non remuneration** for the donation (measures preventing organ trade or trafficking).

Figure 1. Legislation for protection of the donor



There are laws in place covering the therapeutic use of organs in 27 countries, where they are legally binding and in two where they are as technical guidelines. In 22 of the countries surveyed, there are also legally binding requirements when the final use of the organs is for research purposes.

### 2.1.2. *The Living donor*

The consent of the living donor is regulated by law in most of the countries.

The consent for living donations to genetically-related recipients is regulated by law in 26 countries. In two it is included in guidelines or recommendations that professionals should follow, but this requirement is not enforceable by law. In one country it is simply not authorised.

In all 26 Member States where there are legal requirements, informed consent is imperative. Legally binding written consent is required in 16 countries. In ten countries a witnessed official ‘body’ is required and in 3 of them this witnessed body has to be the court.

Living donations to other relatives (not genetically related) is not authorised in three countries. There is missing information for two countries and in 23 it is regulated by law. In 22 of them written consent is necessary, in 9 a witnessed official body is required and in 3 of them this witnessed body has to be the court.

Living donors unable to consent legally (minors or others who are incapacitated) are excluded from donation by law in 18 countries. Three countries give legal authorisation for these types of donors if permission is given by parents or guardians. Three other countries give this authorisation only if in addition to such consent it is an emergency situation. In a remaining four countries, it is only authorised under specific circumstances and with the previous authorisation of a court.

Medical examination to evaluate the suitability of the donor is required by law in 21 of the countries and in another seven it is indicated in the technical guidelines. Nine countries include psychological evaluation as binding criteria for the assessment of the donor. It is included in technical guidelines in ten more countries.

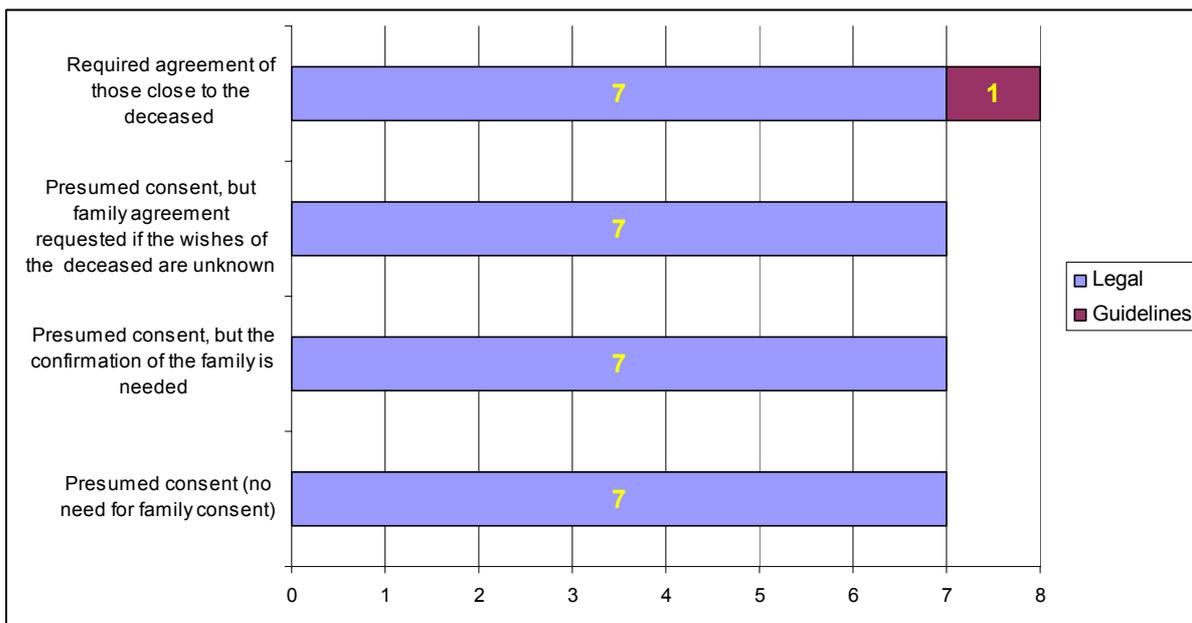
Eighteen countries include a legal provision indicating that the living donor is able to withdraw the consent at any time.

### 2.1.3. *The deceased donor*

In 28 countries the consent for a donation from the deceased donor is embedded in a binding law. Only in one is it organised through guidelines.

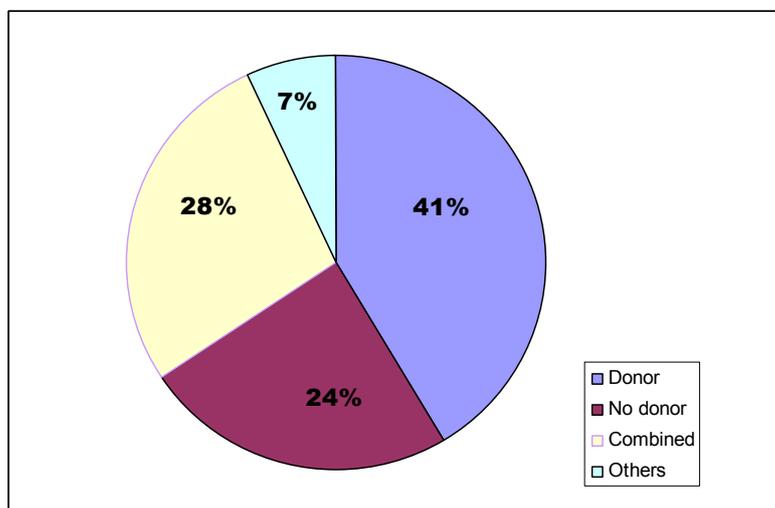
Figure 2 illustrates four forms of consent that are found among the countries surveyed. (The bars represent number of countries)

Figure 2. Type of consent



Most of the countries (20) have a donor register in place; in 16 the existence of these registers is compulsory by law. There are different types of registers: dedicated registers of donors, non-donors, combined and other types such as a register of inhabitants that incorporates also the information about the willingness – or not - to donate or other kind of registers such as driving license or donor cards. See figure 3.

