COLLECTION LAWS SLOVAK REPUBLIC

Year 2016

Announced: 29/11/2016 Time version of the regulation effective from: April 29, 2017

317

THE LAW

of 19 October 2016

on requirements and procedures for the collection and transplantation of humanorgan, human tissue and human cells and on the amendment certain laws (transplant law)

The National Council of the Slovak Republic has resolved on the following Act:

Art. I FIRST PART
GENERAL PROVISIONS

§ 1
Subject matter

(1) This Act regulates

(a) requirements and procedures to ensure the quality and safety of the human organ; donation, procurement, testing, characterization, preservation, distribution and transplantation,

(b) procedures for the replacement of a human organ intended for transplantation,

(c) requirements to ensure the traceability of the human organ, human tissue; or human cells and the procedure for reporting serious adverse reactions and serious adverse reactionsevents,

(d) requirements for quality and safety assurance in donation, procurement, processing,preservation, testing, storage, distribution and transplantation of human tissue; or human cells, including hematopoietic stem cells from peripheral blood, hematopoietic stem cells of human umbilical cord blood, hematopoietic stem cellshuman bone marrow cells human reproductive cells, human tissue or human fetal envelope cells and adult human stem cells,

(e) requirements to ensure quality and safety in the donation, procurement and testing of human beingstissues or human cells intended for the manufacture of their products

(f) requirements to ensure the quality and safety of imported human tissue or tissuescells,

(g) performance of state administration in the field of donation and transplantation of human organ, human tissueor human cells,

(h) the role of the national transplant organization.

(2) This Act does not apply to

(a) human blood, human blood components and blood medicines prepared from human blood,

(b) organ of animal origin, tissue of animal origin, cells of animal origin,

(c) human tissue and human cells intended for autologous use, harvested and transplantedwithin the same surgical medical procedure without storage

(d) human tissue and human cells intended for non-human use.

§ 2

Basic provisions

(1) The human organ is a separate part of the human body made up of various human tissues, whichretains its structure, vascular supply, and ability to perform physiological functions with a significant degree of autonomy, a part of which is also considered to be a human organ if it is part is to be used for the same purpose as the whole human organ in the human body, and at the same time it is preservedstructure and vascular supply; a human organ specification is an anatomical description of a human organ including its type, location in the human body, whether it is a whole or part of a human organhuman organ, specifying its lobe or segment.

(2) The characteristics of a human organ are a set of essential information about a human organnecessary to assess its suitability in order to carry out an appropriate risk assessment, minimize the risk to the recipient of the human organ and optimize the allocation of the human organ.

(3) Human tissue is a group of cells in the human body.

(4) Human cells are isolated human cells or a set of human cells that are not boundconnective tissue.

(5) Reproductive human cells are human tissue or human cells intended for purposesassisted reproduction.

(6) The human use of a human organ, human tissue or human cells is a usehuman organ, human tissue or human cells in a recipient human organ, humantissue or human cells or for extracorporeal use of a harvested human organ, human tissue or cells.

(7) Tissue facility is a health care provider according to a special regulation, which on the basis of a permit for the operation of a tissue establishment pursuant to a special regulation performs collection, testing, processing, preservation, storage and distribution of humantissue or human cells.

(8) The collection organization is a health care provider according to a special regulation or the pathological-anatomical workplace and the workplace of forensic medicine of the Office for Supervision healthcare in which human tissue or human cells are harvested.

(9) The organization responsible for human use is the healthcare provider according to a special prescription, which performs a transplantation of a human organ, human tissue orhuman cells.

(10) The transplant center according to a special regulation is the operational unit of the provider institutional health care according to a special regulation.

(11) The donation of a human organ, human tissue or human cells is a provisionhuman organ, human tissue or human cells intended for human use.

(12) Partner donation for the purposes of this Act is the donation of human reproductive cellsbetween a man and a woman who declare that they have an intimate physical relationship.

(13) The donor of a human organ, human tissue or human cells for the purposes of this Act is a living person or a dead person from whose body a human organ, human tissue or human tissue is takencells.

(14) The characteristics of a human organ donor are a set of essential information about the human donor necessary to assess its suitability for human organ donation for the purpose of perform an appropriate risk assessment and reduce the risk to the human organ recipient to a minimum and optimize human organ allocation.

(15) The recipient of a human organ, human tissue or human cells is a living person to whomthe body is transplanted with a human organ, human tissue or human cells.

(16) The collection of a human organ, human tissue or human cells is a procedure by which human organ, human tissue or human cells are taken from the body of a donor of a human organ,human tissue or cells.

(17) Processing for the purposes of this Act is all performances in the preparation, handling,preserving and packaging human tissue or human cells for human use.

(18) Testing for the purposes of this Act is the performance of laboratory tests for the examination of a donorhuman organ, human tissue or cells and microbiological examination of the sample processed human tissue or human cells.

(19) Quarantine for the purposes of this Act is a situation in which human tissue or human tissue is removed a cell isolated in a physically or otherwise effective manner and awaiting a decision to accept them or their rejection.

(20) Conservation of the human organ is the use of chemicals, changes in environmental requirements environment or the use of other means to prevent or retard biological control degradation or physical deterioration of a human organ from the procurement of a human organ tohuman organ transplantation.

(21) Conservation of human tissue or human cells is the use of chemicals, alterationsenvironmental requirements or the use of other means during processing for prevention or to retard biological or physical degradation of human tissue or human cells.

(22) Storage for the purposes of this Act is the preservation of human tissue or human cells provided that the appropriate requirements are met until they are distributed.

(23) The distribution of a human organ, human tissue or human cells is transportand delivering a human organ, human tissue or human cells to a human the use.

(24) The unique European code is the unique identifier used to identify a human tissue or human cells in the territory of the Slovak Republic and to mark human tissueor human cells in the Member States of the European Union, the Contracting States Agreement on the European Economic Area, and the Swiss Confederation (hereinafterto ensure traceability. The single European code consists of an alphanumeric digit human tissue or human cell donation identification sequences and from alphanumeric product identification sequence.

(25) A unique donation number for the purposes of this Act is an identification number assigned by a nationala transplant organization to a donor of a human organ, human tissue or human cells.

(26) The identification number of the recipient of a human organ is the identification number assigned by the national authoritytransplant organization to the recipient of the human organ.

(27) The direct use of human cells is a process in which human cells are providedand used without any storage.

(28) The allogeneic use of a human organ, human tissue or human cells is a usehuman organ, human tissue or human cells taken from one person and their transplant to another person.

(29) The autologous use of a human organ, human tissue or human cells is a usehuman tissue or human cells taken from one person and transplanted into the same persons.

(30) Release for circulation means the distribution of human tissue or human cells or transportof harvested human tissue, or transport of harvested human cells to a tissue equipment for the further processing and distribution of harvested human organs for human use.

(31) Transplantation of a human organ, human tissue or human cells is a procedure where by which a human organ, human tissue or human cells is transferred from the body of a human donororgan, human tissue or human cells into the body of a recipient human organ, human tissue tissue or human cells for the purpose of restoring certain functions of the human body.

(32) The disposal of a human organ, human tissue or human cells is finaldegradation of a human organ, human tissue or human cells, if not used for transplantation.

(33) Collection in the same container is physical contact or mixing of human tissue orhuman cells that come from more than one donation from the same human donor tissue or human cells, from two donors of human tissue or human cells, orfrom multiple donors of human tissue or human cells.

(34) A serious adverse event is any event that could lead to a transmissioncommunicable disease, cause death, endanger life, cause disability, disability,hospitalization, illness or their extension in connection with

(a) the collection, testing and transplantation of a human organ; or

(b) the collection, testing, preservation, processing, storage and distribution of humantissue or human cells.

(35) A serious adverse reaction is an unintentional response of the human body, including a communicable diseasein a living donor of a human organ, human tissue or human cells or in a recipient human organ, human tissue or human cells that could cause death life, cause disability, disability, cause hospitalization, illness or theirextension in relation to

(a) the collection, testing and transplantation of a human organ; or

b) by collection, testing, canning, processing, storage, distributionand transplantation of human tissue or human cells.

(36) A quality system for the purposes of this Act is a system that includes an organizational structure, established responsibilities, procedures and resources for performing quality management and all activities that

directly or indirectly contribute to quality.

(37) Quality management is the coordinated action to guide and control compliancequality.

(38) Verification for the purposes of this Act is the establishment of the evidence it provides a high degree of certainty that a particular process, part of an installation or environment will be thoroughly preparеda product that meets its predetermined specifications and quality parameters; the procedure is verified

for the purpose of evaluating the performance of the system in terms of its effectiveness in relation to the intended use.

(39) Critical for the purposes of this Act is one that affects or may affect the quality orsafety of human tissue or cells or which comes into contact with human tissue
tissue or with human cells.

(40) A tissue establishment inspector is a person appointed and removed by the Minister of the Slovak Republic for the performance of supervision in a tissue establishment and which isin an employment relationship or in a similar employment relationship with a national transplant

organization or with the Ministry of Health of the Slovak Republic (hereinafter referred to as the “Ministry healthcare).

(41) Standard operating procedures for the purposes of this Act are written procedures which describe the steps of the specific procedure, including the materials and methods to be used for the purpose achieving the expected final product.

(42) Traceability is an option

(a) identify the human organ donor, the institutional healthcare provider, who: performed human organ harvesting as well as locating and identifying the human organ duringany step from donation to transplantation or disposal of a human organ,

(b) identify the donor of human tissue or human cells, the tissue establishment which carried out the collection, preservation, processing, testing, storage or distribution of humantissues or human cells, as well as to locate and identify human or human tissue cells during any step from their collection, processing, testing, preservation,storage after distribution or disposal of human tissue or cells,

c) identify the recipient of a human organ, human tissue or human cells,

an inpatient healthcare provider who has performed a human organ transplant
and the healthcare provider according to a special regulation, 3) who
performed transplantation of human tissue or human cells,

(d) locating and identifying all relevant data relating to products and materials which:came into contact with harvested human organs, human tissues, human cells or
with a transplanted human organ, human tissue or human cells.

(43) An emergency situation is any unforeseen situation in which there is no practical alternativeother than the urgent importation of human tissue or human cells from a Member State or another
as a Member State (hereinafter referred to as a "third State") for immediate use by a specific recipient of human rightstissue or human cells whose health would be seriously endangered without these imports.

(44) A single import of human tissue or cells is an import of human tissue or cellshuman cells that are intended for use in a particular recipient of human tissue; or
human cells, which is an importing tissue establishment and a supplier from a Member Stateor from a third country known before the import takes place. Imports of human tissue or human cells is not considered as a single import if it is a specific human recipient
tissue or human cells more than once. Imports from the same supplier from a Member Stateor from a third country which occurs regularly or repeatedly shall not be considered as:

single import of human tissue or human cells.

(45) The European Union Tissue Facility Database is a register of tissue establishments which:
are authorized by the competent authority of the Member State to operate a tissue establishment,
and this register contains information on the tissue establishment to the extent pursuant to § 33 par. 1 letter in).

(46) The European Union Database of Human Tissue and Human Cells is a register of all types human tissue and human cells circulating in the European Union and their respective codes
according to the three permitted coding systems, which are

(a) the European Product Coding System for Human Tissues and Human Cells (EUTC);

(b) the coding system of the International Blood Transfusion Society for Human Tissuesand human cells

(ISBT128), or

(c) the International Product Coding System (Eurocode).

(47) The European Product Coding System for Human Tissues and Human Cells (EUTC) is a systemencoding human tissues and human cells, which includes a register of all types of human tissues and human cells circulating in the European Union and their respective codes.

(48) An importing tissue establishment is a tissue establishment that imports humantissue or human cells intended for human use on the basis of a written contract with a supplier from a Member State or a third country for the importation of human tissue orcells originating in a Member State or in a third country.

(49) A third country supplier is a tissue establishment or other for the purposes of this Act an authorized person from a third country who supplies human tissue to the importing tissue establishment tissue or human cells intended for human use.

(50) For the purposes of this Act, the Member State of origin is the Member State in which the human organ was locatedtaken for transplantation purposes.

(51) The Member State of destination for the purposes of this Act is the Member State to which a human organ enters supplied for transplantation purposes.

§ 3

General requirements

(1) Collection of a human organ from a human organ donor is performed by a medical professionaltransplant center; the collection of a human organ may be performed by a healthcare professional transplant center and another institutional healthcare provider. Testing, characterization, preservation, distribution and transplantation of the human organtransplant center.

(2) Collection, testing, preservation, processing, storage and distribution of human tissueor human cells for transplantation and scientific research purposes according to standard procedures are performed by a tissue device.

(3) Collection of human tissue or human cells shall be performed by a tissue establishment on the basis of cooperation agreements with the purchasing organization. If there is a tissue establishment and a collection organizationoperated by the same healthcare provider, the conclusion of a contract no cooperation is required. In the case of a dead donor of human tissue or human cells, performs the collection of human tissue or human cells at the pathological-anatomical workplaceand the forensic medicine office of the Office for the Supervision of Health Care tissue establishment worker.

(4) The tissue establishment and the transplantation center shall perform testing of the collected human tissueorgan, human tissue or human cells on the basis of a cooperation agreement with the provider
healthcare system operated by a joint investigation medical facility
and therapeutic ingredients according to a special prescription. 6) If the tissue equipment and medical equipment of joint examination and treatment units operated by the same provider
healthcare, the conclusion of a cooperation agreement is not required.

(5) The cooperation agreement concluded pursuant to paragraph 3 shall contain in particular the following particulars:

a) identification data and obligations of the contracting parties,

b) standard operating procedures for the collection of human tissue or human cells,

(c) the designation of the procurement physician to select the human tissue donor; orhuman cells,

(d) the designation of the healthcare professional collecting human tissue or tissuescells s

1. indicating the type of human tissue or human cells and samples to be tested, which isneed to be removed,
2. by attaching a model to the report following the collection of human tissue or human cellsneed to be filled in.

(6) The tissue establishment and the transplantation center are obliged to keep a list of contractscooperation and keep them for at least 30 years after their conclusion.

(7) Donation of a human organ, human tissue or human cells is voluntaryand free.

(8) Collection of human organ, human tissue, human cells or their transplantation
for the purpose of financial gain, property benefit or any other benefit areprohibited.

(9) Tissue facility and health care provider according to a special regulation 3)
have a duty

(a) maintain anonymity between the donor of a human organ, human tissue or human cellsand recipients of human organs, human tissue or cells and their relatives
persons 7) and vice versa a

(b) to ensure full and effective protection of the personal data of the human organ donor, human tissueor human cells and a recipient of a human organ, human tissue or human cells
according to a special regulation. 8)

§ 4

quirements for the collection of a human organ, human tissue or human cells from the living bodydonor of a human organ, human tissue or human cells

(1) Remove a human organ, human tissue or human cells from the body of a living human donororgan, human tissue or human cells for human use is possible only if

(a) the donation is presumed not to seriously endanger the health of the human organ donor, the human organ donortissue or human cells,

(b) a direct therapeutic benefit is expected for the recipient of the human organ, human tissueor human cells,

(c) the benefit to the recipient of the human organ, human tissue or human cells outweighs it

harm to the donor of a human organ, human tissue or human cells,

(d) it is not possible to obtain a suitable human organ, human tissue or human cells from a dead donorhuman organ, human tissue or cells; and

(e) no other treatment with a better result or a comparable result is known.

(2) A living donor of a human organ, human tissue or human cells may be a personwhich

a) has full legal capacity, 9) which gave rise to the procurement of human organs, human tissueor human cells written informed consent according to a special regulation 10) after
prior instruction, or

b) does not have full legal capacity, but for which he has given his informed legal consentrepresentative, if

1. the collection of regenerative human tissue or regenerative human cells,

2. a suitable donor of human organ, human tissue or human cells is not available,who has full legal capacity under the letter (a),

3. is a potential recipient of a human organ, human tissue or human cells
biological sibling of a donor of a human organ, human tissue or human cells; and

4. the donation of a human organ, human tissue or human cells to the recipienthuman organ, human tissue or human cells life-saving significance.

(3) As part of the written informed consent of a donor of reproductive human cells

intended for partner donation, in addition to the purpose of use, there is also the possibility of using unused ones

human reproductive cells for other reproductive purposes, for scientific research purposes or fortheir disposal.

(4) A person who is in custody or serving a custodial sentence may be a living donorhuman organ, human tissue or human cells, if the recipient of the human organ,

human tissue or human cells is a close person and the donor may donate to that close personsave lives.

(5) Collection of a human organ for the purpose of transplantation of a human organ into the body of a human recipientof an organ directly genetically related to a human organ donor may be performed only after approval

by a council pursuant to a special regulation, 11) which shall assess the fulfillment of the requirements pursuant to paragraphs 1 and 2.

(6) A recipient of a human organ directly genetically related to a donor of a human organ shall, for the purposes ofthis law understands

a) biological parent,

(b) a child in a direct biological relationship with a parent; or

(c) a biological sibling with which the recipient of a human organ shares both biological organsparents.

(7) Collection of a human organ for the purpose of transplantation into the body of a recipient of a human organ remotelygenetically related to a non-human organ donor or recipient of a human organ

genetically related to the donor of a human organ, may be carried out only after approval by the for these purposes, shall be determined by the Ministry of Health and which shall assess compliance with the requirements under paragraphs 1a 2; the recipient of a human organ under this paragraph does not indicate the recipient of the human organ

in paragraph 6.

§ 5

Requirements for the collection of human organs, human tissue or human cells from the bodya dead donor of a human organ, human tissue or human cells

(1) A dead donor of a human organ, human tissue or human cells may only be

a person for whom death has been determined in accordance with a special regulation. 12)

(2) It is possible to remove a human organ, human tissue or human cells from the body of a dead donor onlyif the person has not made a written statement of disagreement with the withdrawal during his or her lifetime human organ, human tissue or human cells after death. For a person who is not full legal capacity, a written declaration of disagreement with the removal of a human organ mayhuman tissue or human cells after death to be a legal representative during her lifetime.

(3) Remove a human organ, human tissue or human cells from the body of a dead human donororgan, human tissue or human cells is possible if

(a) permanent cessation of respiration and cardiac function of the person and this fact is confirmedby council according to a special regulation, 13) or

b) irreversible extinction of all functions of the whole brain according to a special regulation. 13)

(4) From the body of a dead donor of a human organ, human tissue or human cells that is not citizens of the Slovak Republic, it is possible to take a human organ, human tissue or human cells, provided that the transplantation center obtains the verifiable written consent of a close persona dead donor of a human organ, human tissue or human cells for human collection
organ, human tissue or human cells.

(5) Written declaration of disagreement with the removal of a human organ, human tissue or human cells after death with a certified signature according to special regulations 14) is sent by a person which has stated its opposition to the removal of a human organ, human tissue or human cells after the death of the national transplant organization according to § 33 par. 2.

(6) Written declaration of disagreement with the removal of a human organ, human tissue or human cells after death can be recalled at any time; when revoking a written declaration disagreement with the removal of a human organ, human tissue or human cells after death proceed in accordance with paragraph 5.

(7) In connection with the removal of a human organ, human tissue or human cells other than collection of the cornea from a dead donor of a human organ, human tissue or human tissue cells are necropsied according to a special prescription. 15)

(8) If a person during his life or a legal representative during the life of a person who did not have a fulllegal capacity, made a written declaration of disagreement with the performance of the autopsy after death,
autopsy may always be performed after the collection of a human organ, before the collection of human tissue, or
human cells in addition to the collection of the cornea from a dead human organ donor, the humantissue or human cells.

SECOND PART HUMAN AUTHORITIES

§ 6

Human organ procurement requirements

(1) Prior to the procurement of a human organ, a medical professional of a transplant center who:performs the collection of a human organ, obligatory

a) verify the identity of the human organ donor,

(b) ensure, in the case of a living human organ donor, that the human organ donor is signedinformed consent confirmed that

1. understand the information provided,

2. had the opportunity to ask questions and received answers to the questions asked a

3. all information provided is true to the best of his knowledge,

(c) request written confirmation from the national transplant organization that the human donor authority has not expressed his disagreement with the removal of a human organ during his lifetime,

(d) to obtain without delay such information from a close person of the donor of a human organ as they may haveaffect the health status of the recipient of the human organ, if possible,

(e) record, in the case of a dead human organ donor, how and by whom the donor washuman organ credibly identified.

(2) Sterile medical devices are used for the collection of a human organ according to a special prescription. 16) In case of repeated use of medical devices and contaminated medical devices sterilization is performed according to a special regulation. 17)

(3) A medical worker who performs the collection of a human organ is obliged to prepare ita record of the procurement of a human organ, which contains

(a) information on the characteristics of the human organ donor and the characteristics of the human organ in accordance with the Annexno. 1,

b) business name or name, registered office and identification number of the institutional health care provider care from which the transplant center performed a human organ,

c) business name or name, registered office and identification number of the institutional health care provider care whose transplant center performs a human organ transplant.

(4) A council under a special regulation 11) may, in a specific case, on the basis of an assessment benefits to the recipient of the human organ and an analysis of the risk posed by incomplete informationpursuant to paragraph 3 (a) a), decide on the procurement of a human organ.

(5) Laboratory tests for donor characteristics of the human organ and human characteristics authority shall be performed by the provider at the request of the institutional health care provider healthcare system operated by a joint investigation medical facility and therapeutic ingredients that uses CE-marked test kits. Laboratory the tests must be in accordance with current scientific knowledge.

(6) A medical worker who performs the collection of a human organ is obliged to mark the collectedhuman organ by a unique donation number assigned to the human organ donor for security traceability of the harvested human organ. It is about assigning a unique donation number demonstrably requested by a compulsory medical professional who takes a human organnational transplant organization. The unique donation number is part of the National transplantation register [§ 33 par. 2 letter b) and c)].

(7) A healthcare professional who performs the collection of a human organ is obliged to make a copy of the recordon the procurement of a human organ in accordance with paragraph 3 to the national transplant organization.

§ 7

Marking of the transport container

(1) A medical worker who performs the collection of a human organ is obliged

(a) pack the collected human organ in such a way as to avoid contamination

1. human organ,

2. the person carrying out the packaging, and

3. the person carrying out the transport,

(b) mark the packaged human organ with a unique donation number assigned by the national donortransplant organization and place in a transport container suitable for transport
biological material so as to maintain the safety and quality of the human organ, and

(c) ensure distribution of the human organ at a temperature which retains the required propertieshuman organ and its biological function.

(2) The transport container must be marked with the label it contains

(a) the trade name or name, registered office and telephone number of the institutional health care providerthe care taken by the human organ,

b) business name or name, registered office of the institutional health care provider, address
and the telephone number of the transplant center that will perform the human organ transplant,

(c) the text "HUMAN AUTHORITY" indicating the type of human organ, if applicable, of the partythe location in the body of the human organ donor and the text "TAKE CARE CAREFULLY",

(d) human organ distribution requirements, including instructions for maintaining an appropriate temperature and positionshipping container,

(e) the date and time of the start of the distribution of the human organ.

(3) A healthcare professional who performs the collection of a human organ shall send it to the transplant operatorthe center which carries out the transplantation of a human organ,

(a) a transport container with a removed human organ; and

b) a record of the collection of a human organ according to § 6 par. 3.

(4) If the collection of a human organ and the transplantation of a human organ perform a transplantcenter of the same institutional healthcare provider, paragraph 2 shall not apply.

(5) The information pursuant to paragraph 2 must be placed on the transport container in such a way that duringdistribution of the human organ were not damaged and their legibility was maintained.

(6) A medical professional who performs the collection of a human organ is obliged to ensure

that:the packaging of the human organ met the requirements of scientific and technical progress.

§ 8

Human organ transplantation

(1) Transplantation of a human organ into the body of a recipient of a human organ may be carried out if

(a) the state of health of the recipient of the human organ allows it, at the discretion of the doctorstransplant center and

(b) the recipient of the human organ has given informed consent before transplantationprior instruction; informed consent is not required in the case of provision
urgent medical care if it is not possible to obtain it in time, but it is possibleexpect.

(2) The selection of the recipient of a human organ is governed exclusively by a medical aspect.

(3) Before the transplantation of a human organ, the doctor of the transplant center is performing it

human organ transplantation, obliged to verify

a) the identity of the recipient of the human organ,

b) the completeness of the record of the collection of a human organ to the extent specified in Annex no. 1,

(c) maintaining the requirements for the preservation of the human organ and the requirements for the distribution of the human organauthority.

(4) The doctor of the transplant center is obliged to replenish the human organ after transplantationto the data referred to in paragraph 3

a) data on the recipient of the human organ within the scope of the identification number of the recipient of the human organ,

b) data on the control of the transplanted human organ,

(c) time of resumption of blood circulation in the transplanted human organ; and

d) length of cold ischemia and warm ischemia.

(5) The doctor of the transplant center is obliged to send the removed human organ to the histological one examination; if the human organ is not used for transplantation, it shall be mandatory for the data referred to in paragraph 3state the reason for its non-use.

(6) The transplant center is obliged to send a copy of the collection record without delay human organ within the scope of the data referred to in paragraphs 3 to 5 of the national transplant organization.

§ 9

Traceability of the human organ

(1) Institutional health care provider performed by the transplant center collection of a human organ, is obliged to ensure the traceability of the human organ, which was taken, assigned and transplanted on the territory of the Slovak Republic from a human organ donor after the recipient of the human organ and vice versa, in order to protect the health of the donor of the human organand the recipient of the human organ.

(2) Institutional health care provider performed by the transplant center collection of a human organ and transplantation of a human organ, it is obligatory to keep the data necessary necessary to ensure the traceability of the human organ from the human organ donor to recipient of a human organ and vice versa related to procurement and transplantation for at least 30 years from its transplantation or disposal according to a special regulation. 18) For data storage in electronic form, the provisions of the special regulation shall apply mutatis mutandis. 19)

§ 10

Obligations related to human organ procurement and human organ transplantation

(1) Institutional health care provider performed by the transplant center collection of a human organ or transplantation of a human organ is required to establish a standardworking procedures on

a) verification of the identity of the human organ donor,

b) verification of data on the expression of disagreement with the donation of a human organ,

(c) verification of the completeness of the human organ donor characteristics and characteristicshuman organ,

(d) labeling of the human organ during human organ procurement, preservation of the human organand packaging of the human organ,

(e) the distribution of the human organ, aimed in particular at ensuring the integrity of the human organ

during distribution and the appropriate time of distribution of the human organ,

(f) ensuring the traceability of the human organ from the human organ donor to the recipienthuman organ and vice versa,

(g) ensuring accurate, rapid and verifiable reporting of a serious adverse eventand reports of serious adverse reactions,

h) management of a serious adverse event and management of a serious adverse reaction,

(i) the abolition of the distribution of the human organ and the use of the human organ which may be related to serious adverse event or with a serious adverse reaction.

(2) Institutional health care provider whose transplantation center provides procurement of a human organ or transplantation of a human organ is in addition to the obligations laid downin paragraph 1 further mandatory

(a) carry out appropriate control measures within the internal control system so that: operation of activities related to donation, procurement, testing, characterization, conservation, distribution and transplantation of the human organ took place in accordance with this Act,

(b) report without delay any information on a serious adverse reaction and a serious adverse reactionan event that may affect and be related to the quality and safety of the human organ with the testing, procurement, preservation and distribution of the human organ, as well as anya serious adverse reaction observed during or after human organ transplantation national transplant organization; in the case of an institutional healthcare provider, which carries out the procurement of a human organ or the distribution of a human organ, shall notify the following:information also to the transplantation center which carries out the transplantation of a human organ,

(c) keep records of data on

1. type and quantity of human organs removed,
2. the type and quantity of human organs used,
3. type and quantity of human organs distributed,
4. acceptance of a human organ or rejection of a human organ,
5. acceptance of a human organ or rejection of a human organ by a recipient of a human organ,
6. disposal of a human organ unsuitable for transplantation,

d) submit data to the Ministry of Health and the National Transplant Organization without delay related to the

collection, distribution and transplantation of a human organ, which the Ministryor a national transplant organization requests and has a transplant
center available,

e) provide the Ministry of Health and the National Transplant Organization with a summary notification of serious adverse reactions and serious adverse events by 31 March of the yearfollowing the year in which the serious adverse reactions and serious adverse reactions
adverse events have occurred.

Procedure for the exchange of information in the field of human organ exchange between Member State and a third country

§ 11
Import and export of human organs

(1) If the institutional health care provider whose transplant center provides
collection of a human organ, exports of a human organ to the Member State of destination is compulsory to announce characteristics donor human authority and characteristics human authoritythe transplantation center of the Member State of destination and the national transplantation organization

to the extent according to Annex no. 1 of Part A before exporting the human organ to the Member State of destinationcompetent authority of the Member State of destination.

(2) If the institutional health care provider whose transplantation center provides
the collection of a human organ carrying out the export of a human organ to the Member State of destination,does not report the characteristics of the human organ donor and the characteristics of the human organ
the transplantation center of the Member State of destination and the national transplantation organization before exports and obtains data on the characteristics of the organ and the characteristics of the donor of the human organ at a later stage,this institutional healthcare provider shall send it to the transplantation center without delay
the Member State of destination and the national transplant organization in order to allow this information medical decision.

(3) Institutional health care provider that performs the import of a human organ
from a third country or the export of a human organ to a third country must have for each import of a human organ
authority from a third country or the export of a human organ to a third country by the written consent of the national authoritytransplant organization and is obliged to ensure the traceability of each imported

human organ from a third country and ensure its use in accordance with this Act.

§ 12

Information necessary to ensure the traceability of the human organ

(1) The national transplantation organization shall notify the competent authority of the Member State of destinationinformation necessary to ensure the traceability of the human organ to the extent of:

(a) a human organ specification consisting of an anatomical description of the human organ, including its type, if necessary, the location of its location in the body of the donor of a human organ and details of whetherit is the whole or part of a human organ with the specification of a lobe or segment human organ,

b) unique donation number,

c) date of removal of the human organ,

d) business name or title, registered office, identification number and telephone number of the constitutional providerhealthcare that the human organ has removed from the transplant center.

(2) The national transplant organization shall notify the competent authority of the Member State of originthe information needed to ensure the traceability of the human organ to the following extent:

(a) the identification number of the recipient of the human organ or the reason for not using the human organ, ifdid not use a human organ for transplantation,

(b) the date of transplantation of the human organ, if the human organ was used for transplantation;

c) business name or title, registered office, identification number and telephone number of the transplant center,who performed a human organ transplant.

§ 13

Reporting of a serious adverse reaction or serious adverse event

(1) If the national transplant organization receives information on a serious adverse reaction, orof a serious adverse event suspected of being related to a human organ taken by a from the Member State of origin, it shall immediately notify the competent authority of the Member State of origininformation and submit the first report of a serious adverse reaction report or a serious report adverse event according to Annex no. 2 part A.

(2) If the national transplant organization receives information on a serious adverse reaction, ora serious adverse event suspected to be related to a human organ donor,

whose human organ has been delivered to the Member State of destination, to the competent authority without delaythe Member State of destination shall communicate this information and transmit the first report of the serious
adverse reaction or report of a serious adverse event in accordance with Annex No. 2 part A.

(3) If, after the first report, a report of a serious adverse reaction or a report of a serious adverse reactionadditional information occurs to the adverse event, this national transplant organization immediately

(a) to the competent authority of the Member State of origin if the additional information relates to the information receivedhuman organs in accordance with paragraph 1, or

(b) to the competent authority of the Member State of destination if the additional information relates to the information suppliedhuman organs in accordance with paragraph 2.

(4) The National Transplant Organization shall submit a joint final report on seriousadverse reactions or serious adverse events according to Annex no. 2 part B
as a general rule, within three months of receipt of the first report of a serious adverse reaction report or the reporting of a serious adverse event to the competent authority of the Member State of destination. Nationalthe transplant organization shall communicate the information for the purpose of drawing up the joint final reports of serious adverse reactions or serious adverse events
competent authority of the Member State of origin. The national transplant organization shall draw upa joint final report on serious adverse reactions or serious adverse reactions
events after receiving all information from the competent authority of the Member State of origin; or competent authority of the Member State of destination.

§ 14
Common rules for the procedure for exchanging information

(1) The national transplant organization shall immediately notify the information pursuant to Section 12 and the reportaccording to § 13 by electronic means or fax in a language understandable to the sender, etc.
to the addressee; if there is no such language, in a language mutually agreed between the sender and the addressee or, if there is no such language, in English.

(2) The information pursuant to § 12 and the report pursuant to § 13 shall contain

a) date and time of sending information and reports,

(b) the contact details of the person making the information or reporting; and

(c) a statement entitled 'Contains personal data. Protect from unauthorized disclosure oraccess. ".

(3) The National Transplant Organization shall keep the information pursuant to Section 12 and the report pursuant to Section 1330 years after their adoption and shall provide them at the request of another Member State or a third party
state.

(4) The national transplant organization shall confirm the receipt of the information pursuant to Section 12 and the notification pursuant to
§ 13 to its consignor in accordance with the requirements under paragraphs 1 and 2.

(5) The national transplant organization may notify or accept in urgent situations
information according to § 12 and report according to § 13 also in oral form. Information thus communicated and the report submitted shall be subsequently notified by the national transplant organization in accordance with paragraphs 1 to 4.

(6) The National Transplant Organization shall have information pursuant to Section 12 and a report pursuant to Section 13documented and provided at the request of the Member State of origin or the Member State
destination.

THIRD PART
HUMAN TISSUE AND HUMAN CELLS

§ 15

Tissue quality system

The quality system of the tissue device according to § 2 par. 36 is a paper systemand in electronic form, which contains

a) a description of the organizational structure of the tissue establishment,

(b) standard operating procedures for the implementation of quality and safety management aimed at:all activities performed by the tissue establishment,

(c) standard operating procedures describing specific procedures, materials and methods to be obtained expected result,

(d) a description of the procedure for verifying the equipment, environment and procedures with the introduction of evidencedocumentation that provides a high degree of assurance that the equipment,

environment, and procedures
related to the preparation of the product meet predetermined specifications and quality parameters,

e) the procedure for traceability of human tissue or human cells from their collection, processing, preservation, testing, storage after distribution to a recipient of human tissue, or
human cells and vice versa or after their destruction, including the identification of a human tissue donor or human cells, human tissue recipient or human cells, provider
healthcare provider who performs a transplant of human or human tissue cells, and to identify all relevant data on products and materials that
come into contact with human tissue or cells,

f) a description of the use of the single European code,

(g) defining the critical level of equipment, environment and procedures with a potential effect on quality human tissue or cells,

(h) standard operating procedures for the prompt reporting of a serious adverse reaction and a serious adverse event found in a living donor of human tissue or human cells
and the immediate notification of the conclusion of the investigation into this serious adverse reaction and the serious adverse reaction adverse event,

(i) standard operating procedures for the prompt reporting of a serious adverse reaction and a serious adverse event found during human or human tissue transplantation
cells or after it and without delay the notification of the conclusion of the serious adverse reaction and serious adverse event,

(j) standard operating procedures for all types of human tissue or human cells which: collects, processes, tests, preserves, stores and distributes on

1. verification of the identity of the donor of human tissue or human cells,
2. selection of a donor of human tissue or human cells,
3. collection of human tissue or human cells,
4. evaluation of laboratory tests required for human or human tissue donors cells,
5. labeling of harvested human tissue or human cells and packaging of harvested human tissue or cells,
6. processing of human tissue or human cells,
7. storage of human tissue or human cells,

8. modifying the requirements for the handling of human tissue or human cells which should be disposed of to prevent contamination of other human or human tissuescells, the working environment or healthcare professionals,

9. ensuring the quality of human tissue or human cells during human distributiontissue or human cells,

10. verification of human tissue or cells received,

11. release of human tissue or human cells for distribution;

12. ordering human tissue or human cells with the return of unused human tissue tissue or unused human cells and abolishing the distribution of human tissueor human cells.

§ 16
Selection and evaluation of a donor of human tissue or human cells

(1) Selection of a suitable donor of human tissue or human cells and assessment of selection criteriadonor of human tissue or human cells set out in Annex no. 3 is performed by a doctor designated a procurement organization that confirms in writing the selection of an appropriate human tissue donor; or human cells and the assessment of human tissue or human cell donor selection criteria.

(2) A healthcare professional of a collection organization who performs the collection of human tissue orhuman cells, collect and record medical information on a human tissue donor; or human cells and information on the behaviors of human or human tissue donors cells.

(3) Various sources shall be used to obtain information pursuant to paragraph 2; with a living human donortissue or human cells or his legal representative in the case of a person who is not full legal capacity, at least one interview shall take place. As sources of information are they use in particular:

a) medical documentation of the donor of human tissue or human cells,

(b) an interview with a person who knew the donor of human tissue or human cells, if anya dead donor of human tissue or human cells,

c) an interview with the attending physician of the donor of human tissue or human cells,

(d) an interview with the general practitioner of the donor of human tissue or human cells; or

(e) an autopsy report in accordance with a special regulation; 20) in the case of a dead human tissue donor; or human cells other than the corneal donor.

(4) The criteria for the selection of a donor of human tissue or human cells shall be assessed on the basis ofrisk analysis associated with transplantation of human tissue or human cells. Risks

associated with transplantation of human tissue or human cells are determined by physicalexamination, examination of medical history, history of behavioral habits, testing, other
by appropriate examination, if necessary, and autopsy in the case of a dead human tissue donor; orhuman cells.

(5) If the procurement organization proves that it does not meet any of the criteria for the selection of a human donortissue or human cells, the donor of human tissue or human cells is excluded. Professional
the tissue establishment representative may, on the basis of a documented risk assessmentdecide to accept an excluded donor of human tissue or human cells.

(6) For co-donation of human reproductive cells and for donation of human tissue or human cells intended for autologous use, the provisions of paragraphs 1 to 5 shall not apply.

§ 17
Requirements for the procurement of human tissue or human cells

(1) Collection of human tissue or human cells is performed according to standard procedures procedures governing the procedure for the collection of human tissue or human cells, packaginghuman tissue or cells, labeling of human tissue or cells
and transport of human tissue or human cells until they are taken over by the tissue establishment,or in the case of distribution of human cells to a particular recipient of human cells directly
use, until they are taken over by the healthcare provider according to a special regulation, 3)
who performs their transplantation.

(2) Prior to the collection of human tissue or human cells, the healthcare professional is a collection workerobligatory organization of human tissue or cells

a) verify the identity of the donor of human tissue or human cells,

b) verify and comply with the criteria for the selection of a donor of human tissue or human cells,

(c) evaluate the results of laboratory tests on the donor of human tissue or human cells, if anyavailable,

(d) in the case of a living donor of human tissue or human cells, ensure that the donor of a human tissuetissue or human cells or his legal representative in the case of a person who is not full
legal capacity, by signing the informed consent confirmed that

1. understand the information provided,

2. had the opportunity to ask questions and received answers to the questions asked,

3. all information provided is true to the best of his knowledge,

(e) request written confirmation from the national transplant organization that the human donortissue or human cells or his legal representative did not express during his lifetime disagreement with the removal of human tissue or human cells,

f) to obtain information from a close person of a donor of human tissue or human cells without delay,which may affect the state of health of the recipient of human tissue or human cells, if it is possible,

(g) in the case of a dead donor of human tissue or human cells, record the fact as: and until the donor of human tissue or human cells has been reliably identified.

(3) The collection of human tissue or human cells, other than the collection of semen at home, is can only be performed on the premises of the sampling organization in compliance with standard working conditionsprocedures that minimize bacterial or other contamination of harvested human tissue or harvested human cells.

(4) Sterile medical devices are used for the collection of human tissue or human cellsaids according to a special regulation. 16) When reusing medical devices and contaminated medical devices, sterilization is performed according to a special regulation. 17)

(5) Collection of human tissue or human cells from a living donor of human tissue or human cells is performed in an environment that ensures the health, safety and privacy of the donorhuman tissue or cells.

(6) After collection of human tissue or human cells from the body of a dead human tissue donoror human cells is a healthcare professional who collects human tissue; or human cells, obliged to perform the reconstruction of the donor body of human tissue or humancells so as to be as close as possible to their original anatomical appearance.

(7) After fulfilling the duties of a health worker pursuant to paragraph 2, there is a collection organizationmust mark the harvested human tissue or human cells with a unique donation number assigned to a donor of human tissue or human cells to ensure traceability harvested human tissue or human cells. It is about assigning a unique donation number shall be required to demonstrably request the tissue establishment from the national transplant organization and afterits assignment is a tissue establishment obliged to send a unique donation number to the collection office organizations. The unique donation number is part of the National Transplant Register [§ 33 par. 2 letter b) and c)].

(8) Medical records on the donor of human tissue or human cells shall be keptto the extent provided in § 18 par. 1.

(9) A healthcare professional who collects human tissue or human cells,removes human tissue or human cells in order to procedure

(a) corresponded to the type of human tissue or human cell donor and the type of human donortissue or human cells,

b) protect the safety of a living donor of human tissue or human cells,

(c) ensure the protection of those properties of human tissue or human cells which are requiredin their human use, while minimizing the risk of microbiological contamination during procedure, especially if human tissue or human cells cannot be subsequently sterilized.

(10) In the case of the collection of human tissue or human cells from a dead human tissue donoror human cells, a healthcare professional who collects human tissue; or human cells,

(a) record the site of collection of human tissue or human cells and the time of collection of human tissuetissue or human cells that has elapsed since the death of the human tissue donor; or human cells to a collection of human tissue or human cells to confirm that required biological properties or physical properties of human or human tissuecells are preserved,

b) delimit the site of collection of human tissue or human cells,

c) uses sterile medical devices according to a special regulation 17) to create a localsterile field,

(d) is washed before each collection, using sterile clothing appropriate for the collection of human tissueor human cells, sterile gloves, a face shield and a protective face mask.

(11) The sampling organization is obliged to record and investigate any serious adverse event,

which occurs during the collection of human tissue or human cells which has damaged or which could damage a living donor of human tissue or human cells, including the result
an investigation to identify the causes of this serious adverse event.

(12) Methods and procedures are used for the procurement of human tissue or human cells which:minimize the risk of contamination of human tissue or human cells by medical devices
workers who could be infected with a communicable disease.

(13) When collecting human tissue or human cells, the healthcare professional shall collectthe organization uses CE marked medical devices, verified or specifically
certified and regularly maintained for the collection of human tissue or human cells.
The procurement organization provides training for healthcare professionals who perform procurement human tissue or human cells, on the use of these medical devices.

§ 18
Summary of records of harvested human tissue and human cells

(1) The collection organization is obliged to keep and store the medical documentation of the human donortissue or human cells according to a special regulation, 21) which, in addition to the requisites established
this special regulation contains

(a) personal data of the donor of human tissue or human cells to the extent of first name, surnameand date of birth; in the case of donation of human tissue or human maternal cells, or
the child, the name and date of birth of the mother and, if known, the name and date of birth of the child,

(b) information on the sex, medical history and history of behavior of the donor of the human tissueor human cells to the extent necessary to assess the exclusion criteria of the human donor tissue or human cells,

c) the result of a physical examination of a dead donor of human tissue or human cells,

d) human blood dilution formula, if necessary,

(e) written confirmation from the national transplant organization that the donor of human tissue; or human cells has not expressed disagreement with the removal of human tissue during its lifetime; orhuman cells after death in the case of a dead donor of human tissue or human cells,

f) informed consent, 10) in the case of a living donor,

(g) a recorded and signed evaluation of the criteria for the selection of a human or human tissue donorcells,

h) clinical data,

i) results of laboratory tests,

recorded deviations from the standard related to the evaluation of the human tissue donor; orhuman cells and laboratory testing of a human tissue or human cell donor,
if they have been found

k) in the case of cell cultures intended for autologous use, information on drug allergy,

(l) autopsy report in the case of a dead donor of human tissue or human cells, exceptcorneal donor,

(m) the identification of the partner and the recording of risk factors in the case of human reproductive cells intended for partner donation,

n) a unique donation number from the single European code according to § 24 par. 1.

(2) In the case of a donor of haematopoietic progenitor human cells, the donor of the Hematopoieticcare that performs transplantation of human tissue or human cells,
document the suitability of the human tissue or human cell donor for a particular recipient
human tissue or cells. When donating human tissue or human cells
to a recipient of human tissue or human cells that is not related to a human donor tissue or human cells if the procurement organization has limited access to the datarecipient of human tissue or human cells, the healthcare provider,
who carries out the transplantation of human tissue or human cells shall provide adequate dataabout the donor of human tissue or human cells, confirming his suitability.

(3) A healthcare professional who collects human tissue or human cells is
obliged to ensure that a blood sample is taken and, if necessary, human tissue samples from the donor human tissue or cells; a human blood sample from a human tissue donor; or
human cells and the donor tissue sample of human tissue or human cells must be labeled
a label that contains a unique donation number according to § 17 par. 7, the place of human collection

tissue or human cells and the time of collection of human tissue or human cells.

(4) A healthcare professional who collects human tissue or human cells after

collection of human tissue or cells, prepare a report on the collection of human tissue or human cells, which with a blood sample of a donor of human tissue or human cells,a sample of human tissue, if taken, and a sample of human tissue or samples taken
by human cells to a tissue device that has harvested human tissue or harvested processes, preserves, tests, stores and distributes human cells. Human collection reporttissue or human cells

(a) the trade name or name, registered office and identification number of the sampling organization which carried it outcollection of human tissue or human cells,

(b) the trade name or name, registered office and identification number of the tissue establishment to which theharvested human tissue or human cells are to be delivered,

(c) the data referred to in paragraph 1 (a); a), j), k) and n) and § 16 par. 2,

(d) a description and identification of the harvested human tissue or harvested human cells, includingblood samples from a donor of human tissue or human cells or samples of human tissue at testing,

(e) the name of the healthcare professional performing the tissue collection; orhuman cells, including its signature,

(f) date of collection of human tissue or cells, time of start of collection of human tissue
or human cells, the time of completion of the collection of human tissue or human cells, insteadcollection of human tissue or human cells, identification of the standard used
working procedures, any related events that occurred during the collection of humantissue or human cells,

(g) the environmental requirements of the collection site of human tissue or human cells in the form of a description of the physical environment in which the collection of human tissue or human cells was performed,if necessary,

h) batch numbers of used interacting substances and transport solutions,

(i) in the case of a dead donor of human tissue or human cells, details of the requirements, for which the dead body is kept; in the case of a chilled body, the time of onset of chilling is indicatedbody and the time of completion of the cooling of the dead body,

j) date of death and time of death in the case of a dead donor of human tissue or human cells,

(k) in the case of semen collection in the donor's household, an indication that it is a collection of human tissue; orhuman cells performed in a sperm donor's household.

(5) To the report on the collection of human tissue or human cells pursuant to paragraph 4 medicallya worker collecting human tissue or human cells shall attach a copy of the data pursuant to paragraph 1 (a) f), g), i) and l).

(6) A copy of the report on the collection of human tissue or human cells pursuant to paragraph 5 medicallya worker collecting human tissue or human cells attaches to an autopsy protocol.

(7) The records referred to in paragraphs 1 to 4 shall be kept in accordance with a special regulation. 22)

§ 19

Packaging of harvested human tissue or human cells

(1) A healthcare professional who collects human tissue or human cells isobligatory harvested human tissue or human cells

(a) pack so as to prevent contamination

1. human tissue or human cells,

2. the person who performs the packaging of the harvested human tissue or human cells, and

3. a person who carries out the transport of harvested human tissue or human cells,

(b) store at a temperature which preserves the required properties of the human or human tissuecells and the biological function of human tissue or human cells, after transmission to transfer.

(2) A healthcare professional who collects human tissue or human cells is
must pack the harvested human tissue or human cells in a container suitable for transportbiological material so as to maintain their safety and quality.

(3) A container with harvested human tissue or human cells shall be labeled,which contains

a) unique donation number,

b) type of human tissue or human cells,

c) date and time of collection of human tissue or human cells,

d) danger warning,

e) information on the nature of the additive, if used,

f) the words "FOR AUTOLOGICAL USE ONLY" in the case of autologous use,

(g) the name, surname and date of birth of the recipient of the human tissue or human cells, if anyfor the donation of human tissue or human cells to a specific human recipient
tissue or human cells.

(4) If the size of the label on the container does not allow to state the data according to paragraph 3 letter c) to g), isthese particulars must be given on a separate document accompanying the container with the human sample taken tissue or with harvested human cells.

(5) A procurement organization that collects human tissue or human cells ismust be sent to the tissue establishment in the transport container

a) a container with harvested human tissue or harvested human cells,

(b) a blood sample from a donor of human tissue or cells and a sample of human tissue, if anytaken, and

(c) a report on the procurement of human tissue or human cells.

(6) A transport container containing harvested human tissue or human cells must bemark with the following data:

a) the words "HUMAN TISSUES AND HUMAN CELLS" and "HANDLE WITH CARE",

(b) the trade name or name, registered office and telephone number of the sampling organization which collects the humantissue or human cells and which sends the shipping container, including the name and surname of the contact person in case of complications,

c) business name or title, registered office and identification number and telephone number of the tissue establishment,which the transport container with the harvested human tissue or human cells receives, including the name and surname of the contact person,

d) date and time of transport of human tissue or human cells,

(e) a description of the transport requirements that are essential for the quality and safety of human tissue

or human cells,

f) the text "DO NOT RADIATE" in the case of human cells,

g) the text “BIOLOGICAL RISK” and the relevant warning sign according to a special regulation, 23) if it isknown human tissue or cells are known to be positive for a transmissible disease,

(h) the words "FOR AUTOLOGICAL USE ONLY" in the case of autologous use of human tissue; orhuman cells,

(i) a description of the storage requirements of human tissue or human cells.

(7) A healthcare professional who collects human tissue or human cells is obliged to ensure that the packaging of human tissue or human cells meets the requirementsscientific and technical progress.

§ 20

Receipt of human tissue or human cells by a tissue device

(1) Upon receipt of the transport container, the medical professional shall verify the tissue establishmentand document compliance with the requirements

(a) the transport of harvested human tissue or human cells identified by standardtissue establishment procedures,

(b) the identification of the container with harvested human tissue or harvested human cells in accordance with § 19 par. 3,

(c) the identification of the transport container containing the harvested human tissue or harvestedhuman cells according to § 19 par. 6,

d) the content of data according to § 18 par. 4 in the report on the collection of human tissue or human cells,

(e) the identification of the blood sample of the donor of human tissue or human cells and the identification of the samplehuman tissue, if it was removed, according to § 18 par. 3.

(2) A tissue care professional received human tissue or human cells including a blood sample of a donor of human tissue or cells and a sample of human tissue if has been removed, quarantined and reviewed in accordance with standard operating proceduresreport on the collection of human tissue or human cells, evaluate it and document its suitabilitydonor of human tissue or human cells.

(3) If harvested human tissue or harvested human cells on the basis of an examination in accordance with paragraphs 1 and 2 do not meet the suitability requirements, the healthcare professional is a tissue establishmentobliged to reject such human tissue or cells. When it comes to partner donations or autologous use of human tissue or human cells in which a positive result

is not an obstacle to use, the medical professional of the tissue establishment is obliged to make such human store tissue or human cells separately.

(4) Medical worker of the tissue facility after verification and documentation of suitability donor of human tissue or human cells to the harvested human tissue; or
human cells or human tissue donation identification sequence from harvested human cellscells according to Annex no. 4.

§ 21

Laboratory tests on a blood sample from a donor of human tissue or human cells other than the donor reproductive human cells

(1) The tissue establishment is obliged to provide laboratory tests of a blood donor sample from a human donortissue or human cells according to Annex no. 5, which lays down requirements for laboratories

human tissue or human cell donor assays.

(2) Laboratory tests shall be performed by the provider on the basis of a request from a tissue establishmenthealthcare system operated by a joint investigation medical facility
and therapeutic ingredients that uses CE-marked test kits. Laboratory
the tests must be in accordance with current scientific knowledge.

(3) If a donor of human tissue or human cells has suffered a blood loss and has received human blood,blood derivatives, colloidal solutions or crystalloid solutions, the result of the laboratory test need not be be valid due to the result of the human blood dilution formula. Tissue equipment must be assessed
the degree of the result of the human blood dilution formula if the blood sample is from a human tissue donoror human cells

(a) during the lifetime of the human tissue or human cell donor and the human tissue donor; or human cells received human blood, blood derivatives or colloidal solutions 48 hours beforeby taking a blood sample from a donor of human tissue or human cells or if a human donortissue or human cells received crystalloid solutions no more than one hour before collectionblood samples from a donor of human tissue or human cells, or

(b) after the death of the donor of human tissue or cells and the donor of human tissue; or
human cells received human blood, blood derivatives or colloidal solutions 48 hours before deathor if the

donor of human tissue or human cells received the most crystalloid solutions
one hour before death.

(4) If the result of the human blood dilution formula is greater than 50%, the tissue establishment may acceptharvested human tissue or human cells, if

(a) a healthcare provider who operates a joint healthcare facility
examination and treatment components, use a laboratory test validated for this type of plasma, or

(b) a blood sample from a donor of human tissue or human cells taken before is available
by administering human blood, blood derivatives, colloidal solutions or crystalloid solutions.

(5) In the case of a dead donor of human tissue or human cells, for laboratory tests
it is possible to use a blood sample from a donor of human tissue or human cells taken just before hisdeath
or shortly after his death, but not later than 24 hours after his death.

(6) In the case of a living donor of human tissue or human cells, it is for execution In laboratory tests, a blood sample of a human tissue donor or human cells may be used
taken at the time of collection of human tissue or human cells or, if that is not possible, a sample
donor blood of human tissue or human cells collected within seven days of collection of human tissuetissue
or human cells. The provisions of this paragraph do not apply to a living donor
human bone marrow stem cells for allogeneic use and human stem cellsperipheral blood for allogeneic use.

(7) In the case of human tissue or human cells for allogeneic use from a living human donor tissues or human cells that can be stored for a long period of time, repeated
a laboratory test on a new blood sample from a donor of human tissue or human cells shall be performed
after180 days after collection of human tissue or human cells; then take the donor's blood sample
of human tissue or human cells for the first laboratory test
not more than 30 days before the collection of human tissue or human cells up to seven days afterharvesting
human tissue or human cells.

(8) The procedure under paragraph 7 shall not apply to human tissue or human cells that may
to be stored for a long period, during which laboratory tests were performed according to Annex no. 5part A
of the sixth point.

(9) In the case of human tissue or human cells for allogeneic use from a living human donor tissue or human cells that cannot be stored for a long period of time, and repeated blood sampling of a donor of human tissue or human cells is not possible at the laboratorytests, a blood sample of a human tissue donor or human cells taken over time may be usedcollection of human tissue or human cells or, if that is not possible, within seven days of harvesting human tissue or human cells.

(10) In the case of the collection of human bone marrow and peripheral blood stem cells, a blood sampledonor of human tissue or human cells for laboratory testing shall be taken for a maximum of 30 days prior to donation of human tissue or human cells.

(11) In the case of a donor of human tissue or human cells up to the seventh day of life from birth, laboratory tests may be performed on a mother blood sample from the donor of this human tissueor human cells in order to avoid a medically unnecessary procedure on such a donor.

§ 22

Laboratory tests of blood samples from a donor of reproductive human cells

(1) A procurement organization that collects human reproductive cells intended for direct use, in the case of partner donations, is not required to comply with the donor selection criteria reproductive human cells listed in Annex no. 3 part A and is not obliged to perform the laboratory tests on the blood sample of the donor of reproductive human cells set out in the Annexno. 5 part B.

(2) A procurement organization that collects non-human reproductive human cells intended for direct use, in the case of partner donations, must comply with the selection criteriadonor of human reproductive cells listed in Annex no. 3 of Part A and perform laboratory testsblood sample of a donor of reproductive human cells according to Annex no. 5 part B.

(3) A procurement organization that collects reproductive human cells from another donor reproductive human cells as a partner, is required to comply with donor selection criteria reproductive human cells listed in Annex no. 3 of Part A and perform laboratory tests blood sample of a donor of reproductive human cells according to Annex no. 5 part B.

(4) A procurement organization that collects reproductive human cells intended for nofor direct use in a partner donation, is obliged to take a blood sample from a human donor tissue or human cells for laboratory tests up to three months before the first donation reproductive human cells. In the case of repeated collection of human reproductive cells from of the same donor in a partner donation, is the result of laboratory tests on a donor blood samplehuman tissue or cells is valid for a maximum of 24 months from collection.

(5) In the case of partnership donation, in the case of semen not intended for direct use, processed intointrauterine insemination not intended for storage and if it is shown that take into account the risk of cross - contamination and exposure of healthcare professionals throughusing proven procedures, laboratory tests are not required.

(6) Genetic testing for autosomal recessive genes in accordance with international We know from scientific knowledge that they predominate in the ethnic profile of human reproductive donorscells, and assessing the risk of transmission of inherited requests that are known to occur in relatives of donors of human reproductive cells, should be performed after obtaining consent recipient of human tissue or human cells. Complete information on the resulting riskand the measures taken to alleviate it is the doctor of the healthcare provider, who carries out the human use of such reproductive human cells must notifyand clearly explained to the recipient of human reproductive cells.

§ 23
Processing

(1) A tissue establishment is obliged to process human tissue or human cells according to standard operating procedures so that it is not rendered clinically ineffective; or to a detrimental state for the recipient of human tissue or human cells.

(2) The tissue establishment is obliged to provide tests for microbiological examination of the samplefrom each package of processed human tissue or human cells at the provider healthcare system operated by a joint investigation medical facilityand therapeutic ingredients.

(3) Tissue establishment is obligatory processed human tissue or processed human cellspack in containers suitable for processing and storage to prevent contamination processed human tissue or human cells. Human tissue thus wrapped orhuman cells must be quarantined.

(4) Tissue equipment is obligatory for processed human tissue or processed
assign a human identification sequence to human cells, indicating the number of human tissue; orhuman
cells from the European Union Human Tissue and Human Cells Database, heading
subgroups of the series and the expiry date.

(5) Packaging with processed human tissue or processed human cellsintended for human use
shall be identified by a label containing

a) a single European code,

b) type of human tissue or human cells,

c) business name or title, registered office, identification number and telephone number of the tissue
establishment,which human tissue or cells have processed,

d) the expiry date of the human tissue or human cells,

(e) the text "FOR AUTOLOGICAL USE ONLY" with the personal data of the recipient of the human tissueor human
cells in the range of name, surname and date of birth, if autologous
use of human tissue or human cells,

f) personal data of the recipient of human tissue or human cells in the range of name, surnameand date of birth
in the case of donation of human tissue or human cells to
a specific recipient of human tissue or human cells,

(g) the text "BIOLOGICAL RISK" if it is known that human tissues or human cells are positive forcommunicable
disease,

h) description and dimensions of packaged human tissue or human cells,

(i) morphology and functional data, if necessary;

j) date of distribution of human tissue or human cells,

k) results of laboratory tests,

l) recommendation for storage,

m) instructions for opening the container, packaging and for any handling,

n) expiry date after opening,

o) an instruction to report a serious adverse reaction or serious adverse event,

(p) the presence of a possible harmful residue.

(6) If the size of the label on the packaging does not allow to state the data according to paragraph 5 letter a), e), f) and h) to p), isit is necessary to indicate this information on a separate document inseparably attached to the packaging
with harvested human tissue or harvested human cells.

(7) Tissue equipment is obligatory on processed human tissue or on processed onesrecord the date, time and method of processing in human records
human tissue or human cells according to standard operating procedures.

(8) If it is necessary to apply a method of disposal to processed human tissue or human cells
effectiveness of micro-organisms, the tissue establishment is obliged to use only a validated method and this document the method.

§ 24
Single European code

(1) Human tissue or human cells intended for distribution for human and human use
tissue or human cells imported from a third country shall be legibly marked with a uniform Europeancode according to Annex no. 4.

(2) Human tissue or human cells intended for distribution for human use are labeleda single European code so that it cannot be deleted or removed.

(3) The sequence for identifying the donation of human tissue or human cells may be varied, only if it is necessary to correct an error related to the allocation of the donor identification sequencehuman tissue or cells. Any change is mandatory for the tissue device
record and notify the national transplant organization.

(4) Repair of incorrectly labeled human tissue or human cells

(5) The provisions of paragraph 1 shall not apply to

a) reproductive human cells from partner donation,

b) human tissue or human cells distributed to a particular recipient of human tissueor human cells for immediate use,

(c) human tissue or human cells for use in an emergency.

(6) The human tissue or human cells referred to in paragraph 5 shall be identified by an identification sequencedonation of human tissue or human cells.

(7) The tissue establishment is obliged to print a single European code with a sequence of identificationdonation of human tissue or human cells and the product identification sequence that are separated by one space or listed in two consecutive lines.

§ 25
Storage

(1) A tissue establishment is obliged to store processed human tissue or human cells according to storage requirements with indication of the maximum storage time according to standard working procedures according to § 30.

(2) The tissue establishment is obliged to continuously monitor the storage requirements of the processed tissuehuman tissue or cells.

(3) A tissue establishment is obliged to store processed human tissue or human cells in quarantine until the tissue establishment doctor confirms suitability with his signaturehuman tissue or human cells for human use based on evaluation

a) reports on the collection of human tissue or human cells according to § 18 par. 4,

b) records on the processing of human tissue or human cells,

(c) the results of laboratory tests; and

d) autopsy protocol.

(4) In the case of a positive laboratory test result, blood samples from a living human tissue donoror human cells intended for autologous use, the tissue device may be such a human store, process and distribute tissue or human cells if they are stored separately so that prevented

a) cross-contamination with other human tissue or human cells,

(b) contamination by foreign agents; or

c) their confusion.

(5) Tissue establishment is mandatory human tissue or human cells unsuitable for human use

discard and dispose of the use.

§ 26
Distribution of processed human tissue or human cells

(1) The tissue establishment distributes human tissue in accordance with standard operating proceduresor human cells that are tested, processed, and evaluated by a tissue device physician as suitable for human use.

(2) The tissue establishment is obliged to ensure the quality of human tissue or human cells during transport according to standard operating procedures.

(3) The tissue establishment handles applications for the distribution of human tissue or human cellsin terms of standard working procedures according to § 30.

(4) Human tissue or human cells are distributed in a shipping container and labeledwith the following data:

(a) the words "HANDLE WITH CARE" and "HUMAN TISSUES OR HUMAN CELLS",

b) business name or title, registered office, identification number and telephone number of the tissue establishment,which distributes the shipping container,

(c) the trade name or name, registered office, identification number and telephone number of the healthcare providercare according to a special regulation that performs human use of human tissue or human cells received by the shipping container, including name and surnamecontact person,

d) recommended transport requirements,

e) safety instructions, if necessary,

(f) the text "DO NOT RADIATE" in the case of human cells.

(5) If a healthcare provider performing human use of human tissue

or human cells, the distributed human tissue or cells do not apply to human cellsuse under this law, will return them according to standard tissue procedures equipment.

(6) The tissue establishment shall ensure the implementation of an accurate, rapid and verifiable procedure that:it will allow it to abolish the distribution of human tissue or cells and the use of human tissue or human cells that may be associated with a serious adverse event or seriousadverse reaction.

§ 27

Transplantation of human tissue or human cells

(1) Transplantation of human tissue or human cells into the body of a recipient of human tissueor human cells can be performed if

(a) the state of health of the recipient of the human tissue or human cells so permits on the basis ofassessment by the attending physician and

(b) a recipient of human tissue or cells prior to human tissue transplantation; orhuman cells has given informed consent after prior instruction; informed
consent is not required for the provision of urgent medical care if this is not possibleobtained in time, but it can be assumed.

(2) The selection of the recipient of human tissue and human cells is governed exclusively by medicine point of view.

§ 28

Traceability of human tissue or human cells

(1) The procurement organization that collected the human tissue or human cells is obligatoryensure the traceability of harvested human tissue or harvested human cells from donor of human tissue or human cells to recipient of human tissue or human cellscells and vice versa.

(2) The tissue establishment is obliged to ensure the traceability of each human tissue or human cells that

a) have been processed, stored or distributed in the territory of the Slovak Republic,

(b) have been imported from a Member State or a third country from a donor of human tissue; orhuman cells to a recipient of human tissue or human cells and vice versa a

(c) have been exported to a Member State or to a third country from a donor of human tissue; orhuman cells to a recipient of human tissue or human cells and vice versa.

(3) Traceability pursuant to paragraphs 1 and 2 shall also apply to all relevant data relating to itwith preparations and materials which have come into contact with harvested human tissue, or with human cells.

(4) Tissue equipment is mandatory to ensure the traceability of each human tissueor human cells to use the single European code according to Annex no. 4.

(5) The tissue establishment is obliged to keep medical records for security purposes traceability of human tissue or human cells containing

a) a report on the collection of human tissue or human cells according to § 18 par. 4,

b) documented data on processing according to § 23 par. 7,

c) a single European code according to § 24 par. 1,

(d) determining the type of donation of human tissue or human cells to

1. allogeneic use from a living donor of human tissue or human cells;

2. allogeneic use from a dead donor of human tissue or human cells; or

3. autologous use,

e) information on the suitability of human tissue or human cells for human use according to § 26par. 1 including the date of distribution of human tissue or human cells or unsuitability human tissue or human cells for human use according to § 25 par. 5, inclusive
the date of destruction of human tissue or human cells,

f) business name or name, registered office and identification number of the healthcare provider,which is performed humanely using human tissue or human cells.

(6) A healthcare provider who performs human use of human tissue or human cells, is required to ensure the traceability of human tissue; orhuman cells to store at least the following data:

(a) the trade name or name, registered office and identification number of the tissue establishment which distributed tissue or human cells,

(b) the name and surname of the doctor, the trade name or title, the registered office and the identification number of the providerhealthcare that carries out the humane use of human or human tissue cells,

c) type of human tissue or human cells,

(d) a unique European code identifying the human tissue or cells intended forhuman use,

e) name, surname and date of birth of the recipient of human tissue or human cells,

(f) date of transplantation of human tissue or human cells.

(7) The procurement organization, the tissue establishment and the healthcare provider who: performing human use of human tissue or human cells have an obligation to preserve data strictly necessary to ensure the traceability of human or human tissue

cells from a human tissue donor or human cells to a human tissue recipient; or human cells and vice versa related to the collection, testing, processing, preservation, storage and distribution for at least 30 years from their human use, clinical use
or liquidation. The provisions shall apply mutatis mutandis to the storage of data in electronic form special regulation. 19)

§ 29
Reporting of a serious adverse event and serious adverse reaction

(1) The health care provider 3) is obliged to immediately notify the tissue provider any suspicion of

(a) a serious adverse reaction of a living donor of human tissue or cells, which may affect the quality and safety of human tissue or human cells in the range of data according to Annex no. 6 part A,

(b) a serious adverse reaction of a recipient of human tissue or human cells arising during transplantation of or after human tissue or human cells
with the quality and safety of human tissue or human cells, in the range of data according to Annex no. 6 part A,

c) a serious adverse event arising during the procurement of human tissue or human cells, which may affect the quality and safety of human tissue or human cells, to the extent data according to Annex no. 6 part C,

(d) a serious adverse event arising during transplantation of human or human tissue cells, or which may be related to the quality and safety of human tissue, or human cells, in the range of data according to Annex no. 6 part C.

(2) The health care provider pursuant to a special regulation 3) is obliged without delay notify the tissue establishment of incorrect identification or replacement of reproductive tissue human cells, which is considered a serious adverse event in assisted reproduction,
in the range of data according to Annex no. 6 part C.

(3) Importing tissue equipment is a mandatory without delay announce national transplantation organization any suspected serious adverse

reaction in accordance with Annex No. 6
Part A and for a serious adverse event according to Annex no. 6 part C reported by the supplierhuman tissue or human cells from a third country.

(4) Tissue establishments are obligatory for any suspected serious adverse reaction and seriousinvestigate the adverse event in order to analyze the cause and effect.

(5) A tissue establishment is obligatory to the health care provider according to a special Regulation 3) under paragraphs 1 and 2 and the National Transplant Organization shall promptly notify

(a) the conclusions of the investigation of a serious adverse reaction within the scope of the data set out in Annex II; 6 part B,

b) conclusions from the investigation of a serious adverse event in the scope of data according to Annex no. 6 part D,

(c) measures taken in relation to other human tissues or other human cells distributed for human use with a serious adverse reaction or serious reactionthe adverse event concerns.

(6) Healthcare provider according to a special regulation 3) and tissue establishment they shall be required to record the particulars provided for in paragraphs 1 to 3 and 5 in the medical file.

(7) Tissue facility and health care provider performing humanely use of human tissue or human cells, have the obligation to keep data related to serious adverse reaction or with a serious adverse event 30 years after human administrationuse of human tissue or human cells.

(8) A tissue establishment and a healthcare provider who performs humane the use of human tissue or human cells will ensure the introduction of accurate, rapid and a verifiable procedure that will allow them to discontinue the distribution and use of human tissue; or human cells, which may be associated with a serious adverse reaction or with a serious adverse event.

§ 30
Obligations of the tissue establishment and procurement organization

(1) The tissue establishment is obliged to create standard working procedures according to § 15.

(2) The tissue establishment is obliged to notify the national transplant organization without delay

(a) information that in the case of human tissue or human cells received from anothertissue establishment in the European Union, the requirements for uniform European code,

(b) modification of data contained in the European Union database of human tissue and human cells.

(3) The tissue establishment is obliged to keep records of data on

(a) the type and quantity of samples taken, tested, processed, stored, preservedor distributed human tissue or human cells,

(b) the type and quantity of human tissue or cells imported, the place of origin and the placedestination in the case of imports of human tissue or human cells,

c) the place of origin and the place of use of human tissue or human cells,

(d) acceptance and rejection of human tissue or human cells.

(4) The tissue establishment is obliged to send it to the national transplant organization in paper formin the form of an annual report on its activities, signed by an expert representative by 1 March the following calendar year, which contains data on

(a) the activities for which the tissue establishment is authorized,

(b) the type and quantity of samples taken, tested, processed, preserved, storedand human tissue or human cells distributed or otherwise used,

(c) the type and quantity of human tissue or cells imported, the place of origin and the placedestination in the case of imports of human tissue or human cells,

(d) the type and amount of serious adverse reactions and serious adverse events, includingthe manner in which they are notified and resolved,

(e) the changes that have taken place during the year for which the annual report is prepared.

(5) The professional representative of the tissue establishment shall ensure that

(a) human tissue and human cells intended for human use are harvested, processed, preserved,tested, stored or distributed in accordance with this Act,

(b) provide information to the national transplant organization on any serious adverse reactionsevents and serious adverse reactions referred to in § 29 and to submit a report,
which analyzes the causes and the measures taken,

c) comply with the obligations under this Act and under a special regulation. 24)

(6) A tissue establishment is obliged to hand over human tissue at the end of its activity or human cells, including medical records related to each collection of human tissue
or human cells performed by that tissue establishment, to a tissue establishment that
is licensed for collection, testing, processing, preservation, storage and distribution
and with which, upon application for the consent of a tissue establishment which terminates itsactivity, the

Ministry of Health agreed.

§ 31
Import and export

(1) Tissue establishment that imports human tissue or human cells
from a Member State or a third country must be authorized for this type of activity underspecial regulation. 25)

(2) Tissue establishment that exports human tissue and human cells outside
territory of the Slovak Republic, must have a permit for this type of activity according to the special regulation 25) and written consent of the National Transplant Organization; written consent may request a tissue device that can ensure the distribution and traceability of the human
tissue or human cells. Model application for written consent for the export of human tissue orhuman cells outside the territory of the Slovak Republic is listed in Annex no. 7. National
the transplant organization shall give written consent to the export of human or human tissue

cells if the required amounts of human tissue or human cells are provided forneeds of recipients of human tissue or human cells in the Slovak Republic.

(3) A tissue establishment may import from a Member State without a permit for this species
activities pursuant to a special regulation 25) with the written consent of the national transplant organization,if it is o

a) human cells for direct use in a specific recipient of human cells,

(b) human tissue or human cells in an emergency, if the specific recipient is humantissue or human cells, or

(c) a single import of human tissue or human cells, if the specific recipient is humantissue or human cells.

(4) A tissue establishment may perform a single import of human or human tissue
cells from a third country supplier if the specific recipient is human tissue or human tissue
cells, even without authorization to import human tissue or human cells from a third country underspecial regulation 25) with the written consent of the national transplant organization; such human tissue or human cells must not be used in a person other than a specific human recipient
tissue or human cells.

(5) The single import of human tissue or human cells pursuant to paragraph 4 isthe importing tissue establishment must enclose

a) a copy of the written cooperation agreement with the third country supplier,

(b) a detailed description of the movement of human tissue or human cells since their collection in the third country afteracceptance by tissue devices,

(c) a copy of the relevant document on the basis of which the third - country supplier is authorized to:export of human tissue or human cells, giving the contact details of the person concerned
authority; if the supplier from the third country has not been issued with a document authorizing him to export
human tissue or cells, a copy of the relevant document must be provided,
on the basis of which the third country supplier is authorized for all related activitieswith human tissues or cells,

(d) a copy of the label identifying the human tissue or human tissue removed from the third country supplier cells,

(e) a copy of the label identifying the container with the removed human being from the third country supplier tissue or harvested human cells,

(f) a copy of the label identifying the supplier of human tissue or human cells from a third partystate shipping container,

(g) a copy of the document on the basis of which the donor of human tissue was identified; orhuman cells, the evaluated donor of human tissue or human cells, informed
donor of human tissue or human cells or a close person thereof, method of obtaining
consent of the donor of human tissue or human cells and whether or not the donation washuman tissue or cells voluntarily and free of charge,

(h) a copy of the relevant document authorizing the laboratory to perform the laboratorytesting with a third country supplier and a list of the laboratory tests used,

(i) a copy of the standard working procedures for the processing of human or human tissuecells used by a supplier from a third country,

(j) a copy of the material and technical equipment of the supplier of human tissue or human cellsfrom a third country,

(k) a copy of the standard operating procedures for human tissue distribution requirements; or

human cells used by a supplier from a third country,

(l) particulars of the trade name, registered office and activity of each human tissue subcontractoror human cells with which the third-country supplier has a contract
on cooperation,

(m) a copy of the conclusion of the other inspection carried out on the supplier from the third country by the competent authority,who issued the activity permit,

(n) a copy of the conclusion of the inspection carried out on the supplier from the third country by the importing tissueequipment or on its behalf.

PART FOUR
RESPONSIBILITY OF THE MINISTRY OF HEALTH AND THE NATIONAL TRANSPLANTATION ORGANIZATIONS

§ 32
Ministry of Health

(1) Ministry of Health

a) supervises compliance with this Act, implements control measures in cooperation
with the national transplant organization on a regular basis and imposes sanctions and fines in accordance withspecial regulation; 26) the interval between two inspections in tissue establishments must not be more than two years,

(b) cooperate with the national transplant organization in developing

1. a set of measures to control the procurement of human organs, human tissues or human tissuescells or transplantation of a human organ, human tissue or human cells,
2. guidelines for surveillance requirements and control measures related to sampling, testing,processing, preserving, storing or distributing human tissue; or
human cells,

(c) provide information on the results of surveillance at the request of a Member State or the European Commissionand control measures,

(d) authorizes or withdraws consent to the operation of the transplantation center on the basis ofapplications for the consent of the institutional health care provider,

(e) provide, at the request of a Member State or the European Commission, information on national data authorization requirements

1. a healthcare provider who collects human tissue; orhuman cells,

2. an institutional health care provider who performs human organ procurement,
and consent provider constitutional medical care on the power activitiestransplant center,

(f) provide information on the list at the request of the European Commission or a Member Statetissue establishments and transplantation centers,

(g) in cooperation with the national transplant organization, be the competent authority for the closure a written contract for the exchange of a human organ with the competent authority of a Member State, or by the competent authority of the third country or by an authorized person authorized by it, if such authorized personthe person ensures the fulfillment of the requirements stipulated in this Act,

h) supervises compliance with this Act and implements control measures in cooperationwith the national transplant organization whenever any serious adverse event occursreaction or serious adverse event,

(i) report to the European Commission every three years on compliance activities
the provisions of this Act, including the measure taken in connection with supervision,

(j) supervise compliance with the national transplantation organization
a procedure to ensure quality and safety in collection, processing, testing, preservation,storage or distribution of human tissue or human cells at a third-party supplier
state,

(k) supervise the supplier from the third country also in cooperation with another Member State onat the request of another Member State; the refusal to cooperate must be justified,

(l) send an annual notification to the European Commission by 30 June of the following calendar yearserious adverse reactions and serious adverse events according to Annex no. 8 developed
national transplant organization.

(2) The Ministry of Health, in addition to the activities referred to in paragraph 1

(a) join, as far as possible, the network of competent authorities of the Member States set up The European Commission for the purpose of exchanging information and experience, and

b) supervises compliance with this Act and implements a control measure always on the basis ofduly substantiated request by a Member State.

§ 33

National Transplant Organization

(1) National Transplant Organization

(a) perform tasks related to the procurement of a human organ, human tissue or human cellsand transplants of human organ, human tissue or human cells, provides
cooperation with state administration bodies and control bodies and cooperates with the European the Commission,

b) keep records of the activities of tissue establishments, records of the activities of constitutional providers health care, including the total number of living donors of the human organ, the human
tissue and human cells and dead donors of human organ, human tissue and human cells, as well as the types and numbers of human organs, human tissues and humancells, transplanted human organs, human tissues and human cells
and destroyed human organs, human tissues and human cells,

(c) draw up and make available an annual report on the activities referred to in point (b)through its website,

d) send to the Ministry of Health by 31 May of the following calendar year a summary
a report on the activities of the tissue establishments drawn up on the basis of the annual reports senttissue devices,

(e) coordinate activities at national level relating to human organ transplantation
and cross-border human organ exchange activities in cooperation with the Chief Transplantcoordinator, appointed and removed by the Minister of Health of the Slovak Republic,

(f) is required to establish and maintain a transplantation information system containing data in accordance withAnnex no. 9,

(g) at the request of the tissue establishment and the institutional healthcare provider
sends a written confirmation that the donor of a human organ, human tissue or human tissuecells did not express during his life disagreement with the removal of human organs, humantissue or human cells, indicating the date and time of issue of the confirmation and the nameand the surname of the person who verified this fact,

(h) supervise the exchange of a human organ with the Member State of origin or with a Member State

destination and with a third country,

(i) made publicly available on its website

1. an updated list of tissue establishments and transplantation centers a
2. information on the activities of tissue establishments and transplantation centers,

j) is obliged to establish a system of traceability of all human organs that have been removed, assigned and transplanted in the territory of the Slovak Republic from a human organ donor torecipient of a human organ and vice versa,

(k) assign the European Union tissue establishment code from the tissue classification databaseEuropean Union at the request of the Ministry of Health,

(l) assign a unique donation number to the donor of human tissue or human cells toat the request of the tissue establishment,

(m) assign a unique donation number to a human organ donor at the request of the providerinstitutional health care,

(n) keep statistics relating to the procurement of human organs, human tissues or human tissuescells, by transplantation of a human organ, human tissue or human cells and destruction of the human organ, if not used,

(o) is required to keep a list of unique donor numbers and unique recipients of human recipientsorgans identifying each human organ donor and human organ recipient and ensure the protection of personal data,

(p) carry out the activities of a reference and control laboratory examining human leukocytesantigens within the Slovak Republic,

(q) at the request of the tissue establishment, give written consent to the export of human tissueor human cells outside the territory of the Slovak Republic, if

1. the export is intended for the transplantation of human tissue or human cells; and
2. there is no recipient of human tissue or human cells in the territory of the Slovak Republic,

(r) store data for the purpose of ensuring full traceability of human tissue; or human cells for at least 30 years after their donation; this data may be retainedin electronic form,

(s) is mandatory when reporting a serious adverse reaction and a serious adverse event that may occuraffect the quality and safety of the human organ and which can be attributed to testing, characteristics, procurement, preservation and transport of the human organ, as well as any seriousan adverse reaction observed during or after human organ transplantation that may occur related to these performances, act in coordination with the reporting systemserious adverse event and

serious adverse reaction that may affect quality
and the safety of the human organ,

(t) in the exchange of a human organ with a Member State, receive and notify without delay and without delay information pursuant to § 12 and receives and submits a report pursuant to § 13 to the competent authority of the memberState pursuant to Sections 12 and 13 in accordance with the procedure pursuant to Section 14,

(u) provide an immediate connection between it and tissue and tissue establishmentsdevices to each other, access to this application on the website is authorized;
any unauthorized access to data or systems that allow donor identificationhuman tissue or human cells or a recipient of human tissue or human
cells is prohibited,

(v) immediately update data on tissue classifications in the tissue establishment databaseEuropean Union on the basis of a valid decision to grant an operating permit
tissue establishment, a valid decision to suspend the authorization of the

operation of a tissue establishment and a valid decision to revoke an authorization for
operation of the tissue establishment 27) and subsequently notifies the European Commission of this updatethe Commission and the competent authorities of the Member States,

(w) is required to set up a system for the notification, investigation, registration and dissemination of information on

1. a serious adverse event and a serious adverse reaction that may affect quality
and the safety of a human organ, human tissue or human cells and which mayrelated to the collection, testing, processing, storage or distribution of human organ, human tissue or human cells,

2. a serious adverse reaction observed in a recipient of a human organ, human tissueor human cells during or after transplantation, which may be related to quality
and the safety of human organs, human tissue or cells,

x) determines the coding system according to § 2 par. 46.

(2) The National Transplant Organization shall keep a National Transplant Register, of which are included

a) waiting lists for human organ transplants,

(b) a register of living donors of human organs, human tissues or human cells in accordance withspecial regulations, 28)

c) a register of dead donors of human organs, human tissue or human cells,

d) a register of persons who have expressed disagreement with the removal of human organs during their lifetime,human tissue or human cells after death,

(e) a register of human organ transplants performed.

(3) The purpose of the data processing, the list of processed data and the circle of data subjects about whom the data are processed, as well as the purpose for which they are provided, a list of the data that can be provided,
and third parties to whom data from the National Transplant Register are provided in accordance with paragraph 2,are listed in Annex no. 9.

(4) Processed personal data and confidential statistical data according to a special regulation 29)
from the National Transplant Register pursuant to paragraph 2 shall be provided and made available only to the extentunder this law. Processed personal data from the National Transplant Register according to paragraph 2 shall be provided in anonymised form to the Ministry of Health for enforcement purposesof the State Health Policy and the Ministry of Finance of the Slovak Republic for analytical purposes.The processed data from the National Transplant Register are provided in summary form except for personal data to the Statistical Office of the Slovak Republic and the National Center for Health
information for the purposes of national statistics and for international comparisons. Third parties with the datafrom the National Transplant Register, except for personal data and confidential statistical data according to a special regulation 27) they provide upon request.

PART FIVEFINAL PROVISIONS

§ 34
Transitional provision

For harvested human tissue or human cells that are stored until 29 April 2017,
does not apply to the obligation to mark them with a single European code under this Act, if they are released into circulation no later than 29 October 2021.

17/2016 Coll. § 35 Repeal provision

The following are canceled:

1. Regulation of the Government of the Slovak Republic no. 20/2007 Coll. on details of purchases,tissue and cell

donation, selection criteria for tissue and cell donors, laboratory tests required for tissue and cell donors and on cell or tissue procurement procedures and their takeover by health care providers, as amended by Government Decree no. 119/2014 Coll.,

2. Regulation of the Government of the Slovak Republic no. 622/2007 Coll., Which lays down the details on the processing, preservation, storage or distribution of tissues and cells and on reporting and investigationadverse reactions and events and measures taken as amended by Government Decree no. 9/2016 Coll.,

3. yield Ministries healthcare Slovak of the Republic zo 17. December 2012 no. S09229-OL-2012, which in adjust details on the characteristics authorityand characteristics of the donor, marking of the transport container, record of the organs removed and a record on transplanted organs (Notification No. 426/2012 Coll.),

4. yield Ministries healthcare Slovak of the Republic zo 17. December 2012 no. S09602-OL-2012 laying down the requirements for consent to the export of a tissue or cell outside the territory of the Slovak Republic and a model application for consent for the export of a tissue or cell outsideof the territory of the Slovak Republic (Notification No. 427/2012 Coll.) as amended by the Decree of 24 June 2013 no. 04114-OL-2013 (Announcement No. 197/2013 Coll.).

§ 36

This Act transposes the legally binding acts of the European Union listed in Annex no. 10.

Art. II

Act no. 576/2004 Coll. on health care, services related to the provision of health care and on the amendment of certain laws as amended by Act no. 82/2005 Coll., Act no. 350/2005 Coll., Act no. 538/2005 Coll., Act no. 660/2005 Coll., Act no. 282/2006 Coll., Act no. 518/2007 Coll., Act no. 662/2007 Coll., Act no. 489/2008 Coll., Act no. 192/2009 Coll., Act no. 345/2009 Coll., Act no. 132/2010 Coll., Act no. 133/2010 Coll., Act no. 34/2011 Coll., Act no. 172/2011 Coll., Act no. 313/2012 Coll.,Act no. 345/2012 Coll., Act no. 41/2013 Coll., Act no. 153/2013 Coll., Act no. 160/2013 Coll., Act no. 220/2013 Coll., Act no. 365/2013 Coll., Act no. 185/2014 Coll., Act no. 204/2014 Coll., Act no. 53/2015 Coll., Act no. 77/2015 Coll., Act no. 378/2015 Coll., Act no. 422/2015 Coll., Act no. 428/2015 Coll., Act no. 125/2016 Coll. and the lawno. 167/2016 Coll. is amended as follows:

1. In § 2 par. In the fourth sentence of paragraph 3, the word "and" after the word "devices" is replaced by a comma and the words"Urgent transport of donors and recipients of organs, tissues and cells intended for transplantation "are replaced by the words" urgent transport of a human organ donor and the recipient human authority designated on the transplantation, urgent transportat and the urgent transport of a human organ intended for transplantation '.

2. In § 6 par. 4 and par. 5 letter a) after the words “§ 27 par. 1, "delete the words" § 36 par. 2, § 38par. 1, “.

3. In § 6, paragraph 5 is supplemented by letter d), which reads:"(D) after prior instruction

1. when collecting a human organ, human tissue or human cells from a donor human organ, human tissue or cells; and
2. in the transplantation of a human organ, human tissue or human cells from recipient of a human organ, human tissue or human cells according to the specific

prescription. 5a) “.

Footnote 5a reads:

„ 5a) Sections 3 and 4 of Act no. 317/2016 Coll. on requirements and procedures for the collection and transplantation of human
authority, human fabrics and human cells and about change and additions some

4. Section 6 is supplemented by paragraph 11, which reads:

'(11) A healthcare professional from an institutional care provider who provides health care in the specialized field of gynecology and obstetrics, is
obliged to inform the parent of an aborted or prematurely withdrawn human fetus that
upon written request, he may request the extradition of the aborted or prematurely withdrawnthe human fetus entrusted with the funeral service for their burial. 6aa) “.

Footnote 6aa reads:

„ 6aa) § 3 par. 8 of Act no. 131/2010 Coll. on funeral services'.

5. In § 11 par. 9, point (f) is deleted.

The former letters g) to i) are referred to as letters f) to h).

6. In § 11 par. 10, the following words shall be added at the end: "and to refuse to take a human organ,human tissue or human cells after their death as determined by the special
Regulation 14aa) ’.

Footnote 14aa reads:

„ 14aa) § 5 par. 2 of Act no. 317/2016 Coll. “.

7. In § 14 par. 1 letter (d) the word "authorities" is deleted.
8. Section 19 is supplemented by paragraph 6, which reads:

"(6) A medical record is also a set of data on the collection, processing, testing,preserved, stored and distributed human tissue or cells,
which leads the tissue device according to a special regulation. 20a) “.

Footnote 20a reads:

„ 20a) § 23 par. 5 of Act no. 317/2016 Coll. “.

9. Section 22 is supplemented by paragraph 4, which reads:

"(4) The provider in connection with the collection, testing, preservation, distribution, characteristics, transplantation and traceability of the human organ and in relation to with collection, testing, processing, canning, storage, distribution, transplantation and traceability of human tissue or human cells is mandatory keep medical records in accordance with special regulation 21b) for at least 30 years from

(a) the collection of a human organ, human tissue or human cells,

(b) transplantation of a human organ, human tissue or human cells; and

(c) the destruction of human organs, human tissues or human cells. ".Footnote 21b reads:

„ 21b) § 6 par. 3, § 8 par. 4, § 9 par. 2 and § 28 par. 7 of Act no. 317/2016 Coll. “.

10. The title of the second title shall read:

"Blood collection for transfusion for the preparation of transfusion drugs".

11. Sections 35 to 38, including the headings, are deleted. Footnotes to references 40a, 40b and 41aa are deleted.

12. The title of § 39 is deleted.

13. The headings above Sections 39a, 39e and 39i are deleted.

14. Sections 39a to 39l, including titles, are deleted. Footnotes to references 41a and 41b are deleted.

15. In § 43 par. 8 letter (b) the word "sampling" is replaced by the word "sampling" and the words "deleted" are deleted "(§ 37)" and a reference 45 is placed above the word "cells".

Footnote 45 reads:

„ 45) Section 5 of Act no. 317/2016 Coll.

16. In § 45, paragraph 3 reads:

"(3) The Ministry of Health is the founder of a national transplant organization. 52ab) “.Footnote 52ab reads:

„ 52ab) § 21 par. 5 letter b) of Act no. 523/2004 Coll. on budgetary rules of public administration and amending certain laws.

§ 33 of Act no. 317/2016 Coll. “.

Footnotes to references 52ac and 52ad are deleted.

17. In Section 45, paragraphs 4 to 10 are deleted.

The current paragraph 11 is renumbered as paragraph 4.

18. Annexes no. 1a, 1b and 2 are deleted. Footnote 56 is deleted.

19. Annex no. 3, the following ninth and tenth points are added:

„9. Commission Directive (EU) 2015/565 of 8 April 2015 amending the Directive 2006/86 / EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 9.4.2015).

10. Commission Directive (EU) 2015/566 of 8 April 2015 implementing the Directive 2004/23 / EC unless goes about procedures verification equivalent standards quality and safety of imported tissues and cells (OJ L 93, 9.4.2015). "

Art. III

The law no. 578/2004 Z. z. about providers medical care, medical workers, professional organizations in health care and on the amendment of certain laws as amended by Act No. 720/2004 Coll., Act no. 351/2005 Coll., Act no. 538/2005 Coll., Act no. 282/2006 Coll., Act no. 527/2006 Coll., Act no. 673/2006 Coll., Resolutions of the Constitutional Court Of the Slovak Republic no. 18/2007 Coll. , Act No. 272/2007 Coll., Act no. 330/2007 Coll., Act no. 464/2007 Coll., Act no. 653/2007 Coll., Resolutions of the Slovak Constitutional Court Republic No. 206/2008 Coll., Act no. 284/2008 Coll., Act no. 447/2008 Coll., Act no. 461/2008 Coll., Act no. 560/2008 Coll., Act no. 192/2009 Coll., Act no. 214/2009 Coll., Act no. 8/2010 Coll., Act no. 133/2010 Coll., Act no. 34/2011 Coll., Act no. 250/2011 Coll., Act no. 362/2011 Coll., Act no. 390/2011 Coll., Act no. 512/2011 Coll., Finding Of the Constitutional Court of the Slovak Republic no. 5/2012 Coll., Act no. 185/2012 Coll., Act no. 313/2012 Coll., Act no. 324/2012 Coll., Act no. 41/2013 Coll., Act no. 153/2013 Coll., Act no. 204/2013 Coll., Act no. 220/2013 Coll., Act no. 365/2013 Coll., Act no. 185/2014 Coll., Act no. 333/2014 Coll., Act no. 53/2015 Coll., Act no. 77/2015 Coll., Act no. 393/2015 Coll., Act no. 422/2015 Coll., Act no. 428/2015 Coll., Act no. 91/2016 Coll., Act no. 125/2016 Coll. and Act no. 167/2016 Coll. is amended as follows:

1. Section 7 is supplemented by paragraphs 13 and 14, which read as follows:

"(13) A transplant center is an operating unit of a provider pursuant to paragraph 4 (a). a), who performs medical services on the basis of the written consent of the Ministry of Health connected with collection, testing, characteristics canning, distribution and human organ transplantation; The consent shall include a list of medical procedures that

may be performed by the transplantation center.

(14) The transplantation center shall appoint a transplantation coordinator in accordance with paragraph 13. Details of the coordinators of the procurement program and the transplant program shall be determined the Ministry of Health by a generally binding legal regulation. ".

2. Section 9a, including the footnote to reference 13aa, is deleted.

3. In § 13, paragraph 9, including the footnote to reference 17b, is deleted.

4. After § 13, § 13a is inserted, which, including the title, reads:

„§ 13a
Application for a permit to operate a tissue establishment

(1) Applicant for the issuance of a permit for the operation of a tissue establishment, except for the requisites applications for the issuance of permits referred to in § 13 par. 1 to 5

(a) indicate the type of human tissue or human cells to be harvested, tested, process, preserve, store and distribute for transplantation, and

b) state the e-mail address, telephone number and website,

(c) attach standard operating procedures on the basis of which it will carry out its activities; and

d) enclose copies of cooperation agreements with the health care provider pursuant to § 7 para. 3 letter (a) the second point and point b) and par. 4 letter (a) or by the Authority healthcare pursuant to Special Regulation 17a) (hereinafter referred to as the "Supervisory Authority"), in which human tissue or human cells, if tissue, are harvested the device does not collect human tissue or human cells, and copies of contracts on cooperation for the testing of harvested human tissue or cells with the health care provider according to § 7 par. 3 letter (f) if in points (e) and (f) unless otherwise specified,

e) enclose a written document on the appointment of a doctor by the provider pursuant to § 7 para. 3 letter a) the second point and letter b) and par. 4 letter (a) who selects a human tissue donor; or

human cells, written evidence of the appointment of the healthcare professional performing it collection of human tissue or human cells, a written document indicating the type of human tissuetissue or human cells and test samples to be taken, and a sample
the report to be completed after collection of human tissue or human cells, if any
tissue establishment and provider according to § 7 par. 3 letter (a) the second point and point b)and para. 4 letter a) operated by the same provider,

(f) attach a written document of cooperation to test the harvested human tissue; or
human cells, if the tissue establishment and the provider according to § 7 par. 3 letter f)operated by the same provider.

(2) When applying for a permit to import human tissue or human cells
from a Member State of the European Union, a State party to the Agreement on the EuropeanEconomic Area, and the Swiss Confederation (hereinafter referred to as the "Member State")
equipment in addition to the requirements specified in § 13 par. 1 to 5 and par. 1 letter (d) indicate the type human tissue or human cells to be imported and shall attach a copy of the contract
on cooperation with a supplier from a Member State.

(3) When applying for a permit to import human tissue or human cells from
a non-Member State (hereinafter referred to as a "third State"), a tissue establishment other thanrequisites specified in § 13 par. 1 to 5 and par. 1 letter d)

(a) attach a copy of the written cooperation agreement with the tissue establishment or other personfrom a third country (hereinafter referred to as a "third country supplier"), which contains:

1. guarantee authorizations of the Ministry healthcare in partnership with
with nationalthe transplant organization to supervise the third country supplier during
the validity of the written contract, within two years after the expiry of the written contract;this authorization shall also cover the exercise of periodic surveillance by the importer tissue device,
2. the rights and obligations of the Parties in order to ensure that standards are metquality and safety of imported human tissue or human cells in accordance withspecial regulation, 17b)
3. an undertaking by the third-country supplier to provide copies of the documents referred toin points (l) to (s), including their updates,
4. the obligation for the third country supplier to inform the importing tissue establishmentabout any serious adverse events or reactions,
which may affect the quality and safety of human tissue or human cells imported or intended for import by

an importing tissue establishment, oron the suspicion of such serious adverse events or reactions,

5. the obligation for the third country supplier to inform the importing tissue industry without delaydevice for revocation or temporary suspension of an authorization document
supplier from a third country for the export of human tissue or human cells, including
sending a copy of a document proving this fact,

6. the obligation for the third country supplier to inform the importing tissue industry without delaythe facility of the decision of the competent authority of the third country in which he is entitledthe third-country supplier is established and which decision has or may have meaning or
impact on the quality and safety of imported human tissue or importshuman cells,

7. agreed requirements for the transport of human tissue or human cells betweenthird country supplier and importing tissue establishment,

8. the obligation for the third country supplier and his subcontractor to keep records
about the donor of human tissue or human cells and records of imported human tissuetissues and human cells 30 years after the collection of human or human tissue
cells, including agreed requirements if the third country supplier terminates itsactivity,

9. the agreed requirements for updating the written cooperation agreement with the supplier
from a third country in the event of a change which may affect the quality and safety of the imported person human tissue and human cells,

(b) indicate the type of human tissue or cells it will import,

(c) list the activities carried out by the third-country supplier;

(d) list the activities which the supplier from the third country has contractually secured with anothersupplier from a third country,

(e) indicate the name of the third country that will supply the harvested human tissue to the tissue establishmentor human cells,

(f) provide details of the third country supplier to the extent

1. business name and registered office,

2. name and surname of the person who is a statutory body or name and surnameprofessional representative,

3. telephone number, including international prefix,

4. telephone number for emergency situations,

5. e-mail address,

(g) give a detailed description of the movement of human tissue or human cells since their collectionin a third country after receipt by a tissue establishment,

(h) attach a copy of the relevant document authorizing the supplier from the third country to exporthuman tissue or cells, giving the contact details of the relevant
authority; if the supplier from the third country has not been given a document entitling him to
export of human tissue or human cells, a copy of the relevant tissue must be provideddocument authorizing the supplier from the third country for all activities related to with human tissues or cells,

(i) attach a copy of the label identifying the human tissue removed from the third country supplieror human cells,

(j) enclose a copy of the label identifying the container with the withdrawn container from the third country human tissue or harvested human cells,

k) enclose a copy of the label indicating the shipping container from the third country supplier,

(l) attach a copy of the document on the basis of which the donor was identified and evaluatedhuman tissue or cells, an informed human tissue donor or
human cells or a loved one, the method of obtaining the consent of a human tissue donoror human cells or a nearby donor of human tissue or human cells
for the collection of human tissue or human cells and whether or not there was a donationhuman tissue or cells voluntarily and free of charge,

(m) attach a copy of the relevant document authorizing the laboratory to perform the laboratorytesting with a third country supplier and a list of the laboratory tests used,

(n) attach a copy of the standard working procedures for the processing of human tissue; orhuman cells used by a supplier from a third country,

o) enclose a copy of the material and technical equipment of the supplier from the third country,

(p) attach a copy of the standard operating procedures for human distribution requirementstissue or human cells used by a supplier from a third country,

q) state the scope of the business name, registered office and type of activity performed by eacha subcontractor of human tissue or human cells with which he has a third party contractor concluded a cooperation agreement,

r) attach a copy of the conclusion of the other inspection carried out on the supplier from the third country to the authorities,who has issued a permit to perform his activity,

(s) attach a copy of the conclusion of the inspection carried out on the importing third country suppliertissue establishment or on its behalf.

(4) When applying for an export permit for human tissue or human cells,
tissue establishment in addition to the requisites specified in § 13 par. 1 to 5 and par. 1 letter (d) statethe type of human tissue or cells that it will export. "

Footnotes to references 17a and 17b read as follows:

„ 17a) Section 48 of Act no. 581/2004 Coll. as amended.

17b) § 4 and the third part of Act no. 317/2016 Coll. on collection and transplantation requirements and proceduresthe human organ, human tissue and human cells and amending certain laws (Transplantation Act). "

5. In § 16, paragraph 1 is supplemented by letters c) to f), which read as follows:

"(C) change of e-mail address, telephone number and website, if the permit is onoperation of tissue equipment,

d) change of the trade name and registered office of a supplier from a third country in the case of an authorization for

operation of tissue establishment; to notify of this change tissue establishment
enclose a copy of the relevant document authorizing the supplier from the third country to exporthuman tissue or human cells with new data,

e) the date of revocation or the date of temporary suspension of the documentauthorizing supplier from a third country to export human or human tissue
cells; the change is also the adoption of any other decision by the competent authority
the third country in which the eligible supplier from the third country is established, if thisthe decision has or may have a significance or impact in terms of quality and safety imported human tissue or imported human cells,

f) termination or partial termination of imports of human tissue or cellsfrom a third country. "

6. In § 17 par. 1, after the word "focus", the words "change in the type of activity according tospecial law 17b) ”.

7. After § 17d, § 17e is inserted, which, including the title, reads:

„§ 17e
Change in tissue activity data

(1) Issuance of a new permit, by which the authority competent for issuing the permit shall revoke at the same timeoriginal permit is required for the change

a) the type of human tissue or human cells that the tissue establishment will collect,test, process, preserve, store, distribute for human use or type
human tissue or the type of human cells that the tissue establishment will import
or export,

(b) a description of the movement of human tissue or cells in the case of imports of human tissueor human cells,

(c) in the list of activities carried out by the supplier from the third country in respect of imports of humantissue or human cells,

(d) a supplier from a third country.

(2) In the application for the issuance of a permit pursuant to paragraph 1, the applicant shall state the required change, enclose itthe documents relating to it and a solemn declaration that the other particulars have not changed,
on the basis of which the original permit was issued. ".

8. In § 18 par. 2, the words "af) and ag)" are replaced by the words "af), ag) and ai)" and the words "the Health Care 22) (hereinafter "the Supervisory Authority") "is replaced by" Office
for supervision 22) ’.

9. In § 19 par. 2, the words "af) and ag)" are replaced by the words "af), ag) and ai)".

10. In § 25, letter f) is deleted, including the footnote to reference 17b.The former letter g) is referred to as letter f).

11. The current text of § 25 is referred to as paragraph 1 and is supplemented by paragraph 2, which reads:

"(2) Decision to issue a permit for the operation of a tissue establishment, except
requisites according to § 13a par. 1 letter (d) and the particulars referred to in paragraph 1 include:

(a) the European Union tissue establishment code assigned by the national transplant organization from the European Union tissue classification database upon requestMinistry of Health,

b) the type of human tissue or human cells that the tissue establishment will collect,test, process, preserve, store and distribute for human use,

(c) the type of human tissue or cells that the tissue establishment will export, ifthis is an application for an export permit for human tissue or human cells,

(d) the type of human tissue or cells that the tissue establishment will importfrom a Member State,

(e) in the case of an application for an authorization to import human tissue or human cells

1. the type of human tissue or cells that the tissue establishment will importfrom a third country,
2. a detailed description of the movement of human tissue or human cells since their collection in the third State upon receipt by a tissue establishment,
3. the trade name and registered office of the supplier of the human tissue or human cells from the third party state,
4. a list of activities performed by the supplier of human tissue or human cellsfrom a third country,
5. a list of activities that the supplier of human tissue or human cells from the third party hascontracted with another supplier of human tissue or human cells
   from a third country,
6. the name of the third country where the supplier has human tissue or human cellsfrom a third country. "

12. In § 26, paragraph 1 is supplemented by letter g), which reads:

„G) the national transplant organization at the tissue establishment according to § 11 par. 1 letter d). "

13. In § 26a par. 3 letter b) reads:

"(B) authorization number; in the case of a tissue establishment, also the tissue establishment code of the EuropeanUnion, ’.

14. In § 30 par. 3, the words "a Member State of the European Union, a State Party
Agreement on the European Economic Area, and the Swiss Confederation (hereinafter
"State") or a national of a State which is not a Member State (hereinafter referred to as a "third State"),
"shall be replacedthe words "a Member State or a national of a third country".

15. In § 79 par. 1 letter zs) after the words “organization” the words “and the relevanttransplantation coordinator of the transplantation center ".

16. In § 79 par. 1 letter zz) the words “(§ 9a)” are deleted and placed above the word “equipment”link 55jaia.

Footnote 55jaia reads:
„ 55jaia) § 15 of Act no. 317/2016 Coll. “.

17. Footnote 55jaj reads:

„ 55jaj) § 5 of Act no. 317/2016 Coll. “.

18. In § 79 par. 1 letter and (b) the words "unique numeric code" are replaced by the words "uniqueEuropean code ’.

19. Footnote 55 as follows:

„ 55jak) § 24 of Act no. 317/2016 Coll. “.

20. In § 79 par. 1 letter and (d) the words "Ministry of Health" shall be replaced by the words "nationaltransplant organization ’.

21. In § 79 par. 1 letter (ad) the following third point is inserted after the second point:

„3. information on the type, quantity of imported human tissue or human cells, locationorigin and destination in the case of imports of human tissue or cells, '.

The former points 3 and 4 are referred to as points 4 and 5.

22. In § 79, paragraph 1 is supplemented by letters ai) to ak), which read as follows:

"(Ai) in the collection, processing, preservation, testing, storage or distribution of humantissues or human cells to comply with special regulations, 55jaq)

(aj) propose to the person with chronic kidney disease a kidney transplant before startingdialysis,

if) report the newly assigned person to the relevant transplantation center no later than threemonths after the start of regular dialysis treatment. "

Footnote 55jaq reads:

„ 55jaq) § 17 par. 6, § 21 to 23, § 25 and 26 of Act no. 317/2016 Coll. “.

23. The footnotes to references 55jal to 55jao read as follows:

„ 55jal) § 30 par. 3 of Act no. 317/2016 Coll.

55jam) § 30 par. 6 of Act no. 317/2016 Coll.

55jan) § 3 of Act no. 317/2016 Coll.

55jao) The second part of Act no. 317/2016 Coll. “.

24. § 79 par. 3 letter (g) the words "zz) to af)" are replaced by the words "zz) to af) and ai)".

25. In § 79, paragraph 3 is supplemented by letters h) and i), which read as follows:

"(H) paragraph 1 (a) (aj) apply only to the provider holding the authorization for operation of a specialized outpatient clinic in the specialized field of nephrology,

i) paragraph 1 (a) if) apply only to the provider according to § 7 par. 3 letter c)in the field of nephrology. ".

26. Section 79 is supplemented by paragraph 13, which reads as follows:

'(13) An authorization holder must notify the authority without delay
competent for issuing a permit to change the data specified in § 16, 17 and 17e. ".

27. In § 81, paragraph 1 is supplemented by letter h), which reads:

"(H) the Ministry of Health in cooperation with the national transplant organizationin tissue establishments [(Section 11 (1) (d)) at two-year intervals; if it goes
on the fulfillment of obligations by holders of permits pursuant to § 79, except for § 79 paragraph 1 letter g), za), zu) tozw) and ah) and compliance with the requirements of the operation of the medical facility on the basis of
authorization. ".

28. In § 82 par. 1 letter (a) the words "paragraph 6" are replaced by the words "paragraphs 6 and 13".

29. In § 82 par. 1 letter (d) the words "(af) and (ag)" are replaced by the words "(a), (ag), (ai) to (k)".

30. After § 102v, § 102z is inserted, which, including the title, reads:

„§ 102z
Transitional provisions for adjustments effective from 1 February 2017

(1) A provider who holds a permit to operate a tissue establishment
issued by 31 January 2017, is obliged to apply for a change in the operating permit
tissue establishment no later than 28 February 2017. If the provider within the period under the first does not request a change of permit by 28 February 2017 or does not obtain a permit pursuant to thisof the Act by 28 April 2017, a permit for the operation of a tissue establishment issued by 31 January 2017 expires on April 28, 2017.

(2) Proceedings for the issuance of a permit for the operation of a tissue establishment, which has been initiatedby 31 January 2017, shall be completed in accordance with this Act in the wording effective from 1 February 2017.The legal effects of acts which occurred in the proceedings before 1 February 2017 shall be maintained. ".

31. Annex no. 1, the following points 11 and 12 are added:

„11. Commission Directive (EU) 2015/565 of 8 April 2015 amending the Directive 2006/86 / EC as regards certain technical requirements for the coding of human tissuesand cells (OJ L 93, 9.4.2015).

12. Commission Directive (EU) 2015/566 of 8 April 2015 implementing the Directive

2004/23 / EC as regards the procedures for verifying equivalent quality standardsand safety of imported tissues and cells (OJ L 93, 9.4.2015). "

Art. IV

Act no. 581/2004 Coll. on health insurance companies, health care supervision and on the amendment of certain acts as amended by Act no. 719/2004 Coll., Act no. 353/2005Coll., Act no. 538/2005 Coll., Act no. 660/2005 Coll., Act no. 25/2006 Coll., Act no. 282/2006 Coll., Act no. 522/2006 Coll., Act no. 12/2007 Coll., Act no. 215/2007 Coll., Act no. 309/2007 Coll., Act no. 330/2007 Coll., Act no. 358/2007 Coll., Act no. 530/2007 Coll., Act no. 594/2007 Coll., Act no. 232/2008 Coll., Act no. 297/2008 Coll., Act no. 461/2008 Coll., Act no. 581/2008 Coll., Act no. 192/2009 Coll., Act no. 533/2009 Coll., Act no. 121/2010 Coll., Act no. 34/2011 Coll., Judgment of the Constitutional CourtOf the

Slovak Republic no. 79/2011 Coll., Act no. 97/2011 Coll., Act no. 133/2011 Coll., Act no. 250/2011 Coll., Act no. 362/2011 Coll., Act no. 547/2011 Coll., Act no. 185/2012 Coll.,Act no. 313/2012 Coll., Act no. 421/2012 Coll., Act no. 41/2013 Coll., Act no. 153/2013 Coll., Act no. 220/2013 Coll., Act no. 338/2013 Coll., Act no. 352/2013 Coll., Act no. 185/2014 Coll., Act no. 77/2015 Coll., Act No. 140/2015 Coll., Act No. 265/2015 Coll.,Act no. 429/2015 Coll., Act no. 91/2016 Coll., Act no. 125/2016 Coll., Act no. 286/2016

Z. z. and Act no. 315/2016 Coll. is amended as follows:

1. In § 20 par. 1 letter k) reads:

"(K) carries out autopsies, inspects carcases 64) and pays for funeral services; or a person who is a close person 57) to the deceased, the cost of transporting the corpse

1. from the place of death for autopsy to the relevant pathological-anatomical workplace and workplace forensic medicine and back from the pathological-anatomical workplace and the forensic workplacemedicine to the place of death or to the place of burial, if this place is not further than the place of death or to the refrigeration facility of the funeral service, ifthe funeral service will provide the funeral,
2. the donor of a human organ from the place of death at autopsy to the relevant pathological-anatomical workplace and workplace judicial medicine and back from pathological-anatomical workplaces and forensic workplaces to the place of burial or refrigerationfuneral services, if the funeral service will arrange the funeral. ".

2. In § 48 par. 3 letter e) and par. 5 letter (e) the words "or tissues" are replaced by the words "or beforeby harvesting human tissue or human cells ’.

3. In § 48 par. 8, second sentence, the following words shall be added at the end: “and to the health care providercare, 68aa) who has harvested human tissue or human cells ’.

Footnote 68aa reads:

„ 68aa) § 7 par. 3 letter h) of Act no. 578/2004 Coll. as amended by Act No. 428/2015 Coll. “.

Art. INEfficiency

This Act shall enter into force on 1 February 2017, except for Art. I, Art. II, Art. III points 1, 2, 8, 14 to 29and 31 and Art. IV, which shall enter into force on 29 April 2017.

Andrej Kiska vrAndrej Danko vrRobert Fico vr

Annex no. 1to Act no. 317/2016 Coll.

Characteristics of the human organ donor and characteristics of the human organ

Part A

A set of data to be recorded in the medical records of a human donororgan before human organ donation:

1. business name or title, registered office, identification number and telephone number of the constitutional providerhealthcare that carries out human organ procurement,
2. an indication of whether it is a living human organ donor or a dead human organ donor,
3. blood group of the human organ donor,
4. gender of the human organ donor,
5. cause of death of the human organ donor,
6. date, time and minute of death of the human organ donor,
7. date of birth or estimated age of the human organ donor,
8. weight of the human organ donor,
9. height of the human organ donor,
10. history of intravenous drug use,
11. history of malignant disease,
12. history of communicable diseases,
13. results of laboratory tests to rule out the presence of HIV, HCV and HBV,
14. basic information to evaluate the function of the donated human organ,
15. the unique donation number assigned by the national transplant organization,
16. date, time and minute of start of human organ harvesting and date, hour and minutetermination of human organ procurement,
17. date, hour, minute of interruption of the blood circulation of the human organ,
18. name, description, type and identification of the human organ collected, including the donor's blood sample human tissue or human cells for laboratory tests,
19. other relevant data on human organs taken away.

Part B

A set of additional data to the data to be collected, which are based on the decisioncouncil:

1. business name or title, registered office, identification number and telephone number of the constitutional providerhealthcare that carries out human organ procurement,

2. demographic and anthropometric data on the human organ donor relevant to assessment of the suitability of the human organ for the recipient of the human organ,
3. the medical history of the human organ donor, including information on the medical condition which would could affect the suitability of the human organ for transplantation involving a risk disease transmission,
4. physical and clinical data that could affect the suitability of the human organintended for transplantation

(a) from a clinical examination necessary to evaluate the maintained physiologicalfunctions of a human organ donor,

(b) a finding of a medical condition which was not found during the examination of the donor 's medical report anamnesis,

c) the risk of disease transmission,

5. the results of the laboratory tests required for

a) assessment of the function of the human organ,

b) detection of communicable diseases,

c) identification of possible contraindications in connection with human organ donation,

6. results of imaging tests performed to assess the anatomical condition of the humanorgan intended for transplantation,
7. treatment given to a human organ donor relevant to the assessment of human function organ and suitability for human organ donation, in particular administration of antibiotics, inotropicsupport or treatment with blood derivatives,
8. a description of any event which may have occurred during the procurement of the human organ and which may have occurredimpact on the quality and safety of human organ transplantation.

Annex no. 2to Act no. 317/2016 Coll

REPORTING A SERIOUS ADVERSE REACTION OR REPORTING A SERIOUS ADVERSE REACTIONHUMAN ORGAN COLLECTION AND TRANSPLANTATION EVENTS
HUMAN AUTHORITY

Part A

The first report to report a serious adverse reaction or report a serious adverse eventcontains the following data:

1. the name of the reporting Member State,
2. identification number of the first message: country [country code 30)] national number,
3. contact details of the reporting entity (competent authority or delegated entity in the reporting Member State): telephone number, e-mail address or even faxnumber,
4. trade name or name of the provider of institutional health care, transplantthe reporting center / national transplant organization,
5. contact data coordinator / contact persons (provider constitutional medicalcare center, a transplantation center which carries out collection in the receiving Member State report): telephone number, e-mail address or even fax number,
6. date and time of the report (yyyy / mm / dd / hh / mm),
7. name of the Member State of origin,
8. unique donation number,
9. name of all Member States of destination (if known),
10. the identification number of the recipient of the human organ in accordance with the donor identification systemand beneficiaries,

11th date and timeserious unwanted reactions or serious unwanted events(yy

12. date and time of detection of the serious adverse reaction or serious adverse event(yyyy / mm / dd / hh / mm),
13. a description of the serious adverse reaction or serious adverse event,
14. immediate measures taken or proposed.

Part B

Joint final report on a serious adverse reaction or serious adverse eventcontains the following data:

1. the reporting Member State,
2. message identification number: country [country code 30)] national number,

3. contact details of the reporting entity: telephone number, e-mail address, faxnumber,
4. date and time of the report (yyyy / mm / dd / hh / mm),
5. the identification number (s) of the first report (s) of the reporting of a serious adverse reaction; oron the reporting of a serious adverse event in accordance with Part A of this Annex,
6. description of the fact,
7. the Member States concerned,
8. outcome of the investigation and final conclusion,

9. preventive and corrective measures taken,
10. Conclusion / follow-up, if required.

Annex no. 3to Act no. 317/2016 Coll.

CRITERIA FOR SELECTING A HUMAN TISSUE OR HUMAN CELL DONOR

A. CRITERIA FOR THE SELECTION OF A LIVE DONOR OF HUMAN TISSUE OR HUMAN BUNIEK

GENERAL CRITERIA FOR THE EXCLUSION OF A LIVING HUMAN DONORTISSUES OR HUMAN CELLS

1. History of the disease of unknown cause.
   Current or past history of malignancy other than primary
   basal cell carcinoma, in situ cervical carcinoma and some primary carcinomas
2. tumors of the central nervous system, which must be evaluated on the basis of scientific evidence.
   Risk of transmission of diseases caused by non - cellular infectious particles formed by proteins (prions).
   This risk applies to:
   (a) a person diagnosed with Creutzfeldt-Jakob disease, variant Creutzfeldt-Jakob disease or in whom a close
   iatrogenic Creutzfeldt-Jakob disease,
3. (b) a person with a history of rapid progressive dementia or degenerative neurological disease diseases, including diseases of unknown origin,
   (c) a recipient of hormones prepared from the human pituitary gland (such as growth hormones), the recipient corneal transplants, sclera or hard meninges and the person who underwent undocumented neurosurgery (in which a dura mater could be used).
   Systemic infection not controlled at the time of donation of human tissue or human cells,
4. including bacterial diseases, systemic viral, fungal, parasitic infections or significant local infection of

human tissue or human cells to be donated.

5. History, clinical evidence or laboratory evidence of HIV.
6. History, clinical evidence or laboratory evidence of acute hepatitis B or chronic hepatitis B (except in immunocompromised individuals).
7. History, clinical evidence or laboratory evidence of acute hepatitis C or chronic hepatitis C.
8. Evidence of risk factors or risk of HTLV I / II transmission.
9. History of chronic systemic autoimmune disease that could have deleterious effects on the quality of the human tissue or human cells to be harvested.
10. Indications that the results of laboratory tests on blood samples from a donor of human tissue or human cells will be invalid due to:
(a) the result of the human blood dilution formula, if a blood sample from a human donor is not available tissue or human cells collected prior to the administration of blood derivatives,
b) treatment with immunosuppressive agents.
11. Evidence of any other risk factors for communicable diseases based on evaluation the risks, taking into account the travel and exposure history of the human tissue donor, or human cells and the local prevalence of communicable diseases.
12. The presence of physical symptoms on the donor body of human tissue or human cells that indicate a risk of a communicable disease.
13. Ingestion or exposure to a substance (such as cyanide, lead, mercury, gold) that could recipient of human tissue or human cells at a dose that could be compromised his health.
14. Recent vaccination with live attenuated virus, if the risk of transmission is considered.
15. Xenograft transplantation.

317/2016 Coll. Collection of Laws of the Slovak Republic

PECIFIC CRITERIA FOR THE EXCLUSION OF A LIVING HUMAN TISSUE DONOR OR HUMAN CELLS DEPENDING ON THE TYPE

DONATED HUMAN TISSUE OR HUMAN CELLS

Pregnancy (excluding donors of human umbilical cord blood, amniotic membrane and sibling donors of human hematopoietic progenitor cells).

17. Breastfeeding.

18. In hematopoietic progenitor human cells - the possibility of transmission of inherited diseases.

B. CRITERIA FOR THE SELECTION OF A DEAD DONOR OF HUMAN TISSUE OR HUMAN BUNIEK

GENERAL CRITERIA FOR THE EXCLUSION OF A DEAD HUMAN TISSUE DONOR OR HUMAN CELLS

Unknown cause of death, unless an autopsy is performed to provide information on the cause of death and cannot

1. apply any of the following general exclusion criteria for a dead human tissue donor; or human cells.

2. History of the disease of unknown cause.

Current or past history of malignancy other than primary basal cell carcinoma, nec

situ carcinoma of the cervix and some primary tumors of the central nervous system,

3. which must be evaluated on the basis of scientific evidence. Donor of human tissue or human cells with malignant disease can be evaluated and evaluated for corneal donation in addition to

who suffered from retinoblastoma, hematological malignancy and anterior segment malignancy

eye.

Risk of transmission of diseases caused by non-cellular infectious particles formed by proteins (prions). This risk applies to:

(a) a person diagnosed with Creutzfeldt-Jakob disease, a variant of Creutzfeldt-Jakob Jakob disease or a non-iatrogenic Creutzfeldt-naïve disease in close persons.

Jacob's disease;

4. (b) a person with a history of rapid progressive dementia or degenerative neurological disease including diseases of unknown origin;

(c) a recipient of hormones prepared from the human pituitary gland (such as growth hormones), the recipient

corneal, sclera or meningeal transplants and the person who submitted undocumented neurosurgery (in which a dura mater could be used).

Systemic infection uncontrollable at the time of donation of human tissue or human cells, including

bacterial diseases, systemic viral infections, fungal infections or parasitic infections or

significant local infection of human tissue or human cells to be donated. Darcov

5. human tissue or human cells with bacterial septicemia may be re-evaluated and considered for eye donation only if the cornea is stored in an organ culture that allows detection

any bacterial contamination of the tissue.

6. History, clinical evidence or laboratory evidence of HIV.

7. History, clinical evidence or laboratory evidence of acute hepatitis B or chronic hepatitis B (except in immunocompromised individuals).

8. History, clinical evidence or laboratory evidence of acute hepatitis C or chronic hepatitis C.

9. Evidence of risk factors or risk of HTLV I / II transmission.

10. History of chronic systemic autoimmune disease that could have detrimental effects on the quality of the human tissue or cells to be harvested.

11. Indications that the results of laboratory tests of blood samples from a donor of human or human tissue cells will be invalid due to:

(a) the result of the human blood dilution formula, if a blood sample from a human tissue donor is not available or human cells collected prior to the administration of

blood derivatives,

b) treatment with immunosuppressive agents.

12. Evidence of any other risk factors for communicable diseases based on a risk assessment taking into account the travel and exposure history of the human or human tissue donor cells and the local prevalence of communicable disease.

13. The presence of physical symptoms on the donor body of human tissue or human cells that indicate a risk of a communicable disease.

14. Ingestion or exposure to a substance (such as cyanide, lead, mercury, gold) that could be human tissue or cells in a dose that could endanger his health.

15. Recent vaccination of a donor of human tissue or human cells with a live attenuated virus if the risk of transmission is possible.

16. Transplantation with xenografts.

OTHER EXCLUSION CRITERIA FOR THE DEAD CHILD'S HUMAN DONOR TISSUES OR HUMAN CELLS

Babies born to HIV-infected mothers or children meeting the exclusion criteria described above must be excluded as donors of human tissue or human cells, provided that: it will not be possible to rule out the risk of disease transmission.

a) A child under the age of 18 months who was born to a mother infected with HIV, hepatitis B, hepatitis C, HTLV or those at risk of such infection and during the previous 12 months; such a child cannot be considered a human donor tissue or human cells regardless of the results of laboratory tests.

(b) A child born to a mother infected with HIV, hepatitis B, hepatitis C, HTLV or one who is at risk of such an infection and who has not been breastfed by the mother during the previous 12 months and whose laboratory tests, physical examination and assessment of medical records do not demonstrate the presence of HIV, hepatitis B, hepatitis C or HTLV; such a child may be considered a donor of human tissue or human cells.

Annex no. 4 to Act no. 317/2016 Coll.

DynamicResources \ 5441767a-fb02-48ac-bdb1-c2216feee2b4_2.pdf	numeric characters

STRUCTURE OF THE SINGLE EUROPEAN CODE

1. The sequence for identifying the donation of human tissue or human cells is the first parta single European code consisting of the tissue code of the European Union

   and a unique donation number.
2. The tissue establishment code is a unique identifier for the tissue establishment it hasactivity permit. The tissue establishment code consists of the ISO 30) country code

   (country) and tissue establishment numbers listed in the tissue establishment databaseEuropean Union.
3. The unique donation number is the identification number assigned by the national transplantby an organization to a donor of a human organ, human tissue or human cells.
4. The product identification sequence is the second part of the unique European codeconsisting of a product code made from human tissue or human cells,

   serial subgroup numbers and expiration dates of human tissue, orhuman cells.
5. The product code is the identifier for the relevant specific human tissue typeor human cells. The product code consists of the coding system identifier
   products used by the tissue establishment ("E" for EUTC, "A" for ISBT128, "B" for

   Eurocode) and product numbers made of human tissue or human cellsspecified in the relevant product coding system.
6. The subset number of a lot is a number that distinguishes and uniquely identifies human tissueor human cells that have the same unique donation number and the same product code

   and come from the same tissue device.
7. The expiry date shall be the date until which the human tissue or human tissuecells can use. If it is not possible to determine the expiry date,

   the numeric sequence 00000000 is used.

Annex no. 5

to Act no. 317/2016 Coll.

LABORATORY TESTING

A. Laboratory tests required for a donor of human tissue or human cells other than human reproductive cell donor

1. For a donor of human tissue or human cells intended for autologous use and allogeneic use, in particular laboratory testing for exclusion is required

a) the presence of HIV 1, Anti-HIV 1,

b) the presence of HIV 2, Anti-HIV 2,

c) the presence of hepatitis B virus, HBsAg and Anti-HBc,

d) the presence of hepatitis C virus, Anti-HCV-AB,

(e) syphilis in accordance with the fourth part of Part A of this Annex.

2. In the case of a donor of human tissue or human cells living in the area or originating from an area with a high prevalence of HTLV-I virus, has a sexual partner that originates from this area, or if the biological parents of the donor are human tissue or human cells originating in this field, in addition to the tests referred to in point 1, testing for antibodies is required against HTLV-I.

3. If the Anti-HBc laboratory test is positive and the laboratory test is negative HBsAg test according to the first point (c) further laboratory tests and evaluations are performed risks in order to determine the suitability of human tissue or human cells for human use the use.

4. In the laboratory test according to the first point of letter (e) a validated algorithm is applied testing to rule out the presence of active infection caused by Treponema pallidum. A specific or non-specific non-reactive laboratory test may allow consent to use human tissue or cells. If a non-specific laboratory test is performed, the reactive result is not an obstacle to the harvest of human tissue or human cells; or consent to the use of human tissue or human cells if there is a specific laboratory test on Trepone pallidum unreactive. If it is a donor of human tissue or human a laboratory test of a blood sample reactive to a specific test on Treponem pallidum, a thorough risk assessment is required to determine the suitability of human tissue or human cells for human use.

5. Depending on the donor history of the human tissue or human cells and characteristics donated human tissue or cells may require additional laboratory use tests, in particular for malaria, RhD, HLA, CMV, toxoplasma, EBV or Trypanosoma cruzi.

6. In the case of human tissue or human cells intended for autologous use identical series of laboratory tests as for allogeneic use.

7. If a living donor of human tissue or human cells other than a stem donor human bone marrow cells and human peripheral blood stem cells additionally the blood sample of the donor is tested by human tissue or human cells also by the amplification technique

nucleic acid (NAT) to HIV, HBV and HCV or if the processing is inactivating
step verified for the relevant viruses, repeated laboratory tests of a new donor blood samplehuman tissue or cells are not required.

8. Laboratory tests shall be performed on the serum or plasma of a human tissue donor orhuman cells. Laboratory tests may be performed on other fluids or
excretions, in particular on the vitreous or posterior chamber of the eye, if the use is verifiedlaboratory test for such a fluid is clinically justified.

B. Laboratory tests required for human reproductive cell donors

1. A reproductive cell donor is required to assess the risk of cross-contaminationperforming these laboratory tests for exclusion

a) the presence of HIV 1, Anti-HIV 1,

b) the presence of HIV 2, Anti-HIV 2,

c) the presence of hepatitis B virus, HBsAg and Anti-HBc,

d) the presence of hepatitis C virus, Anti-HCV-AB.

(e) syphilis in accordance with the tenth point of Part B of this Annex.

2. In the case of a donor of human tissue or human cells living in the area or
comes from an area with a high prevalence of the HTLV-I virus, has a sexual partner whocomes from this area, or if the parents of the donor are human tissue or human cells
originating in this area shall be required in addition to the laboratory tests referred to in point 1 of Part B.of this Annex as well as the performance of laboratory tests for antibodies against HTLV-I.

3. If the results of the laboratory tests of the donor of human reproductive cells are not determinedfor direct use in case of HIV 1, HIV 2, hepatitis positive donation
B or hepatitis C or are not available or if the donor is reproductive
human cells knows that it is a source of infection risk, a system of separatestorage.

4. In certain circumstances, additional laboratory tests may be required depending onthe travel and exposure history of the donor of human tissue or human cells
and the properties of the donated human tissue or human cells, especially if applicableabout malaria, RhD, CMV or Trypanosoma cruzi.

5. If the partners are a husband or wife and a woman who declare that they have an intimate physical relationship, positive laboratory test results do not have to be an obstacle for partners
donation.

6. In the case of the donation of human reproductive cells from a person other than the partner,a blood sample from a human reproductive cell donor is taken and tested in a laboratory at the time of each donation.

7. Donated sperm from other persons shall be quarantined for a period of at least 180 days,after which repeated laboratory tests are performed; if the sperm donor subsequentlythe blood sample is also tested by

nucleic acid amplification (NAT) for HIV, HBV
and HCV or if the processing includes an inactivation step validated for the relevant viruses,repeated laboratory tests on a new sperm donor blood sample are not required.

8. Laboratory tests shall be performed on the serum or plasma of a human tissue donor orhuman cells. Laboratory tests may be performed on other fluids or
excretions, in particular on the vitreous or posterior chamber of the eye, if the use is verifiedlaboratory test for such a fluid is clinically justified.

9. In the case of a sperm donor, a laboratory test must be carried out for chlamydia in a urine samplenucleic acid amplification (NAT) technique and the result of this laboratory test
must be negative.

10. In the case of a donor of human reproductive cells intended not for donation,
in addition to the laboratory tests referred to in the first point, a laboratory test is requireddonor blood samples for syphilis. The results of all laboratory tests must be negative.
A validated algorithm is used to evaluate the result of the laboratory test for syphilistesting to rule out the presence of an active infection caused by Treponema pallidum. A specific or non-specific non-reactive laboratory test may allow
consent to the use of human tissue or human cells. If done nonspecifically
laboratory test, the reactive result is not an obstacle to the collection of human tissue orhuman cells or consent to the use of human tissue or human cells, if any
specific laboratory test on Treponem pallidum non-reactive. If it is a human donortissue or human cells whose laboratory test blood samples are reactive for
specific test for Treponem pallidum, a thorough risk assessment is required in order todetermined the suitability of human tissue or human cells for human use.

Annex no. 6to Act no. 317/2016 Coll.

NOTIFICATION OF A SERIOUS ADVERSE REACTION AND SERIOUS ADVERSEEVENTS IN CONNECTION WITH HUMAN TISSUE COLLECTION OR HUMAN CELLS AND HUMAN TISSUE TRANSPLANTATION OR HUMAN CELLS

PART A

NOTIFICATION OF A SERIOUS ADVERSE REACTION

Tissue device

European Union tissue establishment code (if applicable)

Notification of the notification

Notification date (year / month / day)

Recipient of human tissue or human cells or donor of human tissue or human cells

Date and place of collection of human tissue or human cells or humane use (year / month / day)

Unique donation number

Date of serious adverse reaction suspected (year / month / day)

Type of human tissue and human related cells with a suspected serious adverse reaction

Uniform European code for human tissue or human cells associated with the suspicion of severe adverse reaction

The type of serious adverse reaction to which it occurred suspicion

PART B

CONCLUSIONS OF THE SERIOUS ADVERSE REACTION INVESTIGATION

Tissue device

European Union tissue establishment code (if applicable)

Notification of the notification

Confirmation date (year / month / day)

Date of serious adverse reaction (year / month / day) Unique donation number

Confirmation of a serious adverse reaction (yes / no)

Uniform European code for human tissue or human cells associated with confirmed severe adverse reaction (if applicable)

Change in the type of serious adverse reaction (yes / no) If yes, please indicate similarities

Clinical outcome (if known)

- full recovery
- light consequences
- serious consequences
- death

Outcome of the investigation and final conclusions

Recommendations for preventive and corrective measures measures

317/2016 Coll. Collection of Laws of the Slovak Republic

PART C
NOTIFICATION OF A SERIOUS ADVERSE EVENT

Tissue device

European Union tissue establishment code (if applicable)

Notification of the notification

Notification date (year / month / day)

Date of serious adverse event (year / month / day

			Specification	
A serious adverse event that may affect quality and the safety of human tissue, or human cells for deviation in	Damage human fabrics or human cells	Failure devices	An error caused by man	Other (specify)
taken				
transportation testing				
processing storage distribution materials				
other (specify)				

PART D
CONCLUSIONS OF THE SERIOUS ADVERSE EVENT INVESTIGATION

Tissue device

European Union tissue establishment code Notification of the notification

Confirmation date (year / month / day)
Date of serious adverse event (year / month / day)

Root cause analysis (details)

Corrective actions taken (details)

Annex no. 7to Act no. 317/2016 Coll.

MODEL APPLICATION FOR CONSENT TO EXPORT OF HUMAN TISSUE OR HUMAN CELLS OUTSIDE THE TERRITORY OF THE SLOVAK REPUBLIC

1. Identification details of the healthcare provider:
   Title:
   Seat:
   ID:
2. Name of the country to which the human tissue or human cells are to be exported:

3. Identification of the entity and the country to which the human tissue or human cells are to be exported: Title:
   Seat:
