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**STEERING COMMITTEE ON BIOETHICS (CDBI)
EUROPEAN HEALTH COMMITTEE (CDSP)**

**Replies to the questionnaire for member states
on organ trafficking**

The Secretary General of the Council of Europe, in the light of concerns expressed about organ trafficking, in particular by the Parliamentary Assembly, sent a questionnaire in May 2002 to the Council of Europe member states concerning aspects of their law and practice that may be relevant to organ trafficking for the purposes of transplantation. This document contains an analysis of the responses of the 40 member states that replied.

Replies to the questionnaire for member states on organ trafficking

Index:

NS (Not Specified) signifies that a “yes” or “no” answer to the specific question was not given though some additional comments may have been submitted (included as a footnote).

When neither the question nor the answer were mentioned, the box was left blank.

* corresponds to a footnote at the bottom of the table.

A slash (/) signifies that no response was necessary, i.e. that an answer would have been meaningless.

“the former Y R M” means the former Yugoslav Republic of Macedonia.

B/H means Bosnia & Herzegovina.

The language of the replies to the questionnaire:

Country	English	French	Country	English	French
Albania	translation	Yes	Latvia	Yes	translation
Andorra			Liechtenstein		
Armenia	Yes	translation	Lithuania	Yes	translation
Austria	Yes	translation	Luxembourg	translation	Yes
Azerbaijan	Yes	translation	the former YRM	Yes	translation
Belgium	translation	Yes	Malta	Yes	translation
B/H			Moldova		
Bulgaria	Yes	translation	Netherlands	Yes	translation
Croatia	Yes	translation	Norway	Yes	translation
Cyprus	Yes	translation	Poland	translation	Yes
Czech Rep.	Yes	translation	Portugal	translation	Yes
Denmark	Yes	translation	Romania	translation	Yes
Estonia	Yes	translation	Russia	Yes	translation
Finland	Yes	translation	San Marino	translation	Yes
France	translation	Yes	Slovakia	Yes	translation
Georgia	Yes	translation	Slovenia	Yes	translation
Germany	Yes	translation	Spain	Yes	translation
Greece	Yes	translation	Sweden	Yes	translation
Hungary	Yes	translation	Switzerland	translation	Yes
Iceland	Yes	translation	Turkey	Yes	translation
Ireland	Yes	translation	Ukraine	Yes	translation
Italy	translation	Yes	United Kingdom	Yes	translation

I. Prevention of Organ Trafficking

A. Legal instruments

1. Does your State allow organ donation by living donor? (y/n)
 (Answers. Yes: 38 No: 1 Not Specified: 1)

Country	Rep.	Country	Rep.
Albania	Yes	Latvia	Yes
Andorra		Liechtenstein	
Armenia	Yes	Lithuania	Yes
Austria	Yes	Luxembourg	Yes
Azerbaijan	Yes	the former Y R M	Yes*
Belgium	Yes*	Malta	Yes*
B/H		Moldova	
Bulgaria	Yes*	Netherlands	Yes
Croatia	Yes	Norway	Yes*
Cyprus	Yes	Poland	Yes
Czech Rep.	Yes*	Portugal	Yes*
Denmark	Yes	Romania	Yes
Estonia	Yes	Russia	Yes*
Finland	Yes	San Marino	No*
France	Yes	Slovakia	Yes
Georgia	Yes	Slovenia	Yes*
Germany	Yes	Spain	Yes
Greece	NS*	Sweden	Yes
Hungary	Yes	Switzerland	Yes
Iceland	Yes	Turkey	Yes
Ireland	Yes	Ukraine	Yes
Italy	Yes*	United Kingdom	Yes

Belgium:

Yes, under certain conditions.

Bulgaria:

Yes. This issue is regulated by the National Health Act (NHA) Article 33, Article 33a, and Article 35.

Czech Republic:

Yes; it does.

Greece:

The conditions for organ donation by living donors are explicitly stated in article 10 of the transplantation law 2737/99 in force. In any case, organ donation is not allowed in the cases where the donors are minors, except for bone marrow transplants, where parental consent is required, and in the cases of compact organs, where the donation is allowed only to blood relatives of 1st or 2nd degree.

Italy:

No, the only exception is the donation of kidneys.

The former Yugoslav Republic of Macedonia:

Yes, if that doesn't destroy the donor's health, if donor is preliminary warned of an eventual danger and if the donor voluntarily has given a written consent.

Malta:

The only live organ transplantation is that of the kidney.

Norway:

Organs or other biological material may be removed from a living person on certain conditions. (Act no 6 of 9th February 1973 relating to transplantation, hospital autopsies and the donation of bodies etc.)

Portugal:

Yes. In accordance with Article 5, paragraph 1, of the law relating to the removal and the transplantation of organs and tissues of human origin (Law No. 12/93 of the 22.04.93), the donation of tissues or organs for therapeutic transplantations purposes is allowed (though it must not involve remuneration). Any commerce of tissues and organs is forbidden.

Russia:

Transplantation of organs removed from living donors is allowed in the Russian Federation, but only to the immediate family. As in those cases sales are prohibited, such a practice may be considered as donation.

San Marino:

The patients from San Marino needing the organ transplantation refer to Italian or European centers.

Slovenia:**National legislation and international agreements:**

The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act (Official Gazette of RS, Uradni list RS, no. 12/00)

The Health Activities Act (Official Gazette of RS, Uradni list RS, no. 9/92, 26/92, 45/94, 37/95, 8/96, 90/99, 98/99, 31/00, 36/00, 45/01)

Regulation on detailed requirements for carrying out removal and transplantation of human body parts (Official Gazette of SRS, Uradni list SRS, no. 21/86)

Directive on procedures and activities in the area of obtaining donors of human body parts for transplantation (Official Gazette of RS, Uradni list RS, no. 53/02)

Regulation on the composition, method of appointing and rules of functioning of the Ethics Commission for Transplantation (Official Gazette of RS, Uradni list RS, no. 30/02)

Regulation on the procedure of informing about the death of persons who may be considered as donors of human body parts for transplantation (Official Gazette of RS, Uradni list RS, no. 85/01)

Regulation on medical standards, method and procedure of establishing brain death and the composition of the commission for establishing brain death (Official Gazette of RS, Uradni list RS, no. 70/01)

Criminal Code of the Republic of Slovenia (Official Gazette of RS, Uradni list RS, no. 63/94)

Signed and Ratified Agreements and Protocols of the Council of Europe

Cooperation Agreement between Institute for Transplantation of Organs and Tissues of the Republic of Slovenia (Slovenia - Transplant) and Eurotransplant International Foundation (first signature September 1999, revision April 2002)

2. Does your State have legal provisions for regulating the transplantation of organs removed from living donor? (y/n)
 (Answers. Yes: 35 No: 2 Not Specified: 3)

Country	Rep.	Country	Rep.
Albania	Yes	Latvia	Yes*
Andorra		Liechtenstein	
Armenia	Yes	Lithuania	Yes
Austria	Yes*	Luxembourg	Yes
Azerbaijan	Yes	the former Y R M	Yes*
Belgium	Yes	Malta	NS*
B/H		Moldova	
Bulgaria	Yes*	Netherlands	Yes*
Croatia	NS	Norway	Yes*
Cyprus	Yes	Poland	Yes*
Czech Rep.	Yes*	Portugal	Yes*
Denmark	Yes	Romania	Yes*
Estonia	Yes	Russia	Yes*
Finland	Yes	San Marino	No*
France	Yes	Slovakia	Yes
Georgia	Yes	Slovenia	Yes
Germany	Yes*	Spain	Yes*
Greece	NS*	Sweden	Yes
Hungary	Yes	Switzerland	Yes*
Iceland	Yes	Turkey	Yes
Ireland	No	Ukraine	Yes
Italy	Yes*	United Kingdom	Yes*

Austria:

Yes, there are deductive legal provisions, but there is no law regulating directly the transplantation of organs removed from living donors.

Bulgaria:

Yes. The National Health Act, which was adopted in 1973, contains a legal provision that regulates organ transplantation from living donors. The Bulgarian legislation regulates the issue in principle in Articles 33, 33a of the NHA and in detail in Article 35. The issue is also treated in detail in the draft Act on the Transplantation of Organs, Tissues and Cells, which is to be adopted by the National Assembly.

Czech Republic:

Organ donation from living donor is a subject of regulation of Art. 3-9 (Section 1 of the II Title of Transplantation Act Nr. 285/2002Sb. – hereinafter referred as “TA”).

Germany:

Yes, the Transplantation Act (TPG) of 1997, amended in 2001.

Greece:

All cases are covered by the provisions of the aforementioned article.

Italy:

Law 458 from 26.06.67 relating to transplantation of kidneys.

Latvia:

A living person may, under certain conditions, consent to the removal of an organ or tissue for the purpose of implantation into another person. Live organ donation is currently confined primarily to kidneys. The transplantation of organs removed from a living donor takes place generally between persons having a close personal relationship (“Law on Protection of Dead Human Being and use of Human Organs and Tissues” (in force since 01.01.1993)).

The former Yugoslav Republic of Macedonia:

Yes, Official Gazette No from 07.06.1995.

Malta:

None at present. However the legal framework is currently being reviewed in order to be able to regulate such an activity.

The Netherlands:

Yes. The conditions for organ donation by living donors are explicitly stated in sections 3 up to and including article 8 of Act of 24 May 1996 regulating the donation of organs (Organ Donation Act).

Norway:

Act relating to transplantation, hospital autopsies and the donation of bodies etc.

Poland:

Yes. It is the Law of 26 October 1995 relating to the removal and transplantation of cells, tissues and organs. The aforementioned law is complemented by executive orders given by the Minister in charge of Health.

Portugal:

Yes. In accordance with Article 6 of the abovementioned Law, the removal of tissues from a living donor is only authorised if they are regenerative tissues. However, the removal from a living donor of non regenerative tissues or organs, with the view to a donation, is allowed when a family relationship exists between the donor and the recipient.

Furthermore, donations of non-regenerative tissues by minors or persons which do not have the capacity to consent are always forbidden. Similarly, donation is not allowed when there is a strong probability that the physical integrity and the health of the donor may be seriously and permanently diminished.

In conformity with Article 7, the physician must always inform, in a loyal, adequate and intelligible manner, the donor and the recipient of the possible risks, the consequences of the donation and the treatment and its side effects, in addition to the medical follow-up with which they would need to abide.

Romania:

Law No. 8 from 13th January 1998.

Russia:

Transplantation of organs removed from living donors is governed by the Law of the Russian Federation on the Transplantation of Human Organs and/or Tissues No. 1 of 22.12.1992, as amended in 2000, (hereinafter referred to as the " Law") and the Basic Legislation of the Russian Federation on Public Health of 22.07.1993 (hereinafter referred to as the "Basic Legislation").

In addition, certain issues relating to the removal of organs and tissues of human origin are governed by the provisions of the Federal Law on the Donorship of Blood and Its Components of June 9, 1993, No. 5142-1 and the Federal Law on Funeral and Burial Arrangements of January 12, 1996, No. 8-Φ3.

Criminal code of the Russian Federation that entered into force on January 1, 1997, was the first Russian legislative instrument to criminalize acts relating to the removal, transplantation of, and illegal trafficking in, organs and tissues of human origin.

Article 21 of the Constitution of the Russian Federation contains rules governing personal non-property relations which do not cease after the death of an individual. According to that article, the notion of personal dignity protected by the state presumes respect not only for the personality of the deceased, but also for his/her remains.

San Marino:

San Marinee patients who require an organ transplantation are referred to Italian or European centres.

Spain:

Yes. Royal Decree, number 2070, December 20th of 1999, regularizing the activities about clinical obtainment and utilization of human organs, and the territorial coordination of transplant and donation of organs and tissues.

Switzerland:

Yes, in several cantons (AG, BL, FR, GE, NE, SO, TI, VS). At the present moment, a new federal law is being drafted which will regulate the transplantation of organs taken from living donors.

United Kingdom:

The Human Organ Transplants Act 1989.

3. Does the removal from a living donor require authorisation? (y/n)

(Answers. Yes: 29 No: 4 Not Specified: 7)

If so,

- a. what form does this authorisation take?
- b. what are the criteria?

Country	Rep.	Country	Rep.
Albania	No	Latvia	Yes*
Andorra		Liechtenstein	
Armenia	Yes*	Lithuania	Yes*
Austria	Yes*	Luxembourg	NS*
Azerbaijan	Yes	the former Y R M	Yes*
Belgium	Yes*	Malta	Yes*
B/H		Moldova	
Bulgaria	Yes*	Netherlands	Yes*
Croatia	NS	Norway	NS*
Cyprus	No	Poland	NS*
Czech Rep.	Yes*	Portugal	Yes*
Denmark	Yes*	Romania	Yes*
Estonia	Yes*	Russia	Yes*
Finland	Yes*	San Marino	NS*
France	Yes*	Slovakia	Yes*
Georgia	Yes*	Slovenia	Yes*
Germany	No*	Spain	Yes*
Greece	NS*	Sweden	NS*
Hungary	Yes*	Switzerland	No
Iceland	Yes*	Turkey	Yes*
Ireland	Yes*	Ukraine	Yes*
Italy	Yes*	United Kingdom	Yes*

Armenia:

- a. Donor must fulfil an especially composed form of agreement.
- b. There must be no any physical, psychological or duty pressure, neither any material or financial compensation.

Austria:

- a. Consent of the donor is given in written form. The authorisation is given by the ethics committee of the transplantation centre in question.
- b. Precondition for a valid consent of the donor is the prior clearing-up by a physician. Authorisation of the ethics committee can only be given in the case of related persons or close relationship.

Belgium:

- a. Legal authorization: Chapter II of the Law of 13th July 1986 relating to the removal and transplantation of organs. (M.B. from 14.02.1987; M.B. erratum from 26.02.1987; modified by the Law of 17 February 1987 – M.B.: 14 April 1987).
- b. Criteria:
 - age of the donor;
 - prior consent of the donor, signed and given in writing in front of an adult witness;
 - regeneration or not of concerned organs.

Bulgaria:

- a. The form of authorization is a fully informed written consent. Article 35 requires the obtaining of “a fully informed written consent, after explaining in accessible language to the living donor the risks assumed”.
- b. The criteria are as follows:
 - The donor should have attained full legal age (for Bulgaria: the age of 18);
 - The donor should be physically and mentally healthy; this should be confirmed by a commission consisting of three medical experts, whereas one of them is a psychiatrist and the other two must not be members of the team performing the transplantation.
 - The organ that shall be taken and the one which is to be left shall have entirely preserved functions;
 - Biological compatibility between the donor and the recipient shall be established.

Czech Republic:

For some qualified groups of recipients – persons not having close personal relationship to the donor; see Art. 3 § 2 lit. b) 2. in connection with Art.5 §5 lit. a) TA.

- a. Written approval of the respective Ethics Committee – Art. 5 § 5 TA
- b. Basic criteria are listed in Art. 3 § 1 lit. a) – d) TA

Denmark:

Removal of organs and tissues can only be performed by doctors who are occupied on hospitals or institutions like that and who have received an approval from the National Board of Health to do so.

Estonia:

- An informed consent given by the donor expressly and specifically in writing.
- In case of removal from persons without active legal capacity and persons with restricted active legal capacity a consent of the legal representative of the donor and the permission of an administrative court judge for transplantation needs to be obtained.
- b. An organ may be removed from a donor, if:
 - informed consent for transplantation has been obtained from the donor;
 - medical investigations performed on the donor ascertain that the risk to the life or health of the donor implied by the removal is not higher than the risk implied by any other surgical operation of the same degree of complexity;
 - the purpose of the removal of the organ is its implantation for therapeutic purposes into the donor's descendant, spouse, cohabitee, parent, grandparent or their descendants;
 - there is no suitable organ available from a deceased person for implantation.

Finland:

- a. A permit from the National agency of Medico Legal Affairs
- b. See the « Act on the Medical Use of Human organs and Tissues (2001) », Chapter 2.

France:

Yes, when health establishments authorised to remove are concerned.

1) Current state of French legislation

- No for removal of organs from a living donor who is of age (but consent must be expressed in front of a magistrate who is obliged to record if the consent is free and informed.)
- Yes for removal of bone marrow (in the same category as an organ in the current state of French law) from a donor who is a minor.
 - a. Committees of experts are responsible for authorising removal of bone marrow from minors.
 - b. The Committees reach a decision with respect to the main ethical principles (consent – unremunerated), and an assessment of the medical justification for the operation, the risks to which it is likely to lead as well as the foreseeable physical and psychological consequences.

2) Reform in progress

- a. removal of organs from fathers, mothers, sons, daughters, brothers, sisters or spouses may be subject to authorisation by an ad hoc committee if the magistrate responsible for recording consent considers it necessary.
removal of organs from grandparents, uncles, aunts, first cousins, the spouse of the mother or the father of the recipient and from a person who has lived with the recipient for more than two years will be subject to authorisation by an ad hoc committee.
- b. They are identical to the current criteria.

Georgia:

- a. Authorization is usually given by the committee set up at the Ministry of Labour, Health and Social Affairs
- b. The following criteria are defined by the law for the authorization of organ removal from a living donor:
 - i. - the donor shall be competent (having capacity to consent); bone marrow transplantation is allowed when the **donor is minor** (above 7 years) and bone marrow is to be transplanted to the relative of the first or second order whose health is jeopardized and no other therapeutic option exists;
 - ii. - the donor and recipient shall be genetic relatives or spouses;
 - iii. - the donor shall give a written consent to organ donation;
 - iv. - the modern methods of (medical) investigation confirm that immediate or remote, direct or indirect consequences of the operation do not represent significant risk to the life of the donor and will not result in significant deterioration of the donor's health;
 - v. - the relevant studies confirm that the donor complies with the established medical criteria;
 - vi. - the operation for organ removal is to be conducted by the physician possessing relevant certificate and in the institution having the relevant license.

Germany:

No. Nevertheless the removal can only be undertaken if the Commission responsible according to the law of the relevant federal state has submitted an expert opinion as to whether or not there is reason to believe that the consent for organ donation was not given voluntarily or that the organ is to be used for illegal trafficking. The Commission has to include a doctor that is neither involved in the transplantation of the organs nor is obliged to comply with the instructions of a doctor who is involved in such measures, a person qualified to exercise the function of a judge and a person experienced in psychological issues (Article 8 (3) TPG). The Commission's vote is not binding.

Greece:

Surely, the removal from a living donor requires authorization in the form of an affirmation which is signed and accepted by both the donor and the recipient, and in which the degree of relationship is also mentioned.

Hungary:

a. The donor's consent to an organ donation shall be incorporated in a public deed. Such public deed must contain, beyond the general requirements of a consent, the donor's declaration stating that the donation has taken place without force, duress, coercion or deception and that he gives consent to autopsy following his death.

The donor's consent to a tissue donation shall be incorporated in a private deed having full probative force. The consent of the recipient to the transplant must be committed to paper.

b. Removal of transplants from a live donor for transplantation to another person shall be restricted to the following organs or tissues:

one of a paired organ whose removal will not result in severe and permanent disability,
a part of an organ (organ segment) whose removal will not greatly alter physiological functions,
renewable tissues.

Iceland:

- a. The donor gives his consent, oral or written. Prior to that he must be informed thoroughly by a doctor about the procedure and its consequences. The donor is entitled to advice from a doctor other than the doctor of the recipient.
- b. The donor must be at least 18 years of age.

Ireland:

- a. Consent from donor or relative but no formal authorisation.

Italy:

The authorisation in the form of a decree is granted by the relevant local legal authority (Pretore).

- b. The relevant legal authority verifies the presence of conditions stipulated by the law 458: existence of family relationships between donor and recipient, the expression of a free and spontaneous desire for donation, awareness of the medical consequences of the donation, receiving the technical opinion from the medical team which will carry out the transplantation.

Latvia:

Authorisation is required according to the Article 19 and 20 of Convention on Human Rights and Biomedicine and according to the Article 13 of the law "On protection of died person and use of human tissues and organs in medicine". Written consent of donor is required (criteria – minimal risk for donor's health and donor should be informed about aim, causes and risk of intervention).

Law "On protection of died person and use of human tissues and organs in medicine" delegates The Cabinet of Ministers to work out regulations (under preparation) on institutions that are allowed to store and use the donated tissues and organs.

Lithuania:

Removal from living donor is allowed only as the extremely necessary therapy and there is no other alternative. Authorization can be taken from a person older than 18 years old and capable. Regenerate tissues and organs can be taken from minor only with parents or trustees authorization and authorization of child rights preservative office of municipality. If minor is older than 14 years old he also must be asked for authorization. Before removal donor health must be checked, donor must be informed about all donation possibilities and outcomes.

Luxembourg:

- a., b. Only for donors which are minors.

The consent of the minor with the capacity of discernment, of parents having parental authority (disagreement is considered as a refusal), of a committee of three experts appointed by the Ministry of Health.

The former Yugoslav Republic of Macedonia:

- a. The removal from a living donor requires authorisation in form of written consent that is accepted by both the donor and the recipient.
- b. Donor should be informed of an eventual danger on his or her health. It is valid if donor is mentally and physically healthy. If donor is an infant or mentally sick person, the authorisation for removal must be given by the parent or the tutor.

Malta:

- a. Authorization: Renal Services Committee in consultation with the BioEthics Committee
- b. Criteria for living donor transplants are: (1) first-degree relatives and (2) between husband and wife. All requests are then vetted by the Renal Services Committee.

The Netherlands:

- a. Informed consent based on extensive information about the procedure and its possible consequences is always required (in the form of a statement which is at least dated and signed in the donor's own hand; such consent shall be revocable at any time prior to the actual removal of the organ)
- b. An adult who is capable of reasonably assessing his interests in such matters may consent to the removal of a specified organ during his life for implantation in another specific individual. If it is reasonable to assume that the removal of the organ during the donor's life will have permanent consequences for the donor's health, the organ shall be removed only if the life of the recipient-to-be is at risk and if no other equally suitable treatment option exists.

The removal of an organ from a living adult who cannot be deemed capable of reasonably assessing his interests in such matters shall be permissible only if a) the organ in question is regenerative, b) its removal will have no permanent consequences for the donor's health, c) the recipient is to be a blood relative of the

first or second degree whose life is at risk and for whom no other equally suitable treatment option exists and d) the donor has a major interest in the survival of the recipient. The removal of an organ is permissible only with the consent of the donor's lawful representative or, in the latter's absence, his spouse or life partner or, in the absence of any of the said individuals, the donor's parent or adult child, and with the consent of the court.

The removal of an organ from a living minor aged twelve years or more is permissible only if a) the organ in question is regenerative, b) its removal will have no permanent consequences for the donor's health and c) the recipient is to be a blood relative of the first or second degree whose life is at risk and for whom no other equally suitable treatment option exists. The removal of an organ under such circumstances is permissible only with the consent of the donor and of the donor's parents, if the parents have legal responsibility for the donor, or, otherwise, of the donor's legal guardian, and with the consent of the juvenile court.

The removal of an organ from a living minor aged less than twelve years, or from a living minor aged twelve years or more who cannot be deemed capable of reasonably assessing his interests in such matters is permissible only if a) the organ in question is regenerative, b) its removal will have no permanent consequences for the donor's health, c) the recipient is to be a blood relative of the first or second degree whose life is at risk and for whom no other equally suitable treatment option exists and d) the donor has a major interest in the survival of the recipient. The removal of an organ under such circumstances is permissible only with the consent of the donor's parents, if the parents have legal responsibility for the donor, or, otherwise, of the donor's legal guardian, and with the consent of the juvenile court.

Norway:

Removal from a living donor who has reached 18 years of age requires written consent. When special circumstances so indicate, also persons under 18 years may give their consent with the endorsement of their guardian and the person who has parental custody and is responsible for the care of the minor. In such cases, the operation must be approved by the County Medical Officer.

Poland:

A special authorisation is not required for the removal of an organ with the view of a transplantation for the benefit of a close personal contact, in other words: cousin in a direct line, adopted person, brother, sister or spouse (on the other hand, strict conditions relating to consent are imposed). For a removal in favor of other close personal contacts of the donor (not aforementioned), authorisation of the district court within which jurisdiction the potential donor lives is required. This rule does not apply for removals of bone marrow or other regenerative cells and tissues.

In exceptional circumstances and following the strict conditions defined by law, the removal of bone marrow and other regenerative cells and tissues can be undertaken from a donor who is a minor. In this case, the decision of the family affairs and guardianships court in which the potential donor resides is required independently from the authorisation of his or her legal representative and of his or her own consent if he or she has reached 13 years of age.

a. In the cases when the authorisation of a judge is required, it takes the form of a legal decision. The authorization of the legal representative shall be in the written form.

b. Criteria:

- the removal of organs from a living donor can only be performed for the therapeutic benefit of the recipient,
- it can only be performed for the benefit of a recipient having the aforementioned close family relationship with the donor, except in the case of a removal of bone marrow or other regenerative cells or tissues,
- the relevance and the benefit of the removal of an organ, tissues or cells from a specified donor to a specified recipient must be established by the physician preparing the operation,
- prior to the removal, medical interventions must be undertaken with a view to assess whether the potential risk does not exceed the acceptable risk for this kind of intervention and whether the donor's health is not seriously endangered,
- the potential donor must be thoroughly informed about the nature of intervention, the inherent risk, the normal and probable consequences for his or her future health by a physician not directly participating in the transplantation procedure,
- if the potential donor is a pregnant woman, the risk evaluation must also take into account the consequences for the unborn child,
- the potential donor must be fully entitled to his or her rights and express before the physician his or her free written consent to the removal of an organ, tissues or cells with a view to transplanting them to a specified recipient (in the case of removal of bone marrow and other regenerative cells and tissues there is no obligation to mention the specified recipient in the content of the consent),

- the potential donor must also be informed about the consequences for the recipient which may result from the withdrawal of his or her consent to the removal, which are linked to the final stage of preparation of the transplantation recipient,

- the potential recipient must be informed of the inherent risk of the removal and the possible consequences for the health of the donor and must give his or her free consent to receiving the organ, tissues or cells from the specified donor (in the case of removal of bone marrow and other regenerative cells and tissues there is no obligation to mention the specified donor in the content of the consent),

- in case of impending danger for a life and when the transplantation of bone marrow is the only way to circumvent this danger, the removal of bone marrow can be undertaken from a minor for the benefit descendants and ascendants, brothers or sisters on condition that there is no foreseeable risk for the health of the donor. In this case, consent from his or her legal representative is required in addition to the consent of the minor, if he or she is over 13 years of age. Authorisation by a court is also required. The court rules on a request presented by the legal representatives of the potential donor, after having heard the concerned minor and considered the opinion of an expert psychologist. The request can be made by a minor himself or herself on condition that he or she has reached 16 years of age. This request must be accompanied by a medical opinion certifying that the removal being considered does not present a foreseeable risk for the health of the donor who is a minor.

Portugal:

Yes. In accordance with Article 8, paragraph 1 of the abovementioned law, the donor (and the recipient) must give his or her free, informed and unambiguous consent and the donor can identify the recipient. In accordance with the same article, consent is given before a physician designated by the "Clinical Director" of the establishment in which the removal is undertaken, who should not be a member of the medical team responsible for the transplantation. If the donors are minors, consent must be given by the parents unless they are deprived of their exercise of parental authority or, in the case where the exercise of parental authority has been removed from the parents, by the court. The donation of tissues or organs by minors having a capacity of discernment and able to demonstrate their desires is also conditioned by their consent. The removal from adults who do not have the capacity to consent because of a mental disorder can only be undertaken with a legal authorisation. The consent of the donor or of his or her legal representative can be freely withdrawn.

Romania:

The removal of an organ from a living donor is authorized under the Law No. 8/1998 which stipulate:
Article 5. Tissues and organs can only be removed from living adults who have a full mental capacity if this does not put the life of the donor in any danger and he or she has given his or her free written consent.

Prior to the operation, the clinical and laboratory examination of the donor is compulsory.

The donor is entitled to change his or her mind at any time before the removal of the organ or tissue.

Article 7. Bone marrow can also be removed from a minor but only for the benefit of a brother or a sister.

Bone marrow can only be removed from a minor if consent from each of the persons having parental custody or from the minor's legal representative is obtained. The consent is given in front of the President of a district court, or where appropriate the municipality of Bucharest, within which jurisdiction the minor resides, or in front of a judge after a compulsory investigation by the competent authority which represents the child.

Refusal of the minor prevents the removal.

Russia:

a. In accordance with Article 1 of the Law the removal of organs and/or tissues from a living donor is permissible only if a council of medical specialists considers that this will not lead to a significant damage to the donor's health. Donor shall give free and informed consent in writing to the removal of his/her organs and/or tissues.

b. Donor should be a blood relative of the recipient and should be 18 or older (father, mother, brothers, sisters).

San Marino:

Not applicable.

Slovakia:

Article 45 (Act 277/1994 On Health Care) Removal and transplantation of tissues and organs

(1) Removal and transplantation of tissues and organs (hereinafter "Organs") shall be performed by Health-service Institutions and research institutes appointed by the Ministry of Health provided that conditions laid down by this Act are met.

Article 46 (Act 277/1994 On Health Care) Removal and transplantation of Organs from bodies of living donors

(1) Organs may be removed from the body of living donor for the purposes of their transplantation to the body of another person for the purpose of treatment only provided that the donor has full legal capacity and provided that he/she gave his/her written consent prior to the removal. Donor may anytime withdraw his/her consent prior to the removal.

(2) Organs may be removed from living donors only following a review by Expert Consultancy Group who will consider whether successful removing of Organ and its transplantation may be expected as well as whether benefits for recipient exceed donor's loss. No removing shall be allowed if severe risk for the health condition of donor may be expected, even if donor gives his/her written consent. No removal shall be allowed from donors serving sentence in prison.

(3) Organs from living donors may only be removed at State Health-service Institution appointed by Ministry of Health. Such Health-service Institution shall be liable to obtain a separate insurance policy to cover third party liability with respect to donor from whom Organ is to be removed.

(4) Living donor must be instructed concerning potential risks to his/her health.

(5) Any transplants from bodies of living donors to other bodies or their removal for other purposes (Section 45 (3)) against payment shall be prohibited.

Slovenia:

a. Written – ethics commission for transplantation

b. Medical – the risk to donors.

Spain:

Yes. Chapter III explains conditions and requirements for donation and extraction:

Section 9. Living organs donors. Conditions and requirements

1. Extractions of organs from living donors, in order to make a future transplant in a recipient person could be done if the following conditions and requirements meet:

a) Donors must be of lawful age, sound mind and healthy.

b) Only an organ or a part of it can be donated, the extraction should be compatible with life, and his function may be made up for by the rest of the body function, in a correct and safety way.

c) Donors will have to be previously informed about the consequences of their decision, consent must be given in a clear, free, conscious and unselfish way.

d) There is not possibility to extract organs from people with mental diseases or any other reason, which could prevent them to give their consent properly. In no way, an extraction can be made in minors, even with their families or guardians consent.

e) The organ will be send to a specific recipient just to improve his health and life conditions.

2. Extraction of organs from living donors will be held just in case a sure success may be expected, and donors consent were ensured to be free, as it's said in point 1 c) of this section. A written report by the Ethical Committee of the Hospital will be required.

Under no circumstance, organs from living donors will be used when economical, social, psychological or any other type of conditioning may be suspected.

3. Physical and mental health in donors must be guaranteed by a physician who doesn't belong to the transplant team, that physician will inform the donor about the somatic and psychological risks, as the consequences in his private, familiar or professional life, as well as the benefits for the person who receives the transplant.

These terms should be evidenced by a medical certificate related to the health, all the information given, the answers, and the reasons expressed in freedom, also if there was any clue of external coercion.

The certificate will include the name of the physician in charge of the transplant, and also a list with the names of all the professionals who have collaborated in this task.

4. In order to proceed to the extraction of an organ from a living donor, the person concerned has to submit his written consent to a judge, belonging to the Municipal Registry Office, having heard the advice of the team who is going to extract the organ, and in presence of the physician referred in the point 3 of this section, the physician put in charge of the transplant and the person who allows the operation, in accordance with the authorization document issued by the Hospital.

The document in which the donor agrees will be signed by the recipient, the physician who undertakes the extraction, and the rest of the transplant team. Any of them may be opposed to the operation, if he considers

any doubt about it, for example, if donor consent has not been given in a clear, free, conscious and unselfish way. The person recipient should be provided with a copy of this document.
Under no circumstance the extraction could be carried out without the required signature of this document.

5. Between the signature of the donation document, and the extraction, at least, it must be expired twenty-four hours, donors can revoke their consent at any time before the operation, even without alleging any reason. In no case, revocation implies an indemnification.

6. Extractions of organs from living donors only may be done in authorized Hospitals by the Health Authorities of the Autonomous Community. Conditions and requirements of Hospitals are explained in section 11 of that Royal Decree.

7. Notwithstanding section 8, Medical care must be provided for donors.

Sweden:

According to the Transplantation Act biological material intended for transplantation may not be taken from a living person if it is to be feared that the action will seriously endanger the donor's life or health. Biological material for transplantation may be taken from a living person only if he or she has consented thereto. If the organ or material to be taken is not regenerative or if the action can otherwise entail considerable harm or inconvenience to the donor, the consent shall be in writing.

Turkey:

a. It is forbidden to remove tissues and organs from people who have not completed the age of eighteen and who are not major. In order to be able to remove tissues and organs from a person who has completed the age of eighteen and who is major, a written and signed protocol by donor which was previously given clearly, consciously and without being influenced, with the presence of at least two people or a protocol which was declared orally and then signed under the witness of at least two people has to be approved by a doctor.

b. Doctors who will remove tissues and organs have to:

Give information to the donor on the dangers that might arise from the removal of tissues and organs and the medical, psychological, familial and social outcomes in a convenient way and in detail;

Inform the donor about the benefits that the donor will provide for the receiver;

Refuse the removal of tissues and organs from people who are willing to donate their tissues and organs but who are not in a position to be able to decide mentally;

Know through making researches whether the spouse of the donor has any information about the decision of the donor and determine through a written protocol that she/he is informed, in case that the donor is married;

Refuse the removal of tissues and organs which is intended to be given through an idea which is not conformable with a humanitarian purposes or in return for a substitute or any other advantage;

Not to make any statement on the names of the donor and the receiver except from the cases where there is a presence of blood relationships or relationships resulting from marriage or personal relationships.

It is forbidden to remove tissues and organs whose removal will cause the life of the donor to be ended or to be put in a danger absolutely.

It is obligatory to make the necessary medical examination and analyses and the result be identified through a possibility report in order to reduce possible dangers for the life and health of the donor and the receiver before the removal, vaccination and transplant of tissues and organs.

It is necessary that the removal, preservation, vaccination and transplant of tissues and organs are performed by health organizations having necessary specialist personnel, devices and equipment.

Ukraine:

a. Form of writing donor Statement about consent on taking his human transplant and his informing about possible consequences signed consciously and without compulsion after assignment by treating doctor of objective information about possible complications for his health.

b. Living donor can be only adult capable person. Into living donor can be taken as human transplant only one of pair organs or part of organ, or part of other anatomic material. Taking human transplant from living donor allows on council deduction on the base of physicians of suitable health protection establishment whether scientific establishment after his comprehensive medical inspection and for condition, that harm drifted to donor health will be lesser, than danger for life threatening to recipient.

Does not allow taking human transplant from living persons, which: hold out in punishment serving places; suffer on terrible psychic discords; have the diseases can hand down recipient or damage his health; allotted before an organ or part of organ for transplantation.

United Kingdom:

Yes. Special provision is made in section 2 of the Human Organs Transplants (HOT) Act 1989 regarding non-genetically related recipients.

- a. Prior authorization is needed from the Unrelated Live Transplant Regulatory Authority (ULTRA).
- b. A close personal relationship has to be demonstrated between the potential donor and intended recipient.

4. What kind of relationships should exist between the living donor of an organ and the recipient?

Albania:

Usually they are members of the same family.

Armenia:

They could be kinsfolk or not.

Austria:

A relationship does not necessarily have to exist.

Azerbaijan:

Disinterested relationship.

Belgium:

According to Article 4§1 of the Law, neither the donor nor his close personal contacts will be entitled to any rights with respect to the recipient.

Bulgaria:

Solely a person who is a lineal or collateral relative [of the recipient] up to the fourth degree of consanguinity (either a spouse or an adopting parents) may be a living donor.

Cyprus:

- (a) Blood relation
- (b) In-law relation
- (c) Emotional relation (very careful assessment)

Czech Republic:

There are two main groups: persons with a close personal relationship to the donor in terms of the Czech Civil Code – descendants, ancestors, sibling, husband and wife; and the others.

Denmark:

Living donors are only accepted if they are related to the recipient.

Estonia:

Recipient must be donor's descendant, spouse, cohabitee, parent, grandparent or their descendant.

Finland:

Adults: near relative or other person close to them
Underage/ incapacitated donors: sibling

France:

1) Current state of French legislation

For donors of age, removal is not permitted except from the father, mother, sister, brother or spouse of the recipient.

For minor donors, the only removal possible is that of bone marrow (in the same category as an organ in the current state of French law) for the benefit of a brother or sister.

2) Reform in progress

In addition to the father, mother, sister, brother or spouse of the recipient, removal from grandparents, uncles, aunts, first cousins, the spouse of the father or mother of the recipient and from a person who has lived with the recipient for more than two years will be possible.

Bone marrow will not be considered in the same category as an organ. Its removal from a minor remains subject to the authorisation of an expert committee, and it will be possible, in the absence of any other therapeutic solution, for the benefit of siblings, first cousins, uncles and aunts.

Georgia:

Living donor of an organ and the recipient shall be genetic relatives or spouses.

Germany:

The removal of organs which are non-regenerative is only permissible for the transfer to relatives in the first or second degree, spouses, registered partners, fiancés or other persons with whom the donor has particularly close personal relations (Article 8 (1) second sentence TPG).

Greece:

It is stated in paragraph 1.

Hungary:

Donation of organ from a person with legal capacity shall be allowed only if the donor is:

- a) a lineal kin of the recipient,
- b) a sibling of a lineal kin of the recipient,
- c) a sibling of the recipient.

Iceland:

Not defined.

Ireland:

Genetically related.

Italy:

According to Italian law, donation can take place between parents and sons and between brothers.

Latvia:

According to the Article 19 and 20 of Convention on Human Rights and Biomedicine.

Lithuania:

Donor must be genetically close person or must be in marriage contract.

Luxembourg:

- a) For adult donors there are no legal criteria, of course without prejudice to the medical criteria to be respected by the transplantation team.
- b) For minors, the recipient must be a brother or sister of the donor. In conformity with the Oviedo Convention, a draft Bill in progress repeals the removal of organs (in fact, the kidney) from a minor living donor, to permit no more than donation of regenerative tissue.

The former Yugoslav Republic of Macedonia:

No specific relationship is stated.

Malta:

Refer to 3b.

The Netherlands:

In case of donation by a living adult who is capable of reasonably assessing his interests in such matters, the removal of a specified organ may be performed only for implantation in another specific individual, but a special relationship between donor and that individual is not required.

For donation of an organ by a living minor aged twelve years or more it is required that the recipient is a blood relative of the first or second degree whose life is at risk and for whom no other equally suitable treatment option exists.

For donation of an organ by either a living adult who cannot be deemed capable of reasonably assessing his interests in such matters, or by a living minor aged less than twelve years, or by a living minor aged twelve years or more who cannot be deemed capable of reasonably assessing his interests in such matters, is it required that the recipient is a blood relative of the first or second degree whose life is at risk and for whom no other equally suitable treatment option exists, and that the donor has a major interest in the survival of the recipient.

Norway:

Any relationship, both genetic and non genetic.

Poland:

Concerning non-regenerative organs, tissues and cells, close family relations should exist between the donor and the recipient (descendants and ascendants of direct line, adopted persons; brothers, sisters, spouses can only be recipients) without authorization from a judge, for other persons considered as close personal contacts, authorization from a judge is required.

Concerning bone marrow and other regenerative cells and tissues, legal authorisation is not required except in the case of minors which are donors in which case the decision of a family affairs and guardianships court is required. The removal from a minor can only be performed for the benefit of his or her descendants, ascendants and brothers or sisters.

Portugal:

Family relationships up to the 3rd degree, as provided by Article 6, No. 2, of the Law No. 12/93.

Romania:

The donation of tissues and organs by a living adult can only be performed if he or she has consented; the living donor and the recipient can, but do not need to, be related.

Russia:

Except in cases of the bone marrow transplantation the removal of organs from a living donor is only permissible if he/she has a genetic linkage with the recipient. Removal of organs and/or tissues for the purpose of transplantation from persons subordinate to the recipient or otherwise dependent on him is not permissible.

San Marino:

Not applicable.

Slovakia:

None relation is stated by law. Blood (family) related persons are preferred.

Slovenia:

Genetic, family, emotional relationships. Official Gazette 12/00, article of the Act.

Spain:

No specific relationship is established.

Sweden:

An action on a living person whereby non-regenerative biological material is taken for transplantation may only be performed on a donor who is related to the intended recipient or otherwise very close to the recipient. In special cases, however, an action of his kind may be performed on a person other than aforesaid.

Switzerland:

The laws of cantons do not require a particularly close family or emotional relationship between the donor and the recipient.

Turkey:

There does not exist any relationship in the provisions of the law in force between the donor and the receiver like being a relation of the other. However, since organ and tissue removing/buying or selling in return for a substitute or any other advantage is certainly forbidden, it is known that in practice, blood relationships or relationships resulting from marriage are taken into consideration to prevent the removal of organs and tissues that are intended to be given in return for a substitute or any other advantage or an idea which is not conformable with a humanitarian purposes.

Ukraine:

According to fourth part of article 12 of the Law of Ukraine "About organs transplantation and other anatomic materials of man", taking human transplant (barring anatomic materials, fit for regeneration) from living donor admits in cases, when a recipient and donor abide in marriage or are by near relative (father, mother, son, daughter, grandfather, grandmother, grandson, granddaughter, brother, sister, uncle, aunt, nephew, niece).

United Kingdom:

Genetic or close personal.

5. Do legal provisions exist in your State prohibiting the sale or the purchase of an organ:

a. in your own country? (y/n) (Answers. Yes: 30 No: 4 Not Specified: 6)

b. in another country? (y/n) (Answers. Yes: 18 No: 11 Not Specified: 11)

Country	5.a.	5.b.	Country	5.a.	5.b.
Albania	Yes	NS	Latvia	Yes	Yes
Andorra			Liechtenstein		
Armenia	Yes	No	Lithuania	No	NS
Austria	NS*	No	Luxembourg	Yes*	NS*
Azerbaijan	Yes	NS	the former Y R M	Yes*	NS*
Belgium	Yes*	Yes*	Malta	No	No
B/H			Moldova		
Bulgaria	No	Yes*	Netherlands	Yes*	No
Croatia	Yes	Yes	Norway	Yes*	No
Cyprus	Yes	Yes	Poland	Yes*	No
Czech Rep.	Yes*	Yes*	Portugal	NS*	NS*
Denmark	Yes	No	Romania	Yes*	Yes*
Estonia	Yes	No*	Russia	Yes*	Yes*
Finland	Yes	NS	San Marino	NS*	NS*
France	Yes	Yes	Slovakia	Yes	Yes
Georgia	Yes	No*	Slovenia	Yes	Yes
Germany	Yes*	Yes*	Spain	NS*	NS*
Greece	NS*	NS*	Sweden	Yes	Yes
Hungary	Yes	Yes	Switzerland	Yes	Yes
Iceland	NS*	NS*	Turkey	Yes	Yes
Ireland	No	No	Ukraine	Yes	Yes*
Italy	Yes*	Yes*	United Kingdom	Yes	No

Austria:

a. Only indirect: the agreement of a payment may lead to the punishability of the removal as a deliberate bodily injury.

Belgium:

a.b. According to the article 4§1 of the Law, organs and tissues cannot be exchanged with the aim of financial gain whoever the parties may be between which the transaction takes place.

Bulgaria:

b. Yes. According to Article 33a, Para 1, the organs and the tissues intended for transplantation may not be subject to an onerous transaction.

Czech Republic:

Art. 28 TA contains a total ban of all forms of financial gain in relation to the organ and tissue transplantations; international cooperation may be carried out under conditions stipulated in Art. 26 TA.

Estonia:

b. No, because laws of the state are applicable only in territory under the state's jurisdiction.

Georgia:

b. No (however, illegally obtained human organs can not be imported or exported from Georgia).

Germany:

a. Article 17 of the TPG prohibits the sale and purchase of organs in Germany. Article 18 (TPG) declares a breach of the provisions laid down in Article 17 (TPG) to be a punishable offence.

b. German criminal law also applies to organ trafficking (Article 18 TPG) when the offence is committed abroad, regardless of whether the offence is punishable in the country in which it is committed provided that the offender is a German national at the time of committing the offence (Article 5 (15) of the Criminal Code (StGB)).

Greece:

a. By virtue of article 2 of law 2737/99, the sale and purchase of an organ is prohibited, and by virtue of article 20 of law 2737/99, the penal sanctions are defined for the law-breaker.

b. There is no reference for sale and purchase in another country.

Iceland:

Iceland has signed but not ratified The Convention on Human Rights and Biomedicine. There are no provisions in state law banning the sale or purchase of organs per se. However, in Act No.110/2000 on Biobanks it is clearly stipulated that biological samples can only be acquired for a clearly defined and lawful purpose, and not used for other purposes. This is considered to apply for organs also. The sanctions, which the Act on Biobanks stipulates for offenders, are monetary fines or prison up to three years. (The Act on Biobanks is available in English on the Ministry's homepage, www.heilbrigdisraduneyti.is)

Italy:

a. Article 1343 of Civil Code

b. Article 1343 of Civil Code

Luxembourg:

a. According to the law, the transfer and obtaining of any substance or organ must be free, otherwise penal sanctions will be applied.

b. The law does not provide any derogation to the principle of territorial application of criminal law. In other words, Luxembourg law is not applicable if the whole of the sale or purchase operations takes place abroad. If on the other hand, by virtue of the law and jurisprudence governing sale and purchase, the operation is able to be linked in some way to Luxembourg (for example an order being placed from Luxembourg to a foreign country, agreement with conditions sent out from Luxembourg), Luxembourg law has authority to apply to it.

The former Yugoslav Republic of Macedonia:

Yes, any commerce is punishable.

The Netherlands:

a. Yes. Sale or purchase of an organ is punishable, see the answer to question 7.

Norway:

a. Human organs, parts of organs, tissues and cells cannot give rise to financial gain.

Poland:

a. Yes, the law prohibits both the offering and acceptance of financial or other patrimonial profits in exchange of organs, tissues or cells removed from a living or deceased donor.

Portugal:

A draft Law No. 49/IX is currently in discussion in the "Assembleia da Republica" (Parliament), with the view to its approval which is intended to sanction the commerce of organs and tissues of human origin.

Romania:

The aforementioned Law stipulates:

Article 16. Is considered as an offence and is punished by a prison sentence of between 1 to 3 years:

- the act by which a person donates human tissues and/or organs with the intention of making a profit;
- to dishonestly coerce anyone or to compel a person to donate tissues or organs, without any consideration about the manner.

Article 17. The organisation and/or the removal and/or the transplantation of human tissues and/or organs with the aim of making profit through the sale of human tissues and/or organs, is considered as an offence and is punished by a prison sentence of between 3 and 7 years.

Russia:

Human organs and/or tissues cannot be the object of sale or purchase. Sales or purchases of human organs and/or tissues as well as advertising of these operations entail criminal liability in accordance with the Russian legislation (Article 1 of the Law). This provision is also reflected in Article 47 of the Basic Legislation. Sales of organs and/or tissues by medical establishments that are allowed to remove and procure organs and/or tissues from dead bodies, is prohibited.

Those prohibitions do not specify whether they apply to purchases and sales within the country or in foreign countries, so they equally apply to both cases.

San Marino:

a.b. There are no legal provisions.

Spain:

Our law provides that is no possible to obtain any compensation for donors.

Ukraine:

b. Yes (for the overwhelming most of countries in which organs transplantation practices).

6. Is the sale by a person during his or her lifetime of the rights to one of his or her organs with a view to a post-mortem organ removal allowed? (y/n)
 (Answers. Yes: 3 No: 32 Not Specified: 5)

Country	Rep.	Country	Rep.
Albania	No	Latvia	No
Andorra		Liechtenstein	
Armenia	No	Lithuania	No*
Austria	No*	Luxembourg	NS*
Azerbaijan	Yes	the former YRM	No
Belgium	No	Malta	No*
B/H		Moldova	
Bulgaria	Yes*	Netherlands	No*
Croatia	NS	Norway	No
Cyprus	No	Poland	No
Czech Rep.	No*	Portugal	No*
Denmark	No*	Romania	NS*
Estonia	No	Russia	No*
Finland	No	San Marino	No
France	No	Slovakia	No
Georgia	No	Slovenia	No
Germany	No	Spain	NS*
Greece	No*	Sweden	No
Hungary	No	Switzerland	No
Iceland	NS*	Turkey	Yes
Ireland	No	Ukraine	No*
Italy	No	United Kingdom	No

Austria:

No. Sale of organs is in no way allowed.

Bulgaria:

Yes. The provisions of Articles 33 and Articles 34 of the National Health Act regulate the procedure of taking organs intended to be grafted after person's death.

Czech Republic:

It is not allowed; see remarks to the question Nr. 5.

Denmark:

It is not allowed in Denmark.

Greece:

No, the legal provisions mentioned in the previous paragraph explicitly state so.

Iceland:

Iceland has signed but not ratified The Convention on Human Rights and Biomedicine. There are no provisions in state law banning the sale or purchase of organs per se. However, in Act No.110/2000 on Biobanks it is clearly stipulated that biological samples can only be acquired for a clearly defined and lawful purpose, and not used for other purposes. This is considered to apply for organs also. The sanctions, which the Act on Biobanks stipulates for offenders, are monetary fines or prison up to three years. (The Act on Biobanks is available in English on the Ministry's homepage, www.heilbrigdisraduneyti.is)

Lithuania:

Post mortal donation is altruistic and all commercial contracts are unlawful.

Luxembourg:

The law does not envisage this possibility, in particular. However, it seems to be covered by the provision mentioned in question 5.

Malta:

This is not allowed however there is no legal provision and the legal framework is currently being reviewed.

The Netherlands:

No. Sale or purchase of an organ is punishable, see the reply to question 7.

Portugal:

The sale is forbidden, in accordance with Article 5 of the Law No. 12/93 which envisages banning the commerce of human tissues and organs.

Romania:

The sale of the right to remove an organ after the death of a person is prohibited.

Russia:

By implication of the provisions of the Law, that prohibit in principle purchases and sale of organs, the sale of one's rights to a post-mortem use of organs is prohibited.

Spain:

Buying and selling of organs is not legal, neither when donor is alive, nor when is dead, donation is always altruistic.

Ukraine:

No (barring marrow – according to article 18 of Ukraine Law “About organs transplantation and other anatomic materials of man”);

7. What sanctions are provided for offenders, in particular for:

- a. intermediaries?**
- b. health professionals?**

Albania:

Severe sanctions.

Armenia:

a.,b. They are prosecuted according to the law of Republic of Armenia.

Austria:

Sanctions depend on the case.

Azerbaijan:

- a.** Sanctions are provided.
- b.** Sanctions are provided.

Belgium:

The sanctions provided for offenders are addressed in Articles 17, 18 and 19 of the Law relating to the removal and transplantation of organs.

Bulgaria:

The penalty, prescribed according to Article 349a of the Penal Code is a period of one to three years imprisonment and if an offence is committed for mercenary motives, the penalty shall be from three to five years imprisonment.

The law does not envisage different penalties for both mediators and professionals. The wording is rather comprehensive and comprises any violation of rules laid down. Article 349a (inserted OG No.62 of 1997) reads: Para 1. Anyone who violates the rules concerning the taking and delivering of organs and tissues intended for transplantation shall be sentenced to 1 to 3 years imprisonment.

Para. 2. The penalty shall be one to three years imprisonment provided that the offence has been committed from mercenary motives.

Cyprus:

Fine and/or imprisonment.

Czech Republic:

Sanctions are provided for both in TA (Art. 29 - fines) and in the Czech Criminal Code (amended Art. 209a – prohibited handling with organs and tissues – sanction relying on sentence of imprisonment up to two, four or eight years or on prohibition of any activity (e.g. relevant medical profession)).

Denmark:

The sanctions for both intermediaries and health professionals could be a fine.

Estonia:

- a.** Pecuniary punishment, imprisonment up to one year.
- b.** Pecuniary punishment, imprisonment up to one year.

Finland:

A fine for violation of the provisions on medical use of human organs, unless more severe punishment is provided elsewhere in Finnish law.

France:

- a.** 7 years imprisonment and 100 000 Euro fine.
- b.** 7 years imprisonment and 100 000 Euro fine.

Georgia:

- a.** Sanctions exist for intermediaries.
- b.** Sanctions exist for health professionals.

Germany:

a. Imprisonment of up to five years or a fine; in the case of commercial trafficking, imprisonment from one to five years (Article 18 (1 and 2) TPG). The attempt shall be punishable (Article 18 (3) TPG). In the case of organ donors and/or recipients, the court can dispense with a sentence or can reduce the sentence at its discretion (Article 18 (4) TPG, Article 49 (2) StGB).

b. See (a) above in case of facilitators in organ trafficking.

Prison sentences of up to three years or fines are handed down to those who remove an organ from a deceased person

- without consent from the person concerned prior to death, alternatively the consent of the next of kin, or
- if the death of the person concerned has not been determined according to rules that reflect the current level of medical knowledge, or

- if the organ is not removed by a doctor,

or if

- the person whose death has been determined had spoken out against the removal of the organ, or

- prior to the removal of the organ, the final, irreparable failing of the entire functioning of the cerebrum, the cerebellum and the brain stem has not been determined in line with procedural rules that reflect the current level of medical knowledge (Article 19 (1)) TPG.

The attempt shall be punishable (Article 19 (4) TPG).

A prison sentence of up to five years or a fine is handed down when an organ is removed from a living person without

- he/she being of legal age and capable of giving consent or

- he/she being given the information required legally and giving consent

or if

- the organ is not removed by a doctor or

- the non-regenerative organ is removed without the presence of the necessary close relations required between the living donor and the recipient under Article 8 (1) second sentence TPG (see question 4 above) (Article 19 (2) TPG).

The attempt shall be punishable (Article 19 (4) TPG).

Greece:

For both intermediaries and health professionals, the penal sanctions provided in article 20 of law 2737/99.

Hungary:

a. Procedure according to the Penal Code.

b. Withdrawal of diploma.

Iceland:

Iceland has signed but not ratified The Convention on Human Rights and Biomedicine. There are no provisions in state law banning the sale or purchase of organs per se. However, in Act No.110/2000 on Biobanks it is clearly stipulated that biological samples can only be acquired for a clearly defined and lawful purpose, and not used for other purposes. This is considered to apply for organs also. The sanctions, which the Act on Biobanks stipulates for offenders, are monetary fines or prison up to three years. (The Act on Biobanks is available in English on the Ministry's homepage, www.heilbrigdisraduneyti.is)

Ireland:

b. Medical Council which is the registration body for clinicians may impose sanctions, including removing a doctor from its register and prohibiting that person from practising within the State.

Italy:

The sanction provided by article 411 of the Criminal Code for both categories of offenders and is a prison sentence of between 2 and 7 years. In the case of an illegal organ transplantation from a living donor, and in accordance with articles 482 and 483 of the Criminal Code the sentence is a prison term of between 6 and 12 years.

Latvia:

According to the Article 139 of The Criminal Law for a person who commits unlawful removal of tissue or organs from a living or dead human being in order to utilise such for medical purposes, where commission thereof is by a medical practitioner, the applicable sentence is deprivation of liberty for a term not exceeding five years, with or without deprivation of the right to engage in the practice of medical treatment for a period not exceeding five years.

Lithuania:

Country law system applies punishment according to administrative, civil and penal codes.

Luxembourg:

There is no particular sanction

General sanctions: Prison term of between 8 days and 3 years and a fine of 60 to 50 000 euros.

The former Yugoslav Republic of Macedonia:

a.,b. 3 months to 3 years imprisonment.

Malta:

a. None at present

b. Liable to investigation by the Medical Council.

The Netherlands:

a. See the answer under b.

b. According to Section 32, subsection 2 of the Organ Donation Act any of the following parties is punishable by up to one year in prison or a fourth-category fine:

a. a party who deliberately causes or encourages a third party to consent to the removal of an organ during his lifetime in return for payment in excess of the costs referred to in Section 2 of the Act, or to contravene the provisions of Section 7 of the Act;

b. a party who openly offers payment in excess of the costs referred to in Section 2 of the Act for the receipt of an organ, or who puts himself forward as a donor in return for such payment, or who offers services which involve activities which are punishable under a.

Norway:

Anyone who makes a decision regarding the removal of any organ or other biological material, except subject to the conditions prescribed by the Act relating to transplantation, hospital autopsies and the donation of bodies etc. shall be punished by fines, unless the case is punishable under stricter penal prohibitions.

Poland:

a. A prison sentence of between 3 to 10 years.

b. There are no special dispositions.

Portugal:

The draft Law No. 49/IX foresees that “anyone, with the intention of undertaking commerce, uses or removes organs or tissues of human origin for diagnostic or therapeutic and for transplantation purposes is convicted to a prison sentence of between two and ten years”. Article 16 of the Law No. 12/93 establishes that the offenders of the statutory provisions are responsible in civil, criminal and disciplinary terms, according to the general principles of the law.

Romania:

Sanctions provided by the transplantation law, Chapter IV

Article 15. The act of a person who organised or performed a removal which is in opposition to a medico-legal commission solicited according to the law, is considered as an offence and is punished by a prison sentence of between 1 and 3 years.

Article 17. The organisation and/or the removal and/or the transplantation of human tissues and/or organs with aim of making profit through the sale of human tissues and/or organs, is considered as an offence and is punished by a prison sentence of between 3 and 7 years.

Russia:

a. Forced removal of human organs or tissues for subsequent transplantation has been criminalized and incurs criminal responsibility under Article 120 of the Criminal Code of the Russian Federation. Punishment for this offence includes imprisonment for up to 4 years, with or without deprivation of the right to hold certain offices or carry out certain activities during a term of up to three years.

In cases when a forced removal of organs has been committed in respect of a person who was known to the offender as being in a helpless state or in material or other dependence on the offender, the degree of social threat is deemed to be higher. In this case, Article 120, Part 2 of the Criminal Code of the Russian Federation, provides for imprisonment for a period of 2 to 5 years, with or without the deprivation of the right to hold certain offices or carry out certain activities during a term of up to three years.

Paragraph "M" Part 2, Article 105 of the Criminal Code of the Russian Federation provides for criminal responsibility for intentional homicide perpetrated with the purpose to use organs/tissues of the victim. This crime is considered to be a first degree murder and is punished by imprisonment for a period of 8 to 20 years or death penalty, or life imprisonment.

(Note: in pursuance of Part 2, Article 20 of the Constitution of the Russian Federation, the Constitutional Court of the Russian Federation by its Decision No.3-π of 02.02.1999 declared a moratorium on death penalty).

Under Paragraph "ж", Part 2, and Part 3, Article 111 of the Criminal Code of the Russian Federation, intended infliction of a serious damage to health, threatening life or leading to the loss of sight, speech, hearing or any organ ..., perpetrated with the purpose to use organs or tissues of the victim, is punished by imprisonment for a period of 3 to 12 years.

Under Paragraph "ж", Part 2, Article 152 of the Criminal Code of the Russian Federation, purchase and sale of a minor or other deals in respect of a minor in the form of his/her transfer or taking possession of him/her, perpetrated with the purpose to remove his/her organs or tissues for transplantation, is punished by imprisonment for a period of 3 to 10 years.

b. Under Article 16 of the Law public health organizations in addition to the liabilities referred to in the preceding paragraph, are held financially liable to the donor and the recipient in accordance with the legislation of the Russian Federation.

San Marino:

Not applicable.

Slovakia:

a. Sentence to prison of 1-5 years.

b. Sentence to prison of 1-5 years if no serious health harm was caused.

Sentence to prison of 2-8 years if serious health harm was caused.

Sentence to prison of 5-12 years if death of the patient was caused.

Slovenia:

a.b. Regulated by the Criminal Code (official gazette 63/94).

Spain:

It is established by law, it's an illegal activity, which will be prosecuted.

Sweden:

According to the law a person intentionally performing an action or taking biological material from a living or deceased person or using or collecting tissue from an aborted foetus contrary to this Act shall be fined.

A person intentionally and with a view to gain taking, delivering, receiving or procuring biological material from a living or deceased person or tissue from an aborted foetus shall be fined or sentenced to not more than two year's imprisonment.

Switzerland:

The federal Decree dated from March 22 of 1996 relating to the control of transplants stipulates the following sanctions:

Article 32 Offences.

Will be sentenced to a prison term or fined not more than 200 000 francs, unless he or she committed a more serious offence according to the criminal code of Switzerland, whosoever intentionally:

omitted to take the necessary measures to avoid endangering of the health of others during the handling of transplants.

did not test the transplants with the view to detect the pathogenic agents indicated by the Federal Council.

put on the market in Switzerland or in a foreign country coming from Switzerland the transplants of human origin with the aim of financial gain, or transplanted material of human origin for a fee.

The author will be sentenced to 5 years in prison at the most and fined up to 200 000 francs if he or she acted within the scope of his or her duties or with pursuit of profit.

The author will be sentenced to 6 months in prison at the most and fined up to 100 000 francs if he or she acted through negligence.

Turkey:

7.b. In case that the act do not necessitate a heavier penalty those who remove, preserve, transplant, buy and sell organs and tissues illegally, those who mediate in buying and selling or those who are the commissioners of these are sentenced to penalty of imprisonment form 2 years to 4 years and high monetary penalty from 50 000 Turkish Liras to 100 000 Turkish Liras. This sentence is valid for both mediators and for health staff. Monetary penalties have been increased 786 times in the year of 1999 in line with the Law numbered 4421 and dated 28.07.1999 and have been increased every year by evaluation after 1999.

Ukraine:

According to Article 24 of the Law of Ukraine “About organs transplantation and other anatomic materials of man”, the juridical and physical persons, legislations guilty of violation about transplantation, carry responsibility in obedience to Ukrainian laws.

Persons, which attends to mediation in illegal trade by human organs or cloths, specifically, seeking channels for selling, possible buyers and sellers of such organs and cloths, by adjusting relations with doctors being able illegally withdrawal of the organs or man cloths, execution of separate agreements etc. - as accessory is subject to criminal responsibility for appropriate part of article 27 and by appropriate part of article 143 of Criminal code of Ukraine.

By criminal subject, foreseen by parts 4 and 5 articles 143 of Criminal code of Ukraine, taking into account articles demands 18, 19, 22 of the Criminal Code of Ukraine, there is any responsible person by age of 16 years and more.

Jurisdictional, according to part 1 of article 19 prevailing Criminal Code of Ukraine, considers a person, which under commitment time by it of crime will capable to realize its actions (inactivity) and to manage them.

United Kingdom:

There are offences for commercial dealing (under section 1 (5) of the HOT Act) and offences which cover the transplanting of a human organ in non-compliance with section 2 of the HOT Act. All offences attract a fine not exceeding level 5, and in some cases 3 months imprisonment.

B. Organisational measures.

8. Does your State have a nationally recognised system for organ transplantation? (y/n)
(Answers. Yes: 33 No: 3 Not Specified: 4)

9. Is there a nationally recognised system for the approval of organ transplantation centres? (y/n)
(Answers. Yes: 28 No: 9 Not Specified: 3)

Country	8.	9.	Country	8.	9.
Albania	Yes	Yes	Latvia	Yes	Yes
Andorra			Liechtenstein		
Armenia	Yes	Yes	Lithuania	Yes	Yes
Austria	Yes*	Yes*	Luxembourg	Yes	Yes
Azerbaijan	No	No	the former YRM	No	No
Belgium	Yes	No*	Malta	Yes	Yes*
B/H			Moldova		
Bulgaria	Yes*	Yes*	Netherlands	Yes	Yes*
Croatia	NS*	No	Norway	Yes	Yes
Cyprus	Yes	Yes	Poland	Yes*	Yes*
Czech Rep.	Yes*	Yes*	Portugal	Yes*	Yes*
Denmark	Yes	NS*	Romania	Yes*	Yes*
Estonia	Yes	Yes	Russia	Yes*	Yes*
Finland	Yes	Yes	San Marino	No	No
France	Yes	Yes	Slovakia	Yes	Yes
Georgia	Yes	Yes	Slovenia	Yes	Yes
Germany	Yes	No*	Spain	Yes	Yes
Greece	NS*	NS*	Sweden	Yes	No
Hungary	Yes	Yes	Switzerland	Yes	No
Iceland	NS*	NS*	Turkey	Yes	Yes
Ireland	NS*	Yes*	Ukraine	Yes	Yes
Italy	Yes	Yes	United Kingdom	Yes	No

Austria:

- 8. Yes, Eurotransplant, OBIG – Transplant and the transplantation centres.
- 9. Yes, via OKAP – Österreichischer Krankenanstaltenplan.

Belgium:

- 9. The answer is no, but a draft Royal Decree is currently being prepared.

Bulgaria:

- 8. Yes. The building up of a system for transplantation of organs began in 1998. It is to be entirely regulated by the Act on the Transplantation of Organs, Tissues and Cells.
- 9. Yes. The building up of a system for transplantation of organs began in 1998. It is to be entirely regulated by the Act on the Transplantation of Organs, Tissues and Cells.

Croatia:

- 8. We are making first steps toward it.

Czech Republic:

- 8. The new TA could be considered as a legal framework of such a system for organ transplantations.
- 9. See Art. 22 TA

Denmark:

- 9. There exist planning regulations concerning highly specialized treatment to certain quality and expertise.

Germany:

- 9. The Transplantation Act refers to the general prerequisites for the recognition of hospitals (Article 10 (1) TPG) as regulated in federal laws. The approval of hospitals as transplantation centres is the responsibility of the federal states as part of hospital planning.

Greece:

- 8. Greece has a national system for organ transplantation, which is based on and develops according to legally consolidated provisions and internationally accepted criteria.
- 9. There are legal provisions (ministerial decision Y4a/45132/2002) that define the operation mode of the transplantation units.

Iceland:

- 8, 9. There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiatransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Ireland:

- 8. Specialized centres supervise the arrangements for organ transplantation.
- 9. The specialized organ transplantation centres are funded by the Exchequer as designated national specialities.

Malta:

- 9. Organ transplantations are only carried out in the main government general hospital.

The Netherlands:

- 9. Yes. Transplantation centres have to be approved by the Government.

Poland:

8. Yes, the system in question is regulated by the Health Minister's decree of 14 June 1996 relating to the creation of a Transplantation Organisation and Coordination Centre POLTRANSPLANT.

9. Yes, this system is regulated by the Health Minister's decree of 6 February 1997 relating to organisational regulations of the Transplantation Organisation and Coordination Centre POLTRANSPLANT.

Portugal:

8. Yes. Organizacao Portuguesa de Transplantaçao (O.P.T.).

9. Yes – Ministry of Health

Romania:

8. The necessity of removal and of transplantation of human tissues and organs, the coordination and the supervision of these medical activities are the responsibility of the Human Organs and Tissues Transplantation Commission, which operate within the Ministry of Health and the regional transplantation centres.

The composition, the organisation and the duties of this Commission as well as those of regional transplantation centres are established by a rule proposed by the Medical College of Romania and approved by Ministry of Health.

9. Part of the duties of the Commission are:

to organise the activity of transplantation centres on the territory of Romania;
the accreditation of the centres which can perform the transplantation activity, following the opinion of Medical College;
the accreditation of the hospitals where the removal of organs can be performed;
the drawing up of distribution criteria of organs and tissues removed from corpses;
the accreditation of immuno-compatibility centres.

Russia:

8. Russia does have a nationally recognised system for organ transplantation.

9. Yes, there is a nationally recognised system for the approval of organ transplantation centers.

10. Does your State have a nationally recognised system of waiting lists for organ recipients? (y/n)

(Answers. Yes: 30 No: 8 Not Specified: 2)

11. If the State has a nationally recognised system of waiting lists for organ recipients, is this system the same one for all organ recipients whether the organs are removed from living or deceased donors? (y/n)

(Answers. Yes: 18 No: 15 Not Specified: 7)

Country	10.	11.	Country	10.	11.
Albania	Yes	Yes	Latvia	Yes	Yes
Andorra			Liechtenstein		
Armenia	No	No	Lithuania	Yes	NS*
Austria	Yes*	Yes	Luxembourg	Yes*	No
Azerbaijan	No	No	the former YRM	Yes	Yes
Belgium	Yes*	Yes	Malta	Yes	No*
B/H			Moldova		
Bulgaria	Yes*	Yes*	Netherlands	Yes*	No*
Croatia	Yes	Yes	Norway	Yes	No
Cyprus	Yes	No	Poland	Yes*	Yes*
Czech Rep.	Yes*	No*	Portugal	Yes	No
Denmark	Yes	Yes	Romania	No*	No*
Estonia	Yes	Yes	Russia	No*	No*
Finland	Yes	Yes	San Marino	No	NS*
France	Yes	Yes	Slovakia	Yes	Yes
Georgia	No*	NS*	Slovenia	Yes	Yes
Germany	Yes*	No*	Spain	Yes	Yes
Greece	NS*	NS*	Sweden	No	NS
Hungary	Yes	Yes	Switzerland	Yes	Yes
Iceland	NS*	NS*	Turkey	Yes	No
Ireland	Yes*	No*	Ukraine	No	NS
Italy	Yes	No	United Kingdom	Yes	Yes

Austria:

10. Yes, waiting lists are kept with Eurotransplant.

Belgium:

10. It is Eurotransplant. Cf. Royal Decree of 19 July 2001 giving authorization to Eurotransplant as a distribution organization of human organs.

Bulgaria:

10. Yes. Such a system has been entirely built in terms of the waiting list for liver transplantation – the solely organ transplantation that is performed in Bulgaria. A waiting list for liver transplantation and heart transplantation is under preparation, in particular – transplantation programmes, which are to start shortly.

The system of waiting lists is to be regulated by the Act on the Transplantation of Organs, Tissues and Cells.

11. Yes. A single waiting list for liver transplantation is completely built. For liver transplantation to be performed, a patient should have been included in the waiting list for transplantation regardless of whether the transplantation is from a dead person or a living related donor. The system of waiting lists for transplantation is to be regulated by the Act on the Transplantation of Organs, Tissues and Cells.

Czech Republic:

10. Yes. See Art. 25 concerning Transplantation Coordination Centre and Art. 17 concerning the recipient.

11. No. There are different conditions for performing transplantations from living donors with high decision autonomy of the concrete donor and for transplantations from deceased donors where the cogent conditions are stipulated; see Art. 3-10 and Art. 10-16 and Art 17 §§ 1 and 2.

Georgia:

10. No (As a matter of fact, solid organs are currently removed only from living donors. Although all relevant regulations exist, including definition of brain death criteria, solid organs from deceased persons have never been performed in this Country).

11. Please, see question 10. Recently, amendments have been made to the Law on Human Organ Transplantation, which now allows cross-donation (in case of tissue mismatch, genetic relative of one patient may donate organ to another patient and the relative of another patient would give organ to the first one). For this reason, waiting list for organ recipients (whose genetic relatives are willing to donate organ) is being established.

Germany:

10. Yes. The transplantation centres are obliged to maintain lists of patients accepted for transplantation with the details needed for the mediation of organs (Article 10 (2) (1) TPG). In the case of the mediation of organs for which mediation is required, the waiting lists of the transplantation centres are to be treated as one uniform waiting list (Article 12 (3) second sentence TPG).

11. Organs from living donors are not mediated via the waiting lists. In contrast to post mortem organ donations, the organs removed from living persons are not distributed using a (uniform) waiting list. The organ is received by the person from the group of eligible recipients as defined in Article 8 (1) second sentence TPG. The potential donor only donates an organ for concrete relatives, spouses, partners, fiancés or for other persons to whom he/she is clearly very close.

Greece:

10. In Greece there are national lists for prospective organ recipients.

11. The existing valid national recording system of prospective implant recipients regards only organs having been removed from deceased donors.

Iceland:

10, 11. There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiarttransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Ireland:

10. Within each specialised centre waiting lists are maintained, but priority for organ transplantation would also be determined by medical need and the availability of matching organs.

11. The living donors donate organs specifically to genetic relations.

Lithuania:

11. All organ recipients are included to the general national waiting list, and everyone has possibility to be transplanted using organ from genetically close or wedded person according to the existing law system.

Luxembourg:

10. Luxembourg participates in Eurotransplant which manages the waiting lists.

Malta:

11. There is no waiting list for live organs as these transplants are carried out only when and if circumstances arise, according to the criteria listed in question 3b.

The Netherlands:

10. Yes. The professionals determine whether a patient is to be placed on a waiting list for organ transplantation.

11. No. Donation by others than living adults capable of reasonably assessing his interests in such matters, is limited by law.

Poland:

10. Yes, this system is regulated by the Health Minister's decree of 6 February 1997 relating to organisational rules of the Transplantation Organisation and Coordination Centre POLTRANSPLANT.

11. Yes, this particular question is regulated by the Health Minister's decree of 5 November 1966 which indicates health-care establishments and other organisational bodies who regulate waiting lists for cell, tissue and organ recipients.

Romania:

10, 11. The National Transplantation Register is currently being prepared.

The National Transplantation Register is an essential element of an appropriate transplantation activity. The Register will also contain the waiting lists of transplantation centres and contain the supervision of Romanian patients having a transplant treated in different transplantation centres, including abroad. It will also collaborate in an efficient manner with the immunological and medical control group (the sub-commission of hematogenic bone marrow and of stem cells).

Russia:

10. There is no single nation-wide system of waiting list for organ recipients in the Russian Federation due to the vast territory of the country but there is a regional waiting list system.

11. There is no nationally recognised system of waiting lists in the Russian Federation.

San Marino:

11. Not applicable.

12. Does the transplantation system ensure the recording and the control of all organs removed from both living or deceased donors? (y/n)
 (Answers. Yes: 34 No: 3 Not Specified: 3)

Country	Rep.	Country	Rep.
Albania	Yes	Latvia	Yes
Andorra		Liechtenstein	
Armenia	No*	Lithuania	Yes
Austria	Yes*	Luxembourg	Yes*
Azerbaijan	No	the former YRM	Yes
Belgium	Yes	Malta	Yes
B/H		Moldova	
Bulgaria	Yes	Netherlands	Yes*
Croatia	Yes	Norway	Yes
Cyprus	Yes	Poland	No*
Czech Rep.	Yes*	Portugal	Yes
Denmark	Yes	Romania	Yes
Estonia	Yes	Russia	Yes*
Finland	Yes	San Marino	NS*
France	Yes	Slovakia	Yes
Georgia	Yes	Slovenia	Yes
Germany	Yes	Spain	Yes
Greece	NS*	Sweden	Yes
Hungary	Yes	Switzerland	Yes
Iceland	NS*	Turkey	Yes
Ireland	Yes	Ukraine	Yes
Italy	Yes	United Kingdom	Yes*

Armenia:

Yes only in the case of living donors.

Austria:

- a. Recording and control of all transplantations and of removal of organs of deceased donors via Eurotransplant and OBIG - Transplant
- b. Recording and control of the removal of organs of living donors in the transplantation centres.

Czech Republic:

Provisions concerning medical documentation, special registries and protocols take into account all these aspects.

Greece:

The parametric system in practice ensures the recording and control of organs removed from both living donors (transplantation between relatives) and deceased ones.

Iceland:

There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiatransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Luxembourg:

Yes, for deceased donors. Concerning the removal from a living donor, this hypothesis is extremely rare.

The Netherlands:

Yes. The organ centre is responsible for recording and controlling the organs removed from deceased donors. The professionals are responsible for recording and controlling the organs removed from a living donor.

Poland:

No. In Poland there are no legal provisions regulating this issue. The register of living donors of kidneys is currently being implemented.

Russia:

The transplantation system ensures the recording and the control of all organs removed from both living or deceased donors.

San Marino:

Not applicable.

United Kingdom:

Yes. The Human Organ Transplants (Supply of Information) Regulations 1989 provide the statutory framework for the supply of information.

13. Who can remove organs from a living donor and where?

Albania:

Urologist in a hospital.

Armenia:

Organ removal from living donors is done only in specially approved medical foundations and specially established medical commissions.

Austria:

Transplantation centres.

Azerbaijan:

Such mechanism does not exist.

Belgium:

According to Article 3 of the Law, any removal and any transplantation of tissues and organs shall be performed by a physician in a hospital defined by the Law of 23 December 1963 relating to hospitals.

Bulgaria:

Organ transplantation is performed in Transplantation Centers, licensed by the Minister of Health.

Croatia:

Transplantation teams in the transplantation centres.

Cyprus:

Accredited transplant Surgeons at the Cyprus Transplant Center and the Government Hospitals.

Czech Republic:

The removal of organs is allowed only in approved medical hospitals under conditions of the Art. 21 TA or in approved transplantation centres under conditions of the Art. 22. So it may be performed only by responsible physician of the respective medical facility.

Denmark:

Re. answers to Question 3.

Estonia:

Competent physicians (e.g. surgeon-urologists together with anaesthesiologist and other team members) only in a regional hospital. Regional hospital is the only kind of a hospital empowered to practice all the medical specialities.

Finland:

Organ transplantation team physician.

France:

Medical teams at University hospitals.

Georgia:

Organs from living donor shall be removed only by duly certified physician in the institution having the specific license for human organ transplantation.

Germany:

Only a doctor may remove organs from a living person (Article 8 (1) sentence one, number four TPG). The place of the removal is not explicitly regulated. Organs that can be donated alive in part or in their entirety can however only be transplanted in transplantation centres that are approved for the transplantation of the relevant type of organ.

Greece:

Organ removal is only performed by special medical teams, that are nationally recognisable and acceptable for their scientific training and experience, only in Intensive Care Units of recognised hospitals.

Hungary:

The surgeon of the institution designated by the Minister.

Iceland:

There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiatransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Ireland:

All organs removed are approved through National Procurement Office at Beaumont Hospital, Dublin.

Italy:

The law n 458 of 26.06.1967 on transplantation of kidneys stipulates that the removal of an organ can be performed in authorized transplantation centres, in university institutes or in hospitals engaged in scientific research. The removal and the transplantation of organs can only be performed by specialized surgical teams and authorized by the Italian Ministry of Health.

Latvia:

Law "On protection of died person and use of human tissues and organs in medicine" delegates The Cabinet of Ministers to work out regulations (under preparation now) on institutions that are allowed to store and use the donated tissues and organs.

Lithuania:

Removal from a living donor must be made only by certified health professionals in the organ transplantation centers. Removal from a deceased person must be made by a certified health professional in hospital where donor is prepared.

Luxembourg:

Any physician who has the required competence, following the procedural and substantive conditions prescribed by law.

The former Yugoslav Republic of Macedonia:

A doctor (except the doctor that cared for the patient during his/her lifetime if the patient is dead) in a health organization, which fulfils the conditions required by the Ministry of Health.

Malta:

Organs are removed by a transplantation team with suitable qualified health professionals usually at the main government hospital. However the performance of organ transplantation in the private sector cannot be excluded even though it is unlikely as the necessary set-up is not available.

The Netherlands:

Organ removal from a living donor are carried out by transplantation teams in transplantation centres.

Norway:

National harvesting team at donor recognized hospitals.

Poland:

Only persons authorised by the Minister of Health can remove organs for transplantation. This removal can only be performed in transplantation centres which are also subject to authorisation.

Portugal:

The medical professionals in public hospitals.

Romania:

The removal and the transplantation of human tissues and organs can only be performed by specialised physicians and only in hospitals authorized by the Ministry of Health and which are accredited regional transplantation centres.

Russia:

Organs from a living donor can be removed by specialized medical teams at transplantation centers.

San Marino:

Nobody.

Slovakia:

Authorised personnel (transplant surgeon) in authorized centres (transplantation centres).

Slovenia:

Authorised national institutions only

Spain:

The law will authorise Centres in which extractions can be done, following the enforced instructions.

Section 11. Centres for extraction of organs from living donor: General requirements and procedures for granting, renewal and cancellation of the authorization of activities.

1. Extraction of organs from living donors for a prospective transplant in a recipient person, only can be done in authorized Centres by the competent Health Authority of the Autonomous Community.

2. In order to be authorized, Centres in which these activities are done, must accomplish the following requirements:

- a) To be authorised as a Centre for extraction of organs from dead donors, and as a Centre for transplant of organs for which it is required the authorization for extraction from living donor.
- b) To have medical team and nursing personnel available and experienced enough, in order to be successful in the extraction.
- c) To have available equipment to guarantee successful extractions.
- d) To have available medical care services to guarantee an adequate medical study before the operation, and the correct treatment in case the operation isn't successful.
- e) Protocol available to guarantee the adequate selection of donor, the extraction procedure and the revision after the operation, all the process must be guaranteed in a long scope.

3. Abiding by specific rules of the Autonomous Community, procedures for granting, renewal and cancellation of the authorization to Centres for doing extractions from living donors will be the same as the explained regulations in section 12 of that Royal Decree, about authorisation to Centres for extraction of organs from dead donors.

The authorisation will decide the person who, besides the professional who is in charge of the medical service in which the transplant is going to be done, will allow to carry on with the operation, before making sure that conditions and requirements of section 9 of this Royal Decree are met.

Sweden:

A physician.

Switzerland:

There is no regulation.

Turkey:

Organ and tissue removal, preservation, vaccination and transplant have to be carried out by health institutions having necessary specialists, devices and equipment. Organ and tissue transplant centers are transplant centers that are given the operation/activity permission by the Ministry of Health. The conditions necessary for organ and tissues transplant centers and procedures and essentials regarding their operations are determined through the Directives prepared for every organ transplant. In these Directives, the qualities of staff to undertake the responsibility of the center, the qualities of staff to undertake task in the center, departments, devices and equipment that should be available in the center are mentioned.

Ukraine:

Doctor – transplantologist in state and communal establishment of health protection and state scientific establishments, accredited on transplantation activity for list, approved by the decree of the Cabinet of Ministers of Ukraine.

United Kingdom:

A registered medical practitioner in registered health facilities.

14. Are organ transplantation centres subject to approval? (y/n)
(Answers. Yes: 29 No: 3 Not Specified: 8)

15. Are transplantation teams subject to approval? (y/n)
(Answers. Yes: 24 No: 9 Not Specified: 7)

Country	14.	15.	Country	14.	15.
Albania	Yes	Yes	Latvia	Yes	Yes
Andorra			Liechtenstein		
Armenia	Yes	Yes	Lithuania	Yes	Yes
Austria	Yes*	Yes*	Luxembourg	NS*	NS*
Azerbaijan	Yes	Yes	the former YRM	Yes	Yes
Belgium	No	No*	Malta	NS*	Yes*
B/H			Moldova		
Bulgaria	Yes*	Yes*	Netherlands	Yes*	No*
Croatia	Yes	No	Norway	Yes	Yes
Cyprus	Yes	Yes	Poland	Yes*	Yes*
Czech Rep.	Yes*	NS*	Portugal	Yes	Yes
Denmark	NS*	NS*	Romania	Yes*	Yes
Estonia	Yes	No	Russia	Yes*	Yes*
Finland	Yes	No*	San Marino	NS*	NS*
France	Yes	Yes	Slovakia	Yes	Yes*
Georgia	Yes	Yes	Slovenia	Yes	Yes
Germany	NS*	No	Spain	Yes	Yes
Greece	NS*	NS*	Sweden	No	No
Hungary	Yes	No	Switzerland	NS*	NS*
Iceland	NS*	NS*	Turkey	Yes	Yes
Ireland	Yes	Yes	Ukraine	Yes	Yes
Italy	Yes	Yes	United Kingdom	No	No

Austria:

14. Yes, via the OKAP: Osterreichischer Krankenanstaltsplan.

15. Yes, transplantation teams can only operate within transplantation centres, approval is given by the transplantation centres.

Belgium:

15. There is no approval as such of the transplantation teams. The specialist physician who performs the transplantation is subject to approval, however the transplantation coordinator is not subject to approval.

Bulgaria:

14. Yes. By the Minister of Health.

15. Article 33, Para 3 of National Health Act stipulates that organs shall be grafted solely in specialized medical-treatment facilities, designated by the Minister of Health and by specialists expressly trained for this.

Czech Republic:

14. Yes. See Art. 22.

15. Not exactly, subject of approval are transplantation centres and respective health care facilities, transplantation teams are subject of coordination of Transplantation Coordination Centre – see Art. 25 § 2 lit. d.

Denmark:

14. Re. answers to Question 9.

15. Re. answers to Question 3.

Finland:

15. The transplantation teams principally do not have to ask authorities' approval for their activities, because the system is based on centralisation of the activities. When it is question about recovery of organs or tissues in connection with abortion, an explicit authorization for the activities has to be acquired from the National Authority for Medicolegal Affairs (according to the Act of the Medical Use of Human Organs and Tissues, section 7 clause 3). Normally an explicit approval is not needed.

Germany:

14. See answer to question 9.

Greece:

14. Organ transplantation centres, in order to operate, should conform to the provision mentioned earlier in paragraph 9 and obtain an appropriate license from the Minister of Health.

15. Medical transplantation teams are subject to approval from the Minister of Health, in the same way with organ transplantation centres.

Iceland:

14,15. There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiatransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Luxembourg:

14. Concerning the removal of organs, approval is given to an association, which acts as a national coordination service for the removal of kidneys. With regard to the subsequent transplant, it can be performed by any physician with the required competence.

15. See question 14.

Malta:

14. There are no organ transplantation centres other than the one in the main government hospital.
15. They are subject to approval by central government.

The Netherlands:

14. Yes. Transplantation are to be carried out only in transplantation centres as named in the Health Minister's decree on the planning of transplantation.
15. No. The transplantation centres are responsible for creation of adequate transplantation teams.

Poland:

14. Yes, according to the Health Minister's decree of the of 30 November 1996 relating to the conditions for the removal and transplantation of cells, tissues and organs and the supervision procedures for respecting these conditions. The transplantation of organs can only be performed in institutions authorised by the Minister of Health who delivers his or her decision after consultation with the National Transplantation Council.
15. Yes, according to the aforementioned decree, the Minister of Health, after having consulted with the National Transplantation Council authorises both the institutions (hospitals) and the persons undertaking the procedure to remove and to transplant cells, tissues and organs. The latter must have the necessary qualification which are also described by the Minister of Health.

Romania:

14. The conditions for hospital authorisation are proposed by the Romanian Medical College and are established by the authorisation regulation for the removal of human tissues and organs, which is approved by order of the Ministry of Health. See also question 9.

Russia:

14. All organ transplantation centers in the Russian Federation are subject to approval.
15. Transplantation teams are subject to approval.

San Marino:

- 14,15. Not applicable.

Slovakia:

15. Within the transplant centres.

Switzerland:

14. The hospitals are subject to approval by the canton. The transplantation centres are part of these hospitals.
15. The physicians are subject to approval by the canton.

16. Are these organs only transplanted into patients registered on a recognised waiting list?
(y/n).
(Answers. Yes: 30 No: 4 Not Specified: 6)

If not, please provide details.

Country	Rep.	Country	Rep.
Albania	Yes	Latvia	Yes
Andorra		Liechtenstein	
Armenia	NS*	Lithuania	Yes
Austria	Yes	Luxembourg	Yes*
Azerbaijan	No	the former YRM	No
Belgium	Yes*	Malta	Yes
B/H		Moldova	
Bulgaria	Yes*	Netherlands	Yes*
Croatia	Yes	Norway	Yes
Cyprus	Yes	Poland	Yes*
Czech Rep.	Yes*	Portugal	Yes
Denmark	Yes	Romania	Yes
Estonia	Yes	Russia	Yes*
Finland	Yes	San Marino	NS*
France	Yes	Slovakia	Yes
Georgia	NS*	Slovenia	Yes
Germany	Yes*	Spain	NS*
Greece	NS*	Sweden	Yes
Hungary	Yes	Switzerland	Yes
Iceland	NS*	Turkey	Yes
Ireland	Yes	Ukraine	Yes
Italy	No*	United Kingdom	No*

Armenia:

Registration system is not perfect as yet.

Belgium:

Cf. Article 7§1 of the Royal Decree of 24 November 1997 relating to the removal and allocation of human organs. The answer is Yes, but only for nationals or permanent residents of a state participating in the removal of organs within the same organization of allocation of human organs, namely Eurotransplant (the concerned countries are: Belgium, Netherlands, Luxembourg, Germany, Austria). However, when there is no suitable recipient on a waiting list for an organ, this organ can be allocated to a potential recipient who does not fulfil the conditions of nationality or of permanent residency mentioned above.

Bulgaria:

Yes. Organs may be grafted solely to recipients included in a waiting list for transplantation.

Czech Republic:

Yes; but only in the case of transplantation from deceased donor, see different regulation for transplantations from living donor – Art. 17 TA

Georgia:

Please, see question 10 and 11.

Germany:

Yes, as the transplantation of an organ removed from a living person is of lower priority than the possibility of transplanting an organ donated post mortem (Article 8 (1) first sentence, number three TPG).

Greece:

The organs donated are transplanted to the most suitable recipients – as they are pointed out by the parametric recording system of prospective recipients.

Iceland:

There are no transplant centres in the country so all transplantations are done abroad. As for necroorgan transplantation, Iceland is a member of the Scandiatransplant Organization and has a contact with one transplant centre in a Nordic country. All Icelandic patients needing necroorgan transplantation are put on waiting lists at that centre by contact persons appointed for the various transplant organs. Living donor transplantations (kidneys) are done at suitable transplant centres. Removal of organs from deceased donors is performed at three approved intensive care units in the country by a team from the same transplant centre that provides necroorgans for transplantation to Icelandic patients. The ICU's are reimbursed by the transplant centre for their cost connected with the organ removal. The State Social Security Institute handles payment for all organ transplantations performed on Icelandic patients and therefore keeps records of all transplantations and the waiting lists for transplantation. A committee appointed by the Ministry of Health to handle transplantation issues also keeps record of all transplantations to Icelandic patients and all removal of organs for transplantation.

Italy:

No. Exceptions are envisaged in particular cases of emergency when the possible survival of a patient is strictly conditioned by the immediate transplantation of the organ (accidents, natural disasters etc).

Luxembourg:

Yes, the waiting list is managed by Eurotransplant (see the answer for question n 10 aforementioned).

The Netherlands:

Yes. Not necessarily. The recipient-to-be may want to undergo an organ transplantation only if the organ is donated by a living person, for instance his spouse or a relative. In that case the patient may, or may not, be registered on the waiting list.

Poland:

Yes. The transplantation of organs removed from deceased persons is only based on medical criteria and the recipient can only be chosen from the patients registered on a national waiting list. Concerning the removal from living donors – members of the family of the recipient - this principle does not apply and it is possible to transplant the organs to recipients even before their registration on a waiting list. (for example, the case of kidney diseases in patients which were not yet on dialysis).

Russia:

These organs are only transplanted into patients registered on a recognized waiting list.

San Marino:

Not applicable.

Spain:

For being transplanted from a living or cadaverical donor, must be included in a waiting list of a transplant team.

United Kingdom:

No. Non-NHS patients will not be registered.

17. Are the rules on the removal and transplantation of organs applicable to non-resident persons? (y/n)
 (Answers. Yes: 24 No: 7 Not Specified: 9)

Country	Rep.	Country	Rep.
Albania	Yes*	Latvia	Yes
Andorra		Liechtenstein	
Armenia	Yes	Lithuania	Yes
Austria	Yes*	Luxembourg	NS*
Azerbaijan	No	the former YRM	Yes
Belgium	Yes*	Malta	NS*
B/H		Moldova	
Bulgaria	Yes*	Netherlands	No*
Croatia	NS*	Norway	No
Cyprus	Yes	Poland	NS*
Czech Rep.	NS*	Portugal	No
Denmark	NS*	Romania	Yes
Estonia	Yes*	Russia	Yes*
Finland	Yes	San Marino	NS*
France	Yes	Slovakia	Yes
Georgia	NS*	Slovenia	Yes
Germany	Yes	Spain	No*
Greece	NS*	Sweden	Yes
Hungary	No	Switzerland	Yes
Iceland	No	Turkey	Yes
Ireland	Yes	Ukraine	Yes
Italy	Yes	United Kingdom	Yes

Albania:

Yes, but according to the rules.

Austria:

Yes (Austrian law is applicable to all persons being in Austria, also to non-residents).

Belgium:

Cf. Article 7§1 of the Royal Decree of 24 November 1997 relating to the removal and allocation of human organs. The answer is Yes, but only for nationals or permanent residents of a state participating in the removal of organs within the same organization of allocation of human organs, namely Eurotransplant (the concerned countries are: Belgium, Netherlands, Luxembourg, Germany, Austria). However, when there is no suitable recipient on a waiting list for an organ, this organ can be allocated to a potential recipient who does not fulfil the conditions of nationality or of permanent residency mentioned above.

Bulgaria:

Yes. Foreigners, who are long-term residents in Bulgaria enjoy the same rights as Bulgarian citizens as regards the inclusion in a list waiting for organ transplantation. The rule of implied consent of the donation of organ and tissues after a person's death is valid solely to legally capable Bulgarian citizens, who have attained full legal age.

Croatia:

For donating organ Yes, for transplantation only for those who have health insurance in Republic Croatia.

Czech Republic:

Transplantation rules concerning living donor are applicable to non-residents as well. Organ and tissues removal from a deceased foreign national may only be performed under the conditions stipulated by an international agreement that is binding to the Czech Republic – see Art. 11 § 4; at the present time there is not any such agreement.

Denmark:

The regulations are applicable to anyone staying or living in Denmark. But there are regulations concerning access to hospital care. Non-residents can only receive acute care – unless they have access regarding to international regulation.

Estonia:

Yes, at the time of their stay in Estonia.

Georgia:

All protective measures are applicable to non-resident persons as well.

Greece:

The same rules that are applicable to Greek citizens apply also to every foreign citizen residing in Greece or everyone who would wish to undergo transplantation in Greece.

Luxembourg:

The legal principle according to which any deceased person is assumed to be a donor of organs, unless this person objected while still alive, does not extend to non-resident persons.

Malta:

This particular instance has never arisen and it would then be subject for consideration by the Renal Services Committee in consultation with the Bioethics Committee.

The Netherlands:

No. The Organ Donation Act is applicable only to the removal of organs - either from living persons or from deceased persons - in the Netherlands.

Poland:

As for non-residents, the removal of organs must be performed in accordance with the legislation in force in the country of origin of the donor.

The transplantation of organ removed from a deceased person to a non-resident is acceptable only for humanitarian reasons and must be approved by the Minister of Health.

The removal and transplantation of organs from living donors to a non-resident does not meet any legal obstacles if there is a family relationship between the donor and the recipient.

Russia:

The rules on the removal and transplantation of organs are applicable to non-resident persons.

San Marino:

Not applicable.

Spain:

No. If someone wants to accede to a transplant programme in Spain, being an official resident is compulsory.

18. Does the transplantation system ensure that legally removed organs cannot evade its control? (y/n)
(Answers. Yes: 35 No: 1 Not Specified: 4)
19. Is it possible to ensure that illegally removed organs cannot enter your transplantation system? (y/n)
(Answers. Yes: 35 No: 2 Not Specified: 3)

Country	18.	19.	Country	18.	19.
Albania	Yes	Yes	Latvia	Yes	Yes
Andorra			Liechtenstein		
Armenia	NS*	Yes	Lithuania	Yes	Yes
Austria	Yes	Yes	Luxembourg	Yes	Yes*
Azerbaijan	NS	No	the former YRM	Yes	Yes
Belgium	Yes	Yes	Malta	Yes*	NS*
B/H			Moldova		
Bulgaria	Yes	Yes*	Netherlands	Yes*	No*
Croatia	Yes	Yes	Norway	Yes	Yes
Cyprus	Yes	Yes	Poland	Yes*	Yes*
Czech Rep.	Yes*	Yes	Portugal	Yes	Yes
Denmark	Yes	Yes	Romania	Yes	Yes
Estonia	Yes	Yes	Russia	Yes*	Yes*
Finland	Yes	Yes	San Marino	NS*	NS*
France	Yes	Yes	Slovakia	Yes	Yes
Georgia	Yes	Yes	Slovenia	Yes	Yes
Germany	Yes*	Yes*	Spain	Yes	NS*
Greece	NS*	Yes*	Sweden	Yes	Yes
Hungary	Yes	Yes	Switzerland	Yes	Yes
Iceland	No	Yes	Turkey	Yes	Yes
Ireland	Yes	Yes	Ukraine	Yes	Yes
Italy	Yes	Yes	United Kingdom	Yes*	Yes

Armenia:

18. Assurance is made only for important organs.

Bulgaria:

19. Yes. Full guaranties may be given to the organs transplanted in Bulgaria. Understandably, such a guaranty may not be given with respect to transplantation to Bulgarian citizens performed abroad. Detailed legal and organisational regulation of a single national transplantation system is explicitly envisaged in the Act on Transplantation of Organs, Tissues and Cells.

Czech Republic:

18. Yes, see the provisions of the Art. 12 TA.

Germany:

18. Yes, through a system of control carried out by the coordination agency (Article 11 TPG) and the mediation agency (Article 12 TPG) in cooperation with the transplantation centres.

19. Yes, the organs requiring mediation (heart, kidneys, liver, lungs, pancreas and bowel) can only be transplanted when they have been mediated by the mediation agency referred to in Article 12 TPG (Article 9, first and second sentence TPG). Eurotransplant as a mediation agency only mediates organs whose origins are clear. According to Article 12, the mediation agency can only mediate organs removed outside the area of validity of the Act if the organs were removed in line with the legal provisions valid at the place of removal, in so far as their application does not lead to a result that is incompatible with the essential principles of German law, above all fundamental rights. The mediation decision is to be documented for each organ including the reasons behind it (Article 12 (3) third sentence TPG). Furthermore, the transplantation centres are obliged to document each organ transplantation in such a way as to guarantee a comprehensive tracing of organs from the donor to the recipient (Article 10 (2) (4) TPG).

Greece:

18. The transplantation system, as applied currently, ensures the transparency and security of its management.

19. Yes, it is possible to ensure that, because every medical action of transplantation is notified to National Transplantation Organisation (EOM), and in the process of its completion a large number of experts in various fields and subjects is involved.

Luxembourg:

19. Yes. The transplantation system being the one of Eurotransplant.

Malta:

18. Yes, in practice, but in the absence of the legislative framework one cannot classify organ transplantation into legal and illegal but rather as approved by the system or not.

19. With the current structure of available health services, it is practically impossible for illegally removed organs to be transplanted.

The Netherlands:

18. Yes. Evasion will be noticed sooner or later.

19. No. As far as solid organs are concerned the possibility that illegally removed organs enter the system may be considered as highly theoretical.

Poland:

18. The central organisation and coordination system of procedures for the removal and transplantation of organs in Poland ensures total control.

19. Yes. The aforementioned system enables the risk of illegal removals to be eliminate.

Russia:

18. The transplantation system ensures that legally removed organs cannot evade its control.

19. The existing legislation ensures that illegally removed organs cannot enter our transplantation system.

San Marino:

18, 19. Not applicable.

Spain:

19. Our sanitary and legal control is very reliable and strict, extractions and implants are done in the frame of the sanitary official system.

United Kingdom:

18. Yes, through follow-up and audit.

II . Investigation of Organ Trafficking

20. Are you aware of any allegations concerning the illegal removal of organs in your country?
(y/n)

(Answers. Yes: 5 No: 31 Not Specified: 4)

21. Are you aware of any allegations concerning the arrival into your country of organs removed illegally? (y/n)

(Answers. Yes: 3 No: 34 Not Specified: 3)

Country	20.	21.	Country	20.	21.
Albania	No	Yes	Latvia	No	No
Andorra			Liechtenstein		
Armenia	Yes	Yes	Lithuania	No	No
Austria	No	No	Luxembourg	No	No
Azerbaijan	No	No	the former YRM	No	No
Belgium	No	No	Malta	No	No
B/H			Moldova		
Bulgaria	No	No	Netherlands	No	No
Croatia	No	No	Norway	No	No
Cyprus	No	No	Poland	No*	NS*
Czech Rep.	NS*	No	Portugal	No	No
Denmark	No	No	Romania	No	No
Estonia	Yes*	No	Russia	Yes*	No*
Finland	No	No	San Marino	No	No
France	No	No	Slovakia	No	No
Georgia	Yes	No	Slovenia	No	No
Germany	No*	No*	Spain	No	No
Greece	NS*	NS*	Sweden	No	No
Hungary	No	No	Switzerland	No	No
Iceland	No	No	Turkey	Yes	Yes
Ireland	No	No	Ukraine	NS*	No
Italy	NS	NS	United Kingdom	No*	No

Czech Republic:

20. In the Czech Republic there had been undertaken only one public available investigation in regard to this matter. As a result there are some findings of so called Investigation Committee of the Chamber of Deputies concerning conditions for performing transplantations in Faculty Hospital in Ostrava. These findings are in fact incentive for adoption of the new TA. The activity of this Committee relies on some cases that were raised in the public debate.

Estonia:

20. Yes, one case: in 1998 an Israeli Dr Shapira visiting Estonia performed so-called example operations of kidney transplantation in one Estonian hospital, where both recipients and donors were from foreign country (recipients were from Israel and donors allegedly Romanians). However, there were no criminal proceedings started on the basis of this allegation.

Germany:

20, 21. No, there are no concrete findings here.

Greece:

20. There has been no illegal removal of organs in Greece, nor has been any similar allegation.

21. There has never occurred any arrival of organs removed illegally into Greece, and there has never been any suspicion about this.

Poland:

20. During the last 35 years we have not noted any legal procedure relating to the removals of organs in violation to the legal provisions.

21. The transplantation of organs removed in a foreign country can only be performed through the framework of a cooperation between competent national institutions.

With regard to living donors who do not have family relationships with the recipients, the Polish system requires the decision of a court which enables, in an effective manner, the sale of an organ by living donors to be avoided.

Russia:

20. We are aware of some allegations concerning the illegal removal of organs or tissues from deceased donors (see Q.23).

21. We are not aware of any allegations concerning the arrival into this country of organs removed illegally.

Ukraine:

For 2001 year in Ukraine 2 criminal cases were opened for signs of article 143 of Criminal Code of Ukraine (Donetsk and Kharkov regions), a pretrial investigation on these cases continues.

United Kingdom:

20. No, not in the last ten years.

22. Are you aware of any allegations whereby residents of your country have been travelling abroad to illegally sell or procure organs? (y/n)
 (Answers. Yes: 6 No: 30 Not Specified: 4)

If so, to which countries?

Country	Rep.	Country	Rep.
Albania	Yes*	Latvia	No
Andorra		Liechtenstein	
Armenia	No	Lithuania	No
Austria	No	Luxembourg	No
Azerbaijan	No	the former YRM	No
Belgium	Yes*	Malta	No
B/H		Moldova	
Bulgaria	No	Netherlands	No
Croatia	Yes*	Norway	No
Cyprus	Yes*	Poland	NS*
Czech Rep.	No	Portugal	NS*
Denmark	No	Romania	No
Estonia	No	Russia	No*
Finland	No	San Marino	No
France	Yes*	Slovakia	No
Georgia	No*	Slovenia	No
Germany	No*	Spain	No
Greece	NS*	Sweden	No
Hungary	No	Switzerland	No
Iceland	No	Turkey	No
Ireland	No	Ukraine	No
Italy	NS	United Kingdom	Yes*

Albania:

Yes, Italy.

Belgium:

Yes, in the eyes of the federal police, Turkey is a "hub" of organ trafficking.

Croatia:

Far East.

Cyprus:

Yes. Lebanon (to produce organs)

France:

Yes (to procure organs). Turkey, China, India.

Georgia:

No (However, several articles in newspapers were devoted to this problem saying that Georgia citizens travel abroad to sell organs. Still no official data exist about this).

Germany:

No, there are no concrete findings here.

Greece:

There have been published individual cases of patients that have travelled to third world countries in order to undergo a transplantation. However, we have not been officially informed on these cases or on details about them.

Poland:

There is a lack of information concerning the trips of Polish nationals abroad with the aim of selling their organs.

Portugal:

In 2001, because of an anonymous denunciation, a police investigation was opened in order to substantiate a possible case of organ trafficking towards Spain; this allegation was shown to be unfounded.

Russia:

We do not possess any such information.

United Kingdom:

Yes. Some people have travelled to India and received kidney transplants under questionable circumstances.

23. Have there been any official investigations, in the past to ascertain allegations of organ trafficking? (y/n)
(Answers. Yes: 7 No: 29 Not Specified: 4)

If so, please provide details.

24. Are there any official investigations currently taking place to ascertain allegations of organ trafficking? (y/n)
(Answers. Yes: 3 No: 33 Not Specified: 4)

If so, please provide details.

25. Have there been any prosecutions for organ trafficking? (y/n)
(Answers. Yes: 3 No: 34 Not Specified: 3)

If so, please provide details.

Country	23.	24.	25.	Country	23.	24.	25.
Albania	Yes*	NS*	NS*	Latvia	No	No	No
Andorra				Liechtenstein			
Armenia	No	No	No*	Lithuania	No	No	No
Austria	No	No	No	Luxembourg	No	No	No
Azerbaijan	No	No	No	the former YRM	No	No	No
Belgium	No	No	No	Malta	No	No	No
B/H				Moldova			
Bulgaria	No	No	No	Netherlands	No	No	No
Croatia	No	No	No	Norway	No	No	No
Cyprus	No	No	No	Poland	No	No	NS*
Czech Rep.	No	No	No	Portugal	NS*	No	No
Denmark	No	No	No	Romania	No	No	No
Estonia	No	No	No	Russia	Yes*	Yes*	No*
Finland	No	No	No	San Marino	No	No	Yes
France	Yes*	No*	No	Slovakia	No	No	No
Georgia	Yes*	Yes*	No	Slovenia	No	No	No
Germany	Yes*	Yes*	Yes*	Spain	No	No*	No
Greece	NS*	NS*	No*	Sweden	No	No	No
Hungary	No	No	No	Switzerland	No	No	No
Iceland	No	No	No	Turkey	Yes*	No	Yes*
Ireland	No	No	No	Ukraine	NS*	NS*	No
Italy	NS	NS	NS	United Kingdom	Yes*	No	No

Albania:

23. Yes. Some months ago, an Albanian man was arrested with his wife having been accused of sending to Italy children intended for organ trafficking.

24. See answer to question 23.

25. The case is still under investigation.

Armenia:

25. The law of organ and (or) tissue transplantation is in force in Republic of Armenia.

France:

23. Yes, inquiry of the French Transplant Institution (l'Etablissement français des greffes (EFG)) in 2002 with transplant teams and deliberation by the ethics committee of the EFG.

24. No (see reply to 23, investigation carried out in 2002)

Georgia:

23. Yes (please, see question 24)

24. Recently, in September 2002 there was a case in the newspaper ("*The Version*", #60, 2-8 September, 2002) according which patient, recipient of the organ from unrelated donor, died. Wife of the deceased reported that both parties (donor and recipient) were involved in falsification of documents in order to "prove" that they were genetic relatives. Ministry of Labour, Health and Social Affairs submitted this case to the Prosecutor General for relevant investigation. No official information is available about this case since then.

Germany:

23. Yes. Two court judgments were delivered because of organ trafficking. One preliminary investigation by the public prosecutor was discontinued.

24. Two preliminary investigations by the public prosecutor because of organ trafficking are currently pending.

25. See answer to question 23.

Greece:

23. There have been no official investigations to ascertain cases of organ trafficking, because there have been no relevant allegations.

24. The transplantation system does not allow nor provides any possibility even for isolated actions of organ trafficking, therefore there are no relevant investigations currently.

25. There has never been any prosecution for organ trafficking, due to all aforementioned reasons.

Poland:

25. The necessity of implementing legal proceedings in order to prevent organ trafficking has not yet occurred.

Portugal:

23. In 2001, because of an anonymous denunciation, a police investigation was opened in order to substantiate a possible case of organ trafficking towards Spain, this allegation was shown to be unfounded.

Russia:

23. On 18 August 1999 the Prosecutor's Office of the town of Bijsk, Altai region, initiated proceedings based on alleged abuse of authority by the doctors of the Central town hospital when internal organs were removed from deceased donors for the purposes of transplantation, without prior permission of the relatives of the deceased. The criminal action was grounded in the materials collected in the course of investigation of the complaint by Mrs. L. Kaplina alleging the removal of her deceased daughter's kidney at the hospital before her body was admitted to the morgue. Similar facts of post-mortem kidney removals from seven bodies of persons who died at the hospital were revealed in the course of investigation.

Based upon the results of the investigation, a senior investigator of the Altai region Prosecutor's Office decreed that case be terminated due to the absence of the fact of the crime.

As the materials of the case were studied by the Russian Federation Prosecutor General's Office, it was determined that the Russian Federation Law on the Transplantation of Organs and/or Human Tissues, as it concerns consent to organ removal, was at variance with the Federal Law on Funerals and Burial Arrangements dated 12 January 1996. Para 3 of Article 5 of the law provides that relative's permission should be obtained for human organs and/or tissues removal in the case of absence of the declaration of will on the part of the deceased.

Based on the contradictions in the existing legislation regulating the legal basis for removing organs from deceased for the purpose of their transplantation, and taking into consideration that the use of kidneys of the

deceased had not resulted in grave consequences, a conclusion was made that the actions of the officials of the central hospital of the town of Biisk did not constitute fact of crime.

Believing that the mentioned contradictions should be eliminated by amending the legislation regulating the legal basis for removing organs and tissues from deceased for the purpose of their transplantation, the Prosecutor General's Office of the Russian Federation on 30 April 2002 addressed a letter to the State Duma of the Federal Assembly of the Russian Federation, containing respective proposals.

24. On April 6, 2001 the Prosecutor's Office of the Novosibirsk oblast initiated criminal proceedings based on constituent elements of the offence mentioned in Article 286, part 1 of the Criminal Code of the Russian Federation following alleged violations of the Federal Law on Funeral and Burial Arrangements and the Law of the Russian Federation on the Transplantation of Organs and/or Tissues of Human Origin by the officials of medical institutions of the city of Novosibirsk.

In the course of the investigation it was found that A.V. Efremov, the rector of the Novosibirsk State Medical Academy (NSMA), signed an agreement on scientific cooperation with the Institute of Plastination (Heidelberg, Germany). To implement the agreement, A.V. Efremov sent a letter to V.P. Novoselov, the Head of the Oblast Bureau of Forensic Examination (FEX), asking for assistance in obtaining cadaver (dead body) material which could be provided when relatives of the deceased refuse to bury them or when there are no relatives of the deceased whose bodies are delivered for burial from medical institutions or social protection agencies.

In October 2000, the NSMA delivered 56 cadavers to the Institute of Plastination in Germany. The dead body material was provided by the Oblast FEX Bureau, the dead bodies, according to the institution records, having been cremated and the cremains allegedly returned to the relatives for burial. During the inspection of the cadaver storage facility 32 more dead bodies were found in the NSMA laboratory also prepared to be shipped to Germany. Meanwhile, according to the cremation register of the Oblast FEX Bureau, the bodies were registered as cremated, and their cremains allegedly returned to the relatives.

Preliminary investigation of that criminal case has now been suspended due to a grave illness of the defendant, V.P. Novoselov.

25. There have been no prosecutions for organ trafficking.

(Note. Since the Criminal Code of the Russian Federation entered into force on 1 January 1997, the Supreme Court of the Russian Federation or lower federal courts of general jurisdiction have not until now considered any criminal cases mentioned in Article 105 m) or Article 120 of the Criminal Code.

However, on 17 June 2002, the Supreme Court of the Russian Federation held an open hearing in the first instance of a civil case brought by Mr. A. Starchenko requesting that the provisions of two by-laws enacted by the USSR Ministry of Health, *Instruction No. 866 concerning the removal of hypophyses from dead human bodies and their initial conservation* dated 23 September 1997, and order No. 872 of the USSR Ministry of Health on *Improved collection of hypophyses from dead human bodies for the purposes of hormonal compound production* dated 7 July 1987, be declared null and void. The applicant reconfirmed his request in a court hearing claiming that the said provisions of the by-laws violated human rights of the individual and contradicted Federal law.

The Supreme Court determined that the provisions contested by the applicant contradicted Federal law, namely Article 21 of the Constitution of the Russian Federation and Article 5 of the Federal law on *Funerals and Burial Arrangements*, and were not to be applied. Order No. 205 of the Ministry of Health of the Russian Federation dated 21 June 2002, recognized that the two by-laws of the USSR Ministry of Health contested in the Supreme Court were null and void in their entirety on the territory of the Russian Federation.)

Spain:

24. No, buying and selling organs would be very difficult, it's not possible, for that reason there's not a problem in our country.

Turkey:

23. For the claims about organ transplants that had been made illegally, there exist examinations and research performed by the related Provincial Health Directorates of our Ministry, and when necessary the inspectors of the Ministry by the Department of Inspection Council. As a result of this examinations and research, the necessary situations were transferred to the judgement.

25. Concerning organ transplants made illegally, there are cases which are already resulted or which have been going on in judgement.

Ukraine:

23. According to information of the Office of Interpol in Ukraine, in July of 2001 to Ukraine was brought back Ukraine citizen corpse B., which from may of 1999 worked in factory of metallic constructions in Israel.

Taking into account that citizen B. was by practically healthy man, in his wife had suspicion as for causes of his death. Last appealed with statement to procurator's office of Kyiv City and was accorded permission on taking of judicially – medical examination, which it got 26 July 2001 year.

A sealed up coffin was opened in presence of judicial-medical expert, two hospital attendants, relative and friends late. Signs of previous pathologic expertise were not found. Only dissection traces in region of thorax. According to the result of expertise, a sternum is cut and linked by metallic wire, heart bag cut, and heart absent.

Under investigation time of stated case set, that in Israel clinic there is a wife signature of B., to which it lends a right on gratuitous organ (hearts) withdrawal of her men, for condition, that his body will be put over for interment on Ukraine for transplantation Center counting. But, as set by outcome, wife of dead men never comes to state Israel and withheld permission on withdrawal of any organs of her men. Investigation of this criminal case continues.

24. On criminal cases, opened for a. 143 of Criminal code of Ukraine, aforesaid into point 20, by procurator's office of stated regions takes pretrial investigation. In accordance to a. 121 of Criminal procedure code of Ukraine, making public the data of pretrial investigation is forbidden.

United Kingdom:

23. An investigation was held into alleged live donation by Turkish nationals in 1988 – this led to the passing of the Human Organ Transplants Act of 1989. More recently allegations of arranging for organ transplants to be obtained abroad were investigated by Scotland Yard – nothing has yet been proven.