Figure 3. Registers

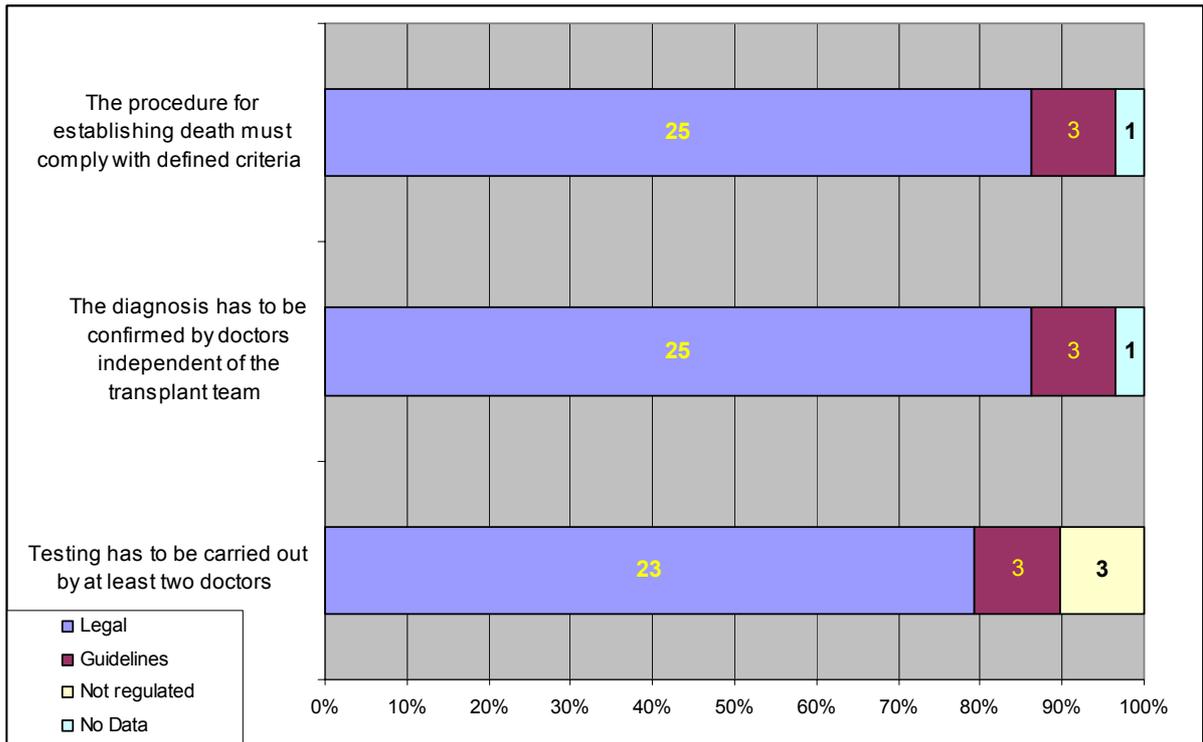


## 2.2. Establishing death

Of the countries surveyed, 86% (25) have binding legislation in place establishing a definition of brain death, three more have technical guidelines with definitions.

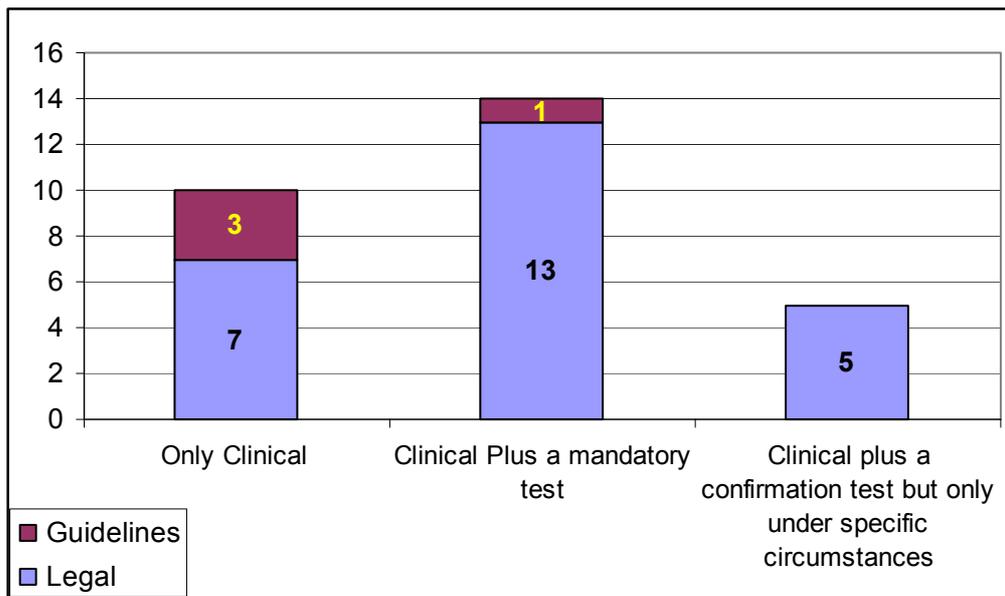
Figure 4 indicates the number of countries which follow different criteria of diagnosing brain death.

Figure 4. Procedures for diagnosis of brain death.



As to which criteria are needed in the different countries for diagnosing brain death, differences are in evidence as indicated in figure 5 (the bars indicate the number of countries):

Figure 5. Criteria for diagnosis of brain death



The number of doctors that have to confirm brain death also varies between the countries; in 10 two doctors have to sign the certificate, in another 10 the number of doctors needed is three, while 8 countries require only one doctor and in one country four doctors are required.

The situation is different regarding a binding definition of death in non-heart beating donors. Only 45% (13) of the countries have this definition in their legislation and five more in technical guidelines.

### 2.3. Authorisation for transplantation procedures

The following figures show the requirements in the different countries in relation with the authorisation of organ procurement (figure 6), organ transplantation (figure 7), and organ exchange and organ importation and exportation (figure 8). The bars indicate the number of countries.

Figure 6. Organ Procurement

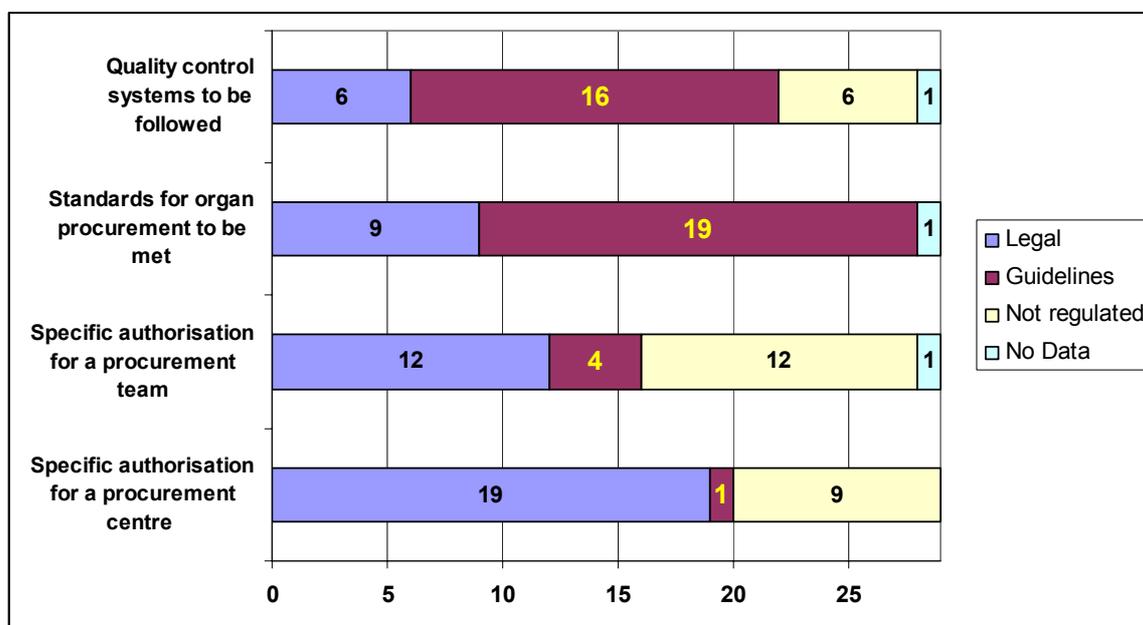


Figure 7. Organ transplantation

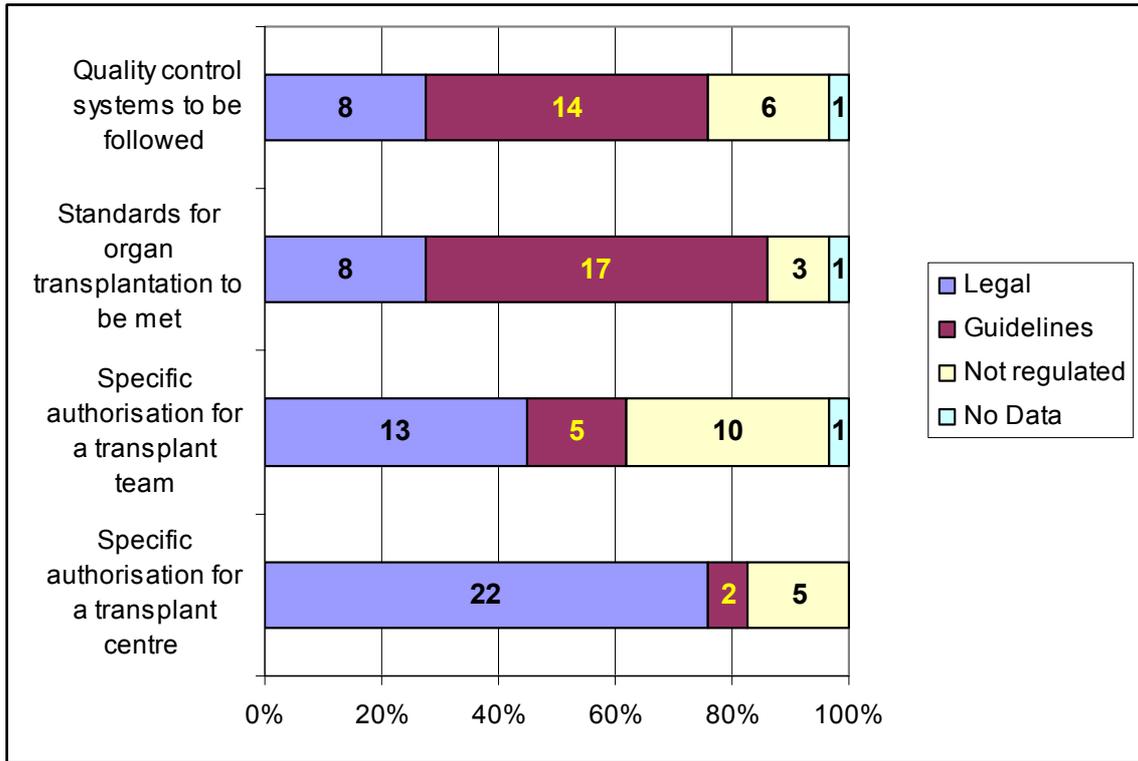
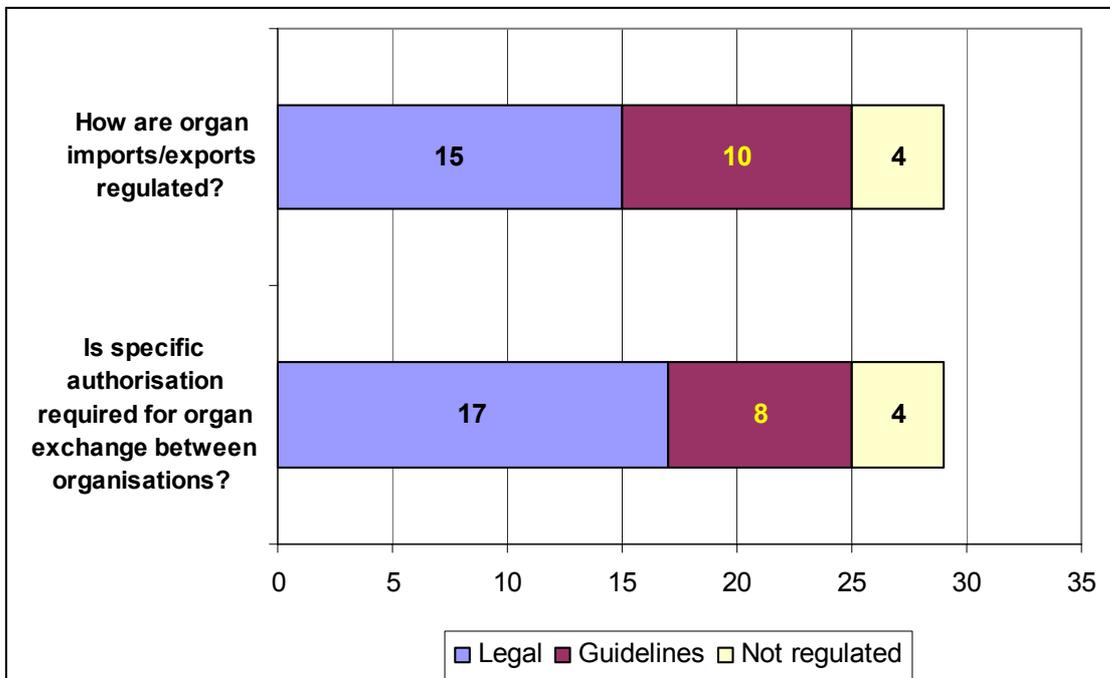


Figure 8. Exchanges and import/export



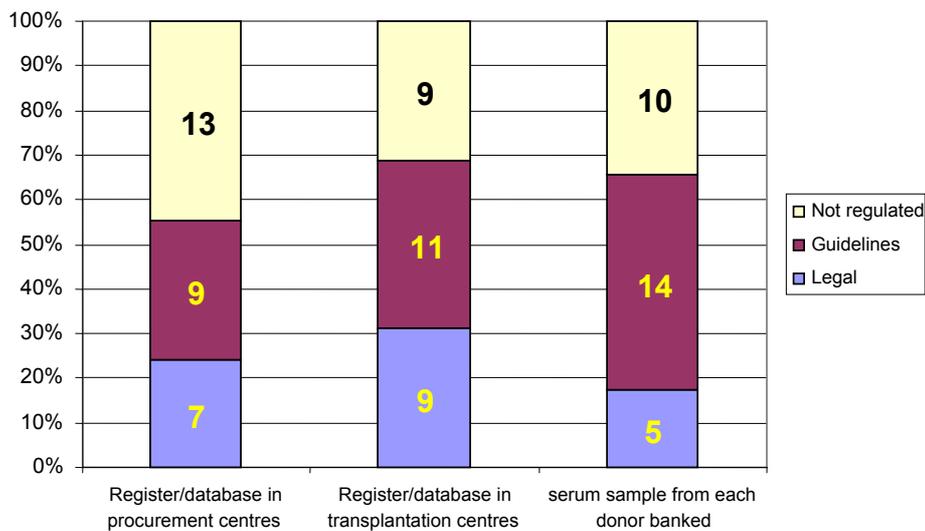
## 2.4. Organ traceability

Twenty-five of the countries surveyed have a national register containing data on the origin and destination of the organs; in 18 of these countries this register is legally binding.

From the countries where a register is in place, 15 have binding rules on restricted access and confidentiality.

The percentage of countries with registers in place in the different settings (procurement sites and transplantation centres) is also indicated in figure (11) It is also indicated the percentage of countries having binding rules for serum samples banked for each donor.

Figure 9



Only in 8 countries is there a binding official mechanism for reporting of serious adverse events. In 12 more the system is driven by guidelines.

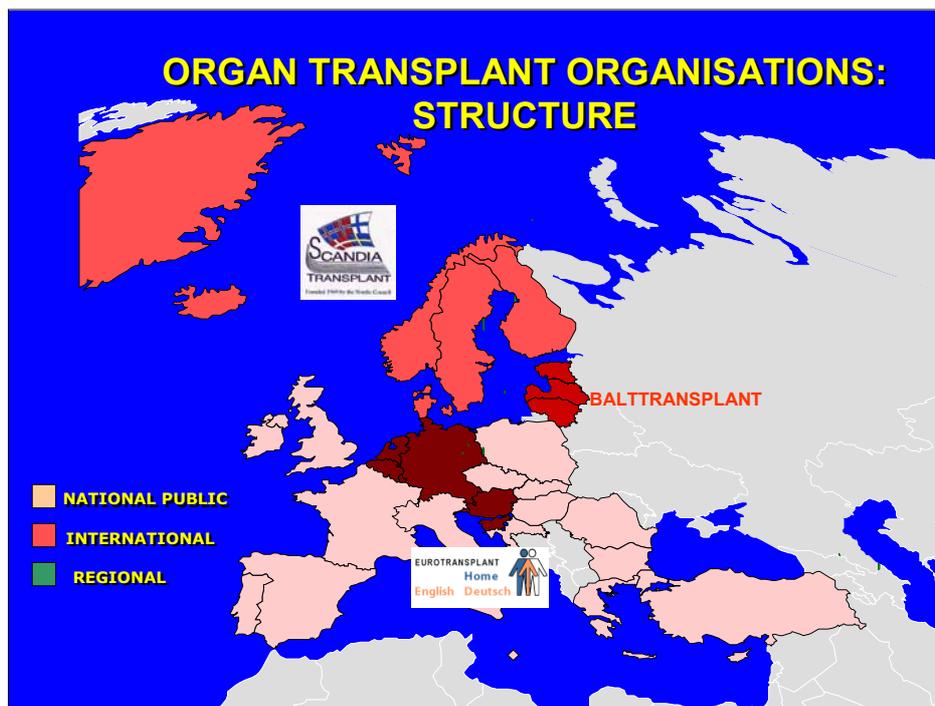
## 2.5. General conclusions regarding the general legal framework

- A high percentage of countries have binding legislation in place on general ethical principles for the protection of the donor
- There is wide variability in the legal procedures related to donor consent, for living and deceased donors.
- There are discrepancies in the way of establishing brain death (criteria, number of doctors) and a low percentage of countries with a binding law for non-heart-beating donors.
- Binding authorisation for Organ procurement and Transplantation procedures is not required in a significant number of European Countries.
- Binding legislation on traceability and notification of adverse reactions is not in place in at least one third of the Countries surveyed.

### 3. ORGANISATIONAL ASPECTS

Most of the 29 countries surveyed have a national public body (25) in charge of the organ transplantation / organ exchange. Some countries (3) have also this type of structure decentralised in regional bodies. Others (14) have in addition an international organisation in charge of some of the functions.

The main European organisations identified are presented below.



The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia. In this international collaborative framework, the participants include all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place. The Eurotransplant region numbers well over 118 million inhabitants.

Scandiarttransplant is a Nordic organ exchange organisation which covers a population of 24 million inhabitants in five countries. According to its by-laws, the purpose of the association is fourfold: (1) Scandiarttransplant shall effect the exchange of organs and tissue between the participating transplant centres; (2) It shall operate a database and communicate information from it; (3) It shall contribute to promoting the provision of human organs and tissue for transplantation; (4) It shall support scientific activities. Scandiarttransplant was founded in 1969 on the initiative of Nordic pioneers within the organ transplantation field.

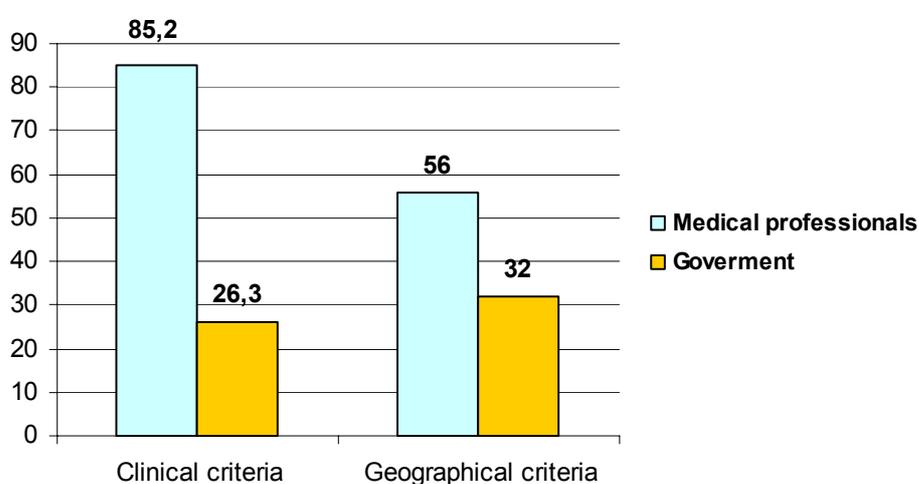
Two other organisation could be considered as having an international scope: Baltransplant, an NGO operating in Estonia, Latvia and Lithuania, and UK Transplant which extends its scope to Ireland.

The specific activities of the national organisations are briefly described in the country reports.

Most of the organ transplantation organisations are also in charge of the activities of human tissues (82% of them) and in a low percentage (57%) they also deal with haematopoietic progenitors.

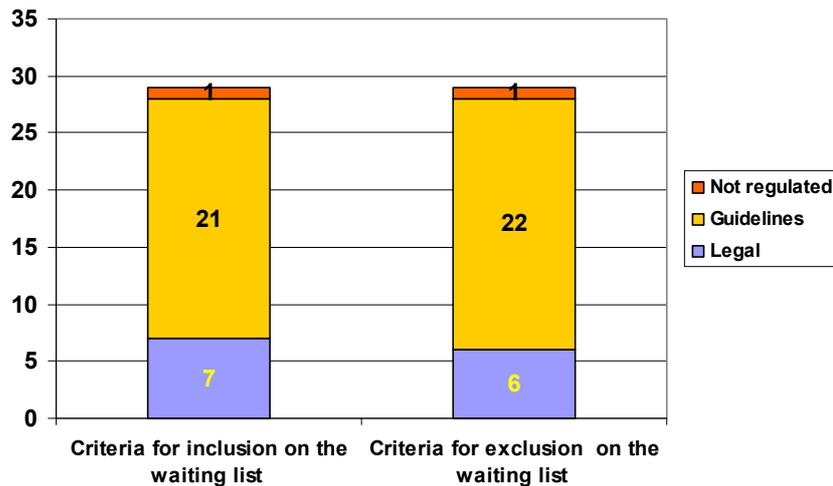
In 17 of the countries surveyed, the allocation criteria for organs are legally binding. There are two general types of criteria: geographical and clinical. The majority of the countries where information is available (we do not have information on this in 10 countries) use a combination of these two types (12 countries). In five countries the criteria are only clinical and in two only geographical criteria are used. The responsibility of establishing the allocation criteria is distributed as indicated in figure 10 (percentage of countries):

**Figure 10 Responsibility for establishing allocation criteria**



These criteria are public in most of the countries (26) (in one country data are not available). Also in most of the countries the organ transplantation organisation is responsible for monitoring compliance with these criteria (26). Changes in the allocation criteria are permitted in most of the countries (21), these changes are based in 72% of the countries on the probability of the transplant for different groups of patients (depending in the age, blood group, place at resident, etc...)

The inclusion and exclusion criteria for waiting lists are governed mainly through technical guidelines, with only few countries having binding criteria, as is shown in figure 11:



**Figure 11 Criteria for inclusion/exclusion in the waiting list**

### General conclusions regarding the legal organisational aspects

1. The majority of countries have in place a public body in charge of organ transplantation. In most cases, this body is also in charge of tissues and cells, and in more than 50% of them deal with haematopoietic progenitor cells.
2. Many countries are grouped in larger organisations, mainly in the area of organ exchange and allocation.
3. Seventeen countries have in place binding allocation criteria with clinical and geographical considerations taken into account for their elaboration.
4. The criteria for inclusion / exclusion in waiting lists are, in the majority of countries, governed through professional guidelines.

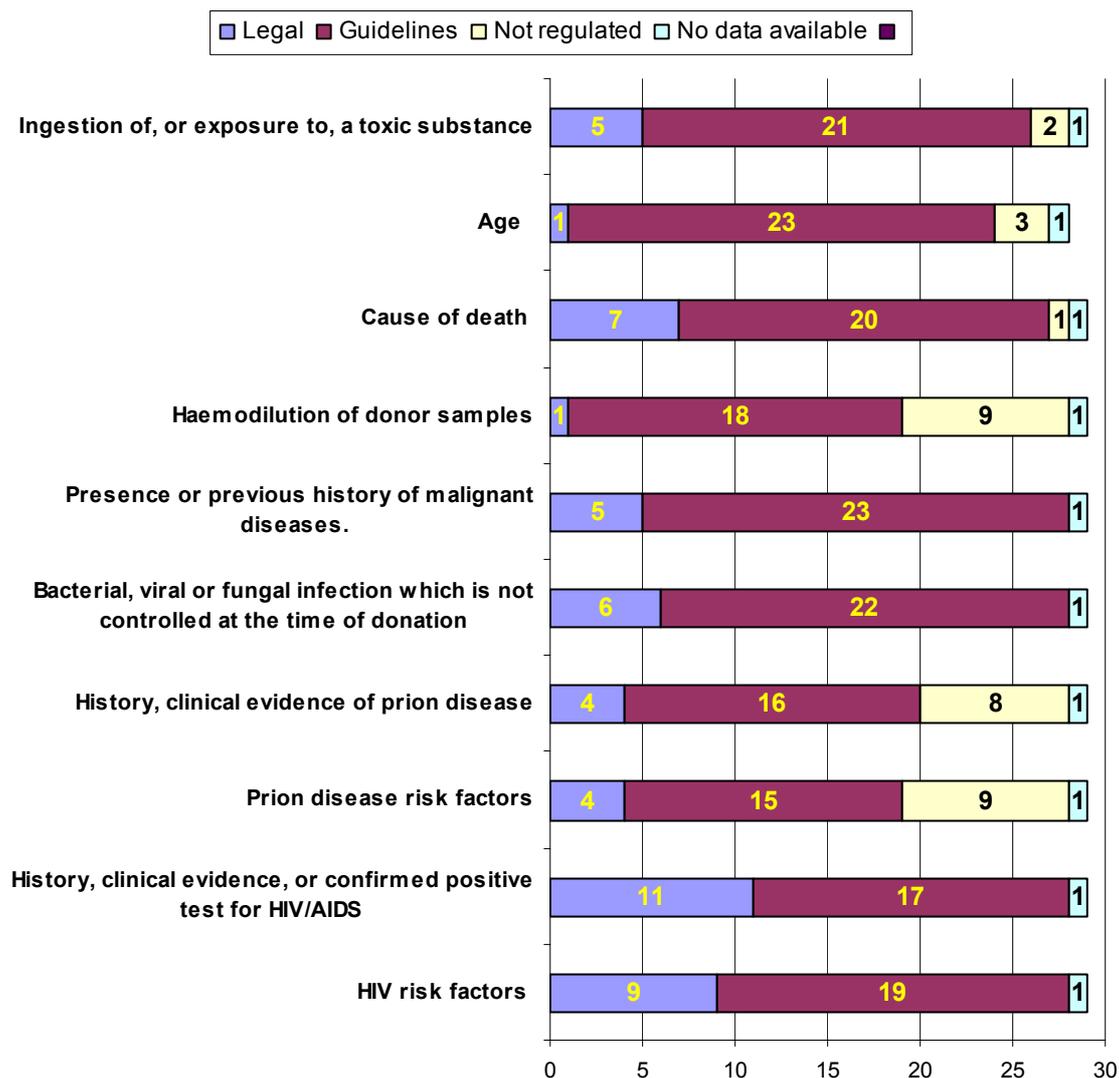
## 4. TECHNICAL ASPECTS

### 4.1. Donor selection criteria

The criteria for cadaver organ selection are regulated by technical guidelines in most countries (23) with only nine having binding selection criteria in place. For the living donor, 13 countries have binding criteria and 15 more have technical guidelines.

Figure 12 shows the different factors included in the risk assessment in the different countries, and how they are regulated (binding requirements, technical guidelines or not regulated).

**Figure 12 Risk assessment criteria**



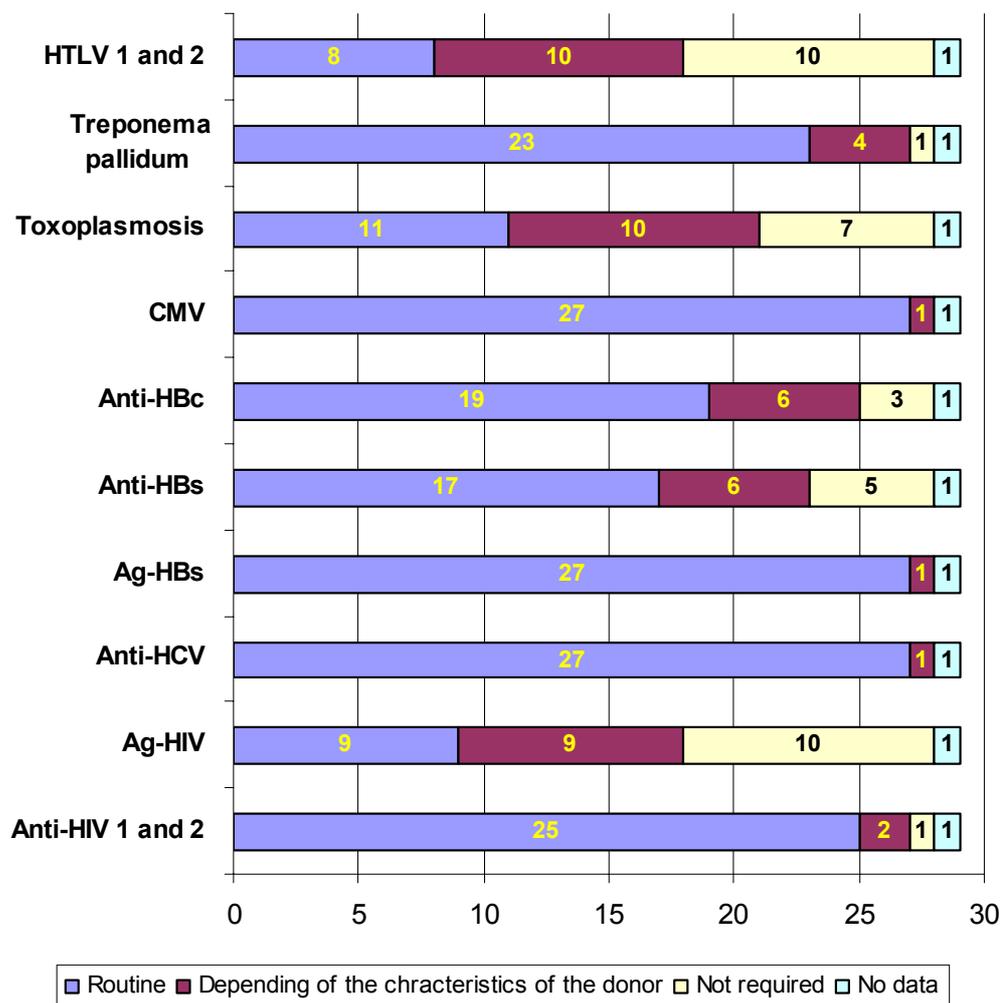
Most of the risk assessment is governed by technical guidelines. With the exception of haemodilution of donor samples and prion diseases, where a considerable proportion of countries do not have any kind of law / guidelines in place, evaluation of the different criteria in the risk assessment are covered in technical guidelines in most of the countries surveyed.

The use of authorised laboratories for carrying out the different tests is a binding requirement in 10 countries, although 15 more include this recommendation in technical guidelines.

The use of authorised tests for testing the donors is a binding requirement only in seven of the countries surveyed. However, 17 more include this provision in technical guidelines.

The following figure 13 shows the biological tests used in the countries and indicates whether these tests are carried out on a routine basis or depending on donor characteristics. (Bars indicate the number of countries)

**Figure 13 Biological tests**



As the figure shows, there is consensus in the use of a number of tests (Anti HIV, Anti HCV, Ag-Hbs or Treponema Pallidum), however this does not apply for some other tests (HTLV, Toxoplasmosis or Ag-HIV).

With respect to tumour markers carried out for donor evaluation, the following figure 14 shows the different practices in the countries surveyed. There is wide heterogeneity, but the results show clearly that few countries carry out these tests on a routine basis.

**Figure 14 Tumour markets**

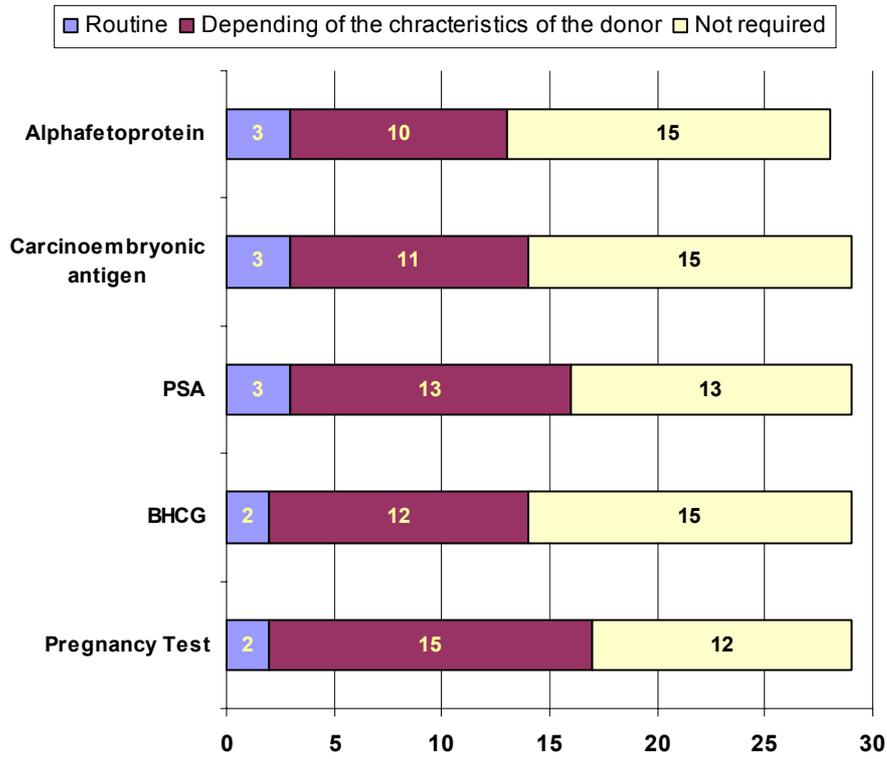
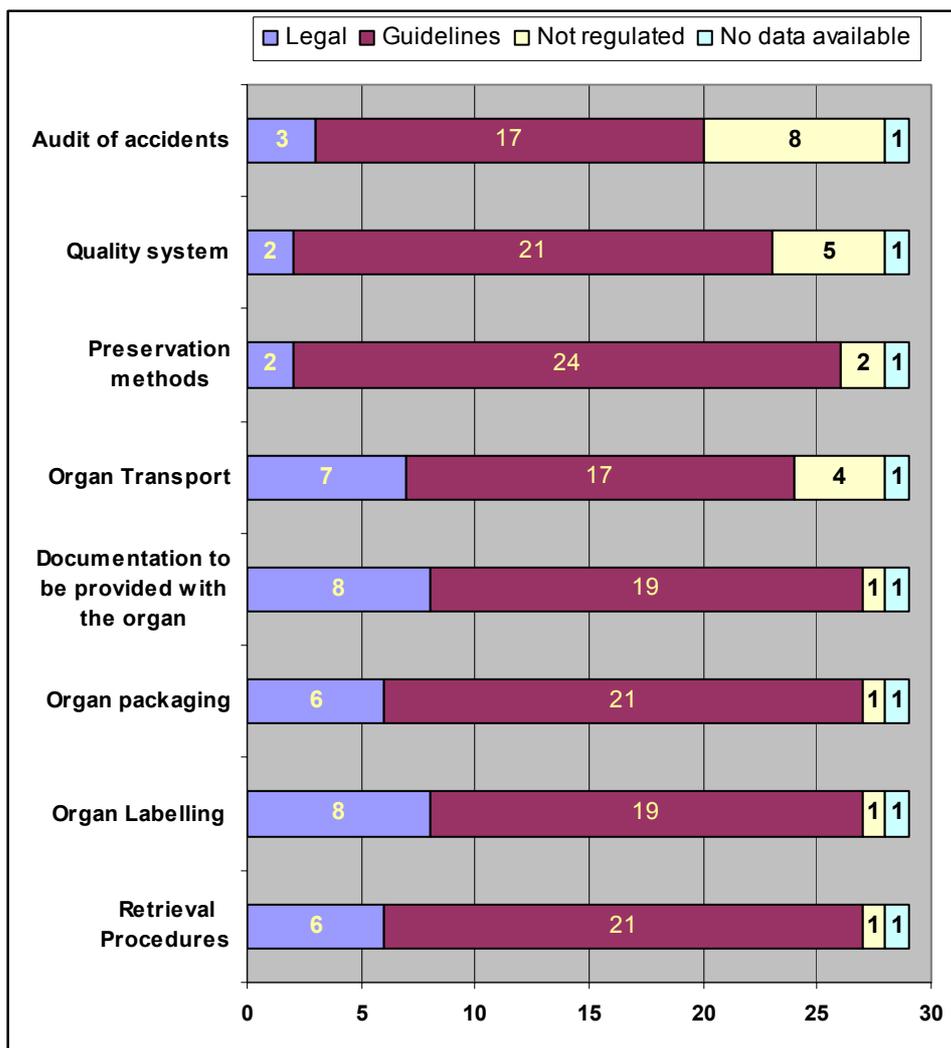


Figure15 shows the different procedures for the retrieval of the organs, their packaging, labelling, preservation and transport, as well as how the documentation to be provided with the organ, the quality systems and the audit of accidents are regulated. It is clear that in the majority of countries (bars represent countries) these procedures are governed by technical guidelines:

**Figure 15 Organ transplantation procedures**



#### 4.2. Some considerations on the general requirements on technical aspects

1. Donor selection criteria are established in the majority of countries through professionals guidelines.
2. The components of the risk assessment of the donor are also part of medical guidelines. The survey has shown discrepancies in some practices (i.e. haemodilution or prion diseases) within the European countries.
3. It is also possible to recognise discrepancies in the serological tests used in donors and in the detection of tumour markers.
4. Binding authorised tests or laboratories are only required in less than 40% of the countries.
5. The procedures related to organ transplantation are regulated mainly through scientific guidelines and not through binding legislation.

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