Law No. 95/2006 on healthcare reform – Chapter V: Transplant

TITLE VI

Procurement and transplant of human organs, tissues and cells for therapeutic purposes

NOTE:

The application norms of title VI “Procurement and transplant of human organs, tissues and cells for therapeutic purposes” from Law no. 95/2006 on the healthcare reform were approved by Order of the Ministry of Public Health no. 1290/2006.

CHAPTER 1

General provisions

ART. 141

(1) The donation and transplant of human organs, tissues and cells intended for therapeutic purposes shall comply with standards of quality and safety to guarantee a high level of human health protection, in line with this title.

(2) This law applies to the donation, testing, assessment, procurement, preservation, distribution, transport and transplant of human organs, tissues and cells intended for transplant.

(3) In case such human organs, tissues and cells are used for research, this law does not apply unless they are intended for human transplant purposes.

ART. 142

For the purposes of this title, the terms and expressions below shall have the following meaning:

a) accreditation – granting the right to perform activities of donation, testing, assessment, procurement, preservation, distribution, transport and transplant of human organs, tissues and cells, based on the specifics of each activity, after acknowledging the observance of criteria set by order of the minister of health. The accreditation shall be granted by the National Transplant Agency officials and approved by order of the minister of health;

b) competent authority – institutions responsible for coordinating, supervising, accrediting and inspecting the transplant activities, as well as the implementation of any provisions on transplant activities;

c) special authorization – the export-import permit issued by the National Transplant Agency for introducing or removing human organs, tissues and/or cells from the country, when the

donation, procurement, processing, preservation, storage, transport and transplant take place in units accredited and/or designated by the National Transplant Agency;

d) designated bank – human tissue and cell bank located outside Romania. In case of third countries, the bank shall comply with the quality and safety standards stipulated by Directive 2004/23/EC of the European Parliament and of the Council of March 31st 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and shall produce supporting documents in this respect. In the case of EU Member States, the bank must be accredited by the competent authority from the respective country;

e) tissue and cell bank – accredited/designated healthcare unit where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken;

f) cell – the basic elementary anatomic and functional unit of living matter. For the purposes of this law, the term cell/cells shall mean the individual human cell or a collection of human cells when not bound by any form of connective tissue;

g) procurement center – a public or private healthcare establishment, a medical team or a unit of a hospital, a person or any other body which undertakes and/or coordinates the procurement of organs, tissues and/or cells and is authorized in the field of transplantation;

h) transplantation center – a public or private healthcare establishment, a medical team or a unit of a hospital, a person or any other body which undertakes the transplantation of human organs, tissues and cells and is authorized in the field of transplantation;

i) preservation – the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs, tissues and cells from procurement to transplantation;

î) disposal – the final placement of an organ, tissue or cell when it is not used for transplantation;

j) donation – the fact of donating organs, tissues and/or cells for transplantation;

k) donor – a person who donates one or several human organs, tissues and/or cells for therapeutic purpose, whether donation occurs during lifetime or after death;

l) donor characterization – collecting relevant information on the characteristics of the donor, needed to evaluate his/her suitability for organ, tissue and cell donation in order to undertake a proper risk assessment and minimize the risks for the recipient and to optimize organ, tissue and cell allocation;

m) organ characterization – collecting relevant information on the characteristics of the organ needed to evaluate its suitability in order to undertake a proper risk assessment and minimize the risks for the recipient and to optimize organ allocation;

n) serious adverse event – any untoward and unexpected occurrence associated with any stage in the chain from donation to transplant that might lead to the transmission of a communicable disease, to death or a life-threatening, disabling or incapacitating conditions for the patient or which might result in or prolong hospitalization or morbidity;

o) organ – means the differentiated part of the human body, capable of a specific function, formed by several tissues or cell types, with own vascularization and innervation. An organ, within this meaning, shall also be a part of an organ if it serves the same purpose as the whole organ, maintaining its structure and vascularization;

p) European organ exchange organization – a non-profit organization, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States;

q) procurement – the collection of human organs and/or tissues an/or cells, morphologically and functionally healthy for the purpose of conducting certain transplant procedures;

r) operating procedures – written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

s) serious adverse reaction – an unintended response, including a communicable disease in the living donor or in the recipient, occurring at any stage in the chain from donation to transplant that is fatal, life-threatening, disabling or incapacitating or which results in or prolongs hospitalization or morbidity;

t) transplantation – the medical activity whereby, for therapeutic purposes, in the body of a patient, hereinafter called recipient, an organ, tissue or cell procured from another person, called the donor, is transplanted or engrafted. The regulations in this law are intended exclusively for *in vitro* fertilization techniques;

ţ) traceability – the ability to locate and identify the organ, tissue or cell at any stage in the chain from donation to transplant or disposal, including the ability to identify the donor and the procurement center, the recipient and the transplant center, to locate and identify all relevant non-personal data regarding the products and materials that come in contact with the respective organ, tissue or cell;

u) tissue – a group of differentiated cells, connected by the amorphous intercellular substance, forming together a topographic and functional association;

v) accredited healthcare unit – a public or private healthcare unit that meets the accreditation criteria for conducting transplant operations, namely donation, testing, assessment, procurement, preservation, distribution, transport and transplant.

ART. 143

(1) The National Transplant Agency and the Ministry of Health, by its health control unit, are the competent authorities in the field of transplantation in Romania.

(2) The National Transplant Agency is responsible for the coordination, supervision, approval and implementation of any provisions on transplantation activities.

(3) The Ministry of Health, by its health control unit, is responsible for the inspection and control measures of transplantation activities.

(4) The human organ, tissues and cells shall be procured in accredited public or private healthcare units. The accreditation criteria shall be set by the National Transplant Agency and approved by order of the minister of health*).

(5) The transplantation of human organs, tissues and cells shall be undertaken in accredited public or private transplantation centers. The accreditation shall specify what type or types of transplantation can be performed. The accreditation criteria shall be set by the National Transplant Agency and approved by order of the minister of health *).

(6) The personnel involved at all stages of the transplant chain, from donation to actual transplantation or, as the case may be, to the disposal of unused/unusable organs, tissues and cells shall be trained and competent to perform the respective tasks and shall have specialized professional training in the field.

(7) The National Registry of Volunteer Donors of Hematopoietic Stem Cells shall be responsible for processing national or international requests for the use of hematopoietic stem cells from unrelated donors.

(8) In order to interconnect with similar international institutions and to obtain accreditation, the National Registry of Volunteer Donors of Hematopoietic Stem Cells referred to in paragraph (7) and the immunogenetics and histocompatibility laboratories (HLA), the registry may pay annual fees and taxes.

(9) The level of taxes and fees provided for at paragraph (8) shall be approved annually by Government Decision and earmarked from the State budget, through the Ministry of Health budget.

CHAPTER 2

Donation and donors of human organs, tissues and cells

ART. 144

(1) The procurement of human organs, tissues and cells from living donors shall be subject to the following conditions:

a) human organs, tissues and cells intended for therapeutic purposes can be procured from living adults, with full exercise capacity, based on their written, free, prior and express informed consent, according to the form in annex no. 1. The procurement of organs, tissues and cells from undiscerning individuals shall be prohibited;

b) the consent shall be signed only after the donor was informed by the medical doctor, the social worker or other specialists with regard to the potential physical, psychological, family, professional and social risks and consequences resulting from the procurement;

c) the donor may reverse their consent, until the moment of the procurement;

d) the transplant of human organs, tissues and cells under physical or moral constraint is hereby prohibited;

e) the donation and transplant of human organs, tissues and cells cannot be performed through legal acts and facts for the purpose of obtaining material or other gains;

f) the donor and the recipient shall sign an authentic document stating that the donation is humanitarian, altruistic and is not subject to any legal acts or facts for the purpose of obtaining material or other gains, according to the form in annex no. 1;

g) the donor shall be exempt from paying the hospitalization/hospitalizations related to donating, as well as the costs for the regular post-donation medical check-ups.

(2) The procurement centers and the transplantation centers shall keep records of living donors that donated in the respective center, in accordance with the national provisions on personal data protection and statistical secrecy.

(3) Monitoring living donor includes mandatory regular check-ups every one, three, six and 12 months after donation, then annually.

ART. 145

(1) The procurement of organs, tissues and cells from potential minor living donors shall be prohibited, except for the cases provided for in this law.

(2) By way of exception from the provisions of paragraph (1), if the donor is minor and related to the fourth degree with the recipient, the procurement of marrow or peripheral hematopoietic cells shall be subject to the following conditions:

a) the procurement of marrow or peripheral hematopoietic cells from minors can only be performed with the minor's consent if he/she is at least 10 and with the written agreement of the legal guardian, parents, tutor or curator respectively, according to annex no. 2. If the minor is not 10, the procurement can be done with the agreement of the legal guardian;

b) if the donor is at least 10, his/her written or verbal consent shall be expressed in front of the chairman of the court from the jurisdiction of the transplantation center or of the court from the constituency of the donor, after the general directorate for social assistance and child protection conducted the mandatory psycho-social investigation.

(3) The minor's written or verbal refusal shall prevent any procurement.

ART. 146

(1) The procurement of organs, tissues and cells from living donors shall be performed with the approval of the committee responsible for approving the donation from a living donor, established in the hospital where the transplantation is undertaken; this committee shall assess the motivation of the donation and make sure the patients' rights are observed, according to the model in annex no. 1.

(2) The committee responsible for approving the donation from a living donor shall be made of the following: a medical doctor trained in bioethics from the county or Bucharest college of physicians, a psychologist or psychiatrist and a primary doctor, a hospital employee with management duties, not involved in the transplantation team.

(3) This committee will operate in line with a written regulation issued by the National Transplant Agency, in consultation with the Bioethics Commission of the Ministry of Health. The regulation will be approved by order of the minister of public health.

(4) The committee will assess both the donor and the recipient, who will be subject to a psychological and/or psychiatric examination to test their exercise capacity and the reason for donating.

(5) The psychological/psychiatric examination will be conducted by a specialist, psychologist or psychiatrist, independent both from the transplant team and from the donor's and recipient's families.

(6) The procurement from living donors of blood, skin, sperm, femur head, placenta, blood from the umbilical cord, amniotic membranes to be used for therapeutic purposes shall be in line with the bioethics rules from the regulation of the committee responsible for approving the donation from a living donor, without requiring the approval of this committee.

(6^1) In case of placental blood, blood samples, skin, sperm, femur head, placenta, amniotic membranes, cord blood and cord tissues collected at birth, the number of the accreditation or designation certificate issued for the bank by the National Transplant Agency shall be specified on the authorization.

(7) Donor and recipient data, including genetic information that third party can access, shall be communicated anonymously, so as neither the donor, nor the recipient can be identified.

(8) If the donor doesn't want to reveal his/her identify, donation confidentiality shall apply, except for the cases when declaring the identity is required by the law.

ART. 147

The organs, tissues and cells from a deceased donor shall be procured as follows:

1. a deceased donor without cardiac activity shall be the person in irresuscitable and irreversible cardio-respiratory arrest, confirmed by two primary doctors in the hospital. The deceased donor without cardiac activity shall be confirmed as such based on the resuscitation protocol, provided for in annex no. 6, except for unequivocal situations;

2. a deceased donor with cardiac activity shall be the person with irreversible arrest of all brain functions, according to the protocol of pronouncing brain death from annex no. 3;

3. brain death shall be pronounced by medical doctors who are not part of the teams that coordinate, procure, transplant the human organs, tissues and cells;

4. the organs, tissues and/or cells from deceased persons shall only be procured based on the written consent of at least one adult family member or relative, in the following order: surviving spouse, parents, descendents, siblings, other collateral relatives up to the fourth degree, included, according to the model provided for in annex no. 4.

5. the procurement can be performed without the consent of family members if, during the lifetime, the deceased person had already expressed his option for donation, by a notary deed of consent for procurement and registration in the National Registry of organ, tissue and cell donors, according to the model in annex no. 5;

6. the procurement shall not be performed if, during his/her lifetime, the deceased person had already expressed his/her option against donation, by a donation refusal deed. The donation refusal deed shall be produced by the family to the transplant coordinator.

ART. 148

(1) The procurement of organs, tissues and cells from living and deceased donors shall be performed only after clinical and lab tests that establish the donor-recipient suitability and exclude any infectious disease, a potential contamination or other conditions that place the recipient at risk, according to the protocols set for each organ, tissue or cell. In case of contaminated stem cells, except for HIV, syphilis and drug resistant infections, they can be stored, upon the donor family’s request, separate from sterile samples.

(2) The distribution of human organs, tissues and cells, except for hematopoietic stem cells, procured in the country, shall be done by the National Transplant Agency, based on its rules on allocation of human organs, tissues and cells within the transplantation system of Romania.

(3) If no recipient compatible with the available human organs, tissues and cells is identified in the country, they can be allocated to the international transplant networks, based on a special authorization issued by the National Transplant Agency, according to the model in annex no. 7.

(4) Procured human organs, tissues and cells can be either immediately used for transplantation or processed and stored in tissue and cell banks accredited or designated by the National Transplant Agency.

(5) The transplant of human tissues and cells shall be performed only in banks accredited or designated by the National Transplant Agency.

(6) Each procurement of human organs, tissues and cells from a deceased donor is immediately announced and registered in the National Transplant Registry of the National Transplant Agency, according to the procedures set by order of the minister of health; in case of living donors, such data is reported to the National Transplant Agency every six months.

(7) The medical doctors performing the procurement of organs and tissues from a deceased person will ensure the reconstitution of the body and face through specific care and means, including surgery, if necessary, in order to provide a decent appearance of the deceased body.

(8) The procurement of human organs, tissues and cells, in forensic cases, shall only be done with the consent of the forensic doctor and shall not compromise the result of the forensic autopsy, according to the model in annex no. 8.

(9) Introducing or removing human organs, tissues and cells from the country, except for hematopoietic stem cells, shall be subject to a special authorization issued by the National Transplant Agency, based on the model from annex no. 7 and annex no. 9 respectively, according to the customs legislation.

(10) The import and export of hematopoietic stem cells shall be subject to an authorization issued by the National Registry of Volunteer Donors of Hematopoietic Stem Cells.

(11) The authorizations issued by the National Transplant Agency shall be reported to the Ministry or Health annually or upon the latter's request.

(12) The disclosure of any information about the donating body or the recipient's identity, except for cases when the donor's family and the recipient agree, as well as cases when the identity must be declared according to the law, shall be prohibited. Donor and recipient data, including genetic data that may be available to third parties shall be communicated anonymously, so as to avoid the identification of both the donor and the recipient. Any unauthorized access of data or systems that makes it possible to identify the donors or the recipients shall be sanctioned according to the legislation in force.

(13) The National Transplant Agency may provide funeral and/or transport services for the body in the case of donors from whom the organs and/or tissues and/or cells were procured.

(14) Each procurement of organs, tissues and/or cells from deceased donors shall be immediately followed by filling in the Organ and tissue procurement chart from annex no. 10.

(15) The public health control unit of the Ministry of Health, together with the National Transplant Agency shall establish a vigilance system for reporting, investigating, recording and sending the information on serious adverse incidents and serious adverse reactions occurring at any stage in the chain from donation to transplant, approved by order of the minister of health.

(16) The public health control unit of the Ministry of Health coordinates and organizes the vigilance system provided for at paragraph (15) for notifying serious adverse incidents and serious adverse reactions in the field of transplant activities.

(17) The National Transplant Agency may delegate the supervision of organ exchanges with third countries to the European organ exchange organizations.

(18) The National Transplant Agency may sign agreements with European organ exchange organizations, provided these organizations observe the requirements of Directive 2010/53/EU of the European Parliament and of the Council of July 7th 2010 on standards of quality and

safety of human organs intended for transplantation, delegating to these organizations, among others, the following:

a) performing the activities referred to in the quality and safety framework;

b) specific tasks for exchanging organs between Romania and Member States and between Romania and third countries.

CHAPTER 3

Transplantation of human organs, tissues and cells

ART. 149

Human organs, tissues and cells shall only be transplanted for therapeutic purposes.

ART. 150

Human organs, tissues and cells shall be transplanted based on the written consent of the recipient, after he/she was informed on the risks and benefits of the procedure, according to the model in annex no. 11.

ART. 151

(1) If the recipient cannot express his/her consent, the consent can be issued in writing by a family member or their legal representative, according to the model in annex no. 11.

(2) If the recipient is unable to express his/her consent, the transplant can be done without the previously specified consent if, due to objective reasons, his/her family or legal representative cannot be contacted in due time and the delay would inevitably lead to the death of the patient.

(3) The situation described at paragraph (2) will be recorded by the head of the ward and by the patient's treating doctor in the form from annex no. 12.

ART. 152

By way of exception from the provisions of art. 150, in case of minors or individuals without exercise capacity, the consent will be given by parents or by the other persons acting as their legal guardians, as applicable, according to the model in annex no. 13.

CHAPTER 4

Financing transplant activities

ART. 153

The cost of the investigations, hospitalization, surgery, medication, healthcare materials, post-operative care, as well as transplant coordination expenses can be settled as follows:

a) from the budget of the Single National Fund of social health insurance, for patients included in the national transplant program;

b) from the state budget and from own revenues of the Ministry of Health, for patients included in the national transplant program;

c) from the patient’s personal contribution or, on the patient’s behalf, from a voluntary healthcare insurance system;

d) from donations and sponsorship from natural persons and legal entities, non-governmental organizations or other interested bodies.

CHAPTER 5

Sanctions

ART. 154*)

The organization and performance of the procurement and/or transplantation of human organs, tissues and/or cells in other conditions than provided for in this title is considered a crime and is punished according to the law.

ART. 155*)

Failure to obtain the consent for the procurement or transplant of human organs and/or tissues and/or cells according to the conditions set out in this title is considered a crime and results in 5 to 7 years of imprisonment.

"ART. 155

(1) Failure to obtain the consent for the procurement of human organs, tissues and cells from living donors according to the law is considered a crime and results in 2 to 7 years of imprisonment and the prohibition of certain rights.

(2) Any attempts shall be punished."

ART. 156*)

The deed of a person who ordered or performed the procurement, thus impairing a forensic autopsy required by the law, is considered a crime and results in 1 to 3 years of imprisonment.

"ART. 156

Performing a procurement which compromises a forensic autopsy requested in accordance with the law is considered a crime and results in 6 months to three years of imprisonment or a fine."

ART. 157*)

(1) The deed of a person who donates human organs and/or tissues and/or cells for the purpose of obtaining material or other gains, for themselves or for another, is considered a crime and results in 3 to 5 years of imprisonment.

(2) Coercing in bad faith or constraining a person to donate human organs and/or tissues and/or cells is considered a crime and results in 3 to 10 of imprisonment.

(3) Publicity for the benefit of a person, for the purpose of obtaining human organs and/or tissues and/or cells, as well as publishing or promoting ads for the donation of human organs and/or tissues and/or cells for material or other gains for self, family or third natural persons or legal entities is considered a crime and results in 2 to 7 years of imprisonment.

"ART. 157

(1) A person’s deed of donating human organs, tissues or cells for the purpose of obtaining material gains, for themselves or for others, is considered a crime and results in 3 months to 2 years of imprisonment or in a fine.

(2) Constraining a person to donate human organs, tissues or cells is considered a crime and results in 2 to 7 years of imprisonment and the prohibition of certain rights.

(3) Publishing or promoting ads about donating human organs, tissues or cells for the purpose of obtaining material gains for self or for another is considered a crime and results in 6 months to 3 years of imprisonment or in a fine."

ART. 158*)

(1) Organizing and/or performing the procurement and/or transplant of human organs and/or tissues and/or cells for the purpose of obtaining material gains for the donor or for the organizer is considered a crime of trafficking human organs and/or tissues and/or cells and results in 3 to 10 years of imprisonment.

(2) The same punishment applies to purchasing human organs and/or tissues and/or cells, for re-sale, in order to gain a profit.

(3) Any attempts shall be punished.

"ART. 158

(1) Organizing and/or performing the procurement and/or transplant of human organs and/or tissues and/or cells intended for transplant, in order to obtain material gains for the donor or for the organizer is considered a crime and results in 2 to 7 years of imprisonment and the prohibition of certain rights.

(2) The punishment provided for at paragraph (1) also applies to the purchasing of human organs, tissues or cells, for re-sale.

(3) Any attempts shall be punished."

ART. 159*)

Introducing or removing human organs, tissues or cells from the country without the special authorization issued by the National Transplant Agency is considered a crime and results in 3 to 10 years of imprisonment.

"ART. 159

(1) Introducing or removing human organs, tissues or cells from the country without the special authorization issued by the National Transplant Agency is considered a crime and results in 2 to 7 years of imprisonment and the prohibition of certain rights.

(2) Any attempts shall be punished."

CHAPTER 6

Transitional and final provisions

ART. 160*)

(1) The procurement and transplantation of human organs, tissues and cells shall be performed by specialized physicians, in public or private healthcare units accredited by the National Transplant Agency and approved by order of the minister of health.

(2) The transplant accreditation of public or private healthcare units shall be valid for a period of five years. Any change occurring in the initial accreditation criteria at the accredited units shall be communicated to the National Transplant Agency for re-accreditation.

(3) The accreditation criteria for healthcare units provided for at paragraph (1) are set by the National Transplant Agency in the application norms of this title, approved by order of the minister of health, in accordance with the relevant European legislation.

(4) The accreditation can be suspended or revoked by order of the minister of health, upon proposal of the public health control unit of the Ministry of Health, if the inspections of the authorized personnel reveal that the unit accredited for transplant does not comply with the legal provisions in force. The inspections shall be conducted regularly and the interval between inspections shall not exceed two years, according to the legislation in force.

(5) The accredited healthcare units shall establish a system of identifying each donation, as well as any related product, based on a single code. The organs, tissues and cells shall bear coded labels that help connect the donor with the recipient and vice-versa. The information shall be kept for at least 30 years, either on paper or in electronic format.

(6) Healthcare units accredited to process and/or use tissues and/or cells shall keep a record of their activity, including the types and quantities of procured, tested, preserved, stored,

distributed or disposed tissues and/or cells, as well as the origin and destination of these tissues and/or cells intended for human use. They will send an annual activity report to the National Transplant Agency. The provisions of this paragraph apply accordingly to organ transplantation.

(7) The National Transplant Agency manages the national registries that provide ongoing monitoring of the transplant activity, the activities of procurement centers and transplantation centers, including the total number of living and deceased donors, the types and number of procured and transplanted or disposed organs, in accordance with the national provisions on personal data and statistical secrecy.

(8) The National Transplant Agency shall establish and maintain an updated record of procurement centers and transplantation centers and shall provide information in this respect, upon request.

(9) Every three years, the National Transplant Agency shall report to the European Commission on activities related to the provisions of Directive 2010/53/EU, as well as on the experience acquired following its implementation.

(10) The National Registry of Volunteer Donors of Hematopoietic Stem Cells shall provide the methodological coordination of the recruitment, testing and donation of hematopoietic stem cells from unrelated donors, shall be responsible for auditing the activities it coordinates and for implementing the Single coding and labeling system in line with the European requirements on coding donation for the transplant of hematopoietic stem cells from unrelated donors.

ART. 161

Healthcare units accredited for tissue and/or cell transplant shall designate a person in charge with assuring the quality of tissues and/or cells processed and/or used in accordance with relevant European and Romanian legislation. The professional training standard of such persons shall be set out in the norms.

ART. 162

The applications norms of this title shall be drafted within 90 days from the publication of the law and shall be approved by order of the minister of public health.

ART. 163

Annexes no. 1 - 13 are integral to this law.

ART. 164

Upon the entry into force of this title, Law no. 2/1998 on the procurement and transplantation of human organs and tissues, published in the Official Journal of Romania, Part I, no. 8 of January 13th 1998, with subsequent amendments and art. 17 (3), art. 21, 23 and 25 from Law no. 104/2003 on handling human bodies and procuring organs and tissues from deceased bodies for the purpose of transplantation, published in the Official Journal of Romania, Part I, no. 222 of April 3rd 2003, with subsequent amendments and additions, shall be revoked.

The provisions of this title transpose Directive 2004/23/EC of the European Parliament and of the Council of March 31st 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and the provisions of art. 1 - 3, art. 4 (3), art. 5 (1), art. 9 (1), art. 10, art. 11 (1), art. 12 - 16, art. 17 (1), (2) letters (b), (g) and (h), art. 18 (1) letters (a) and (c), art. 20 (1), art. 21 - 23 and 31 of Directive 2010/53/EU of the European Parliament and of the Council of July 7th 2010 on standards of quality and safety of human organs intended for transplantation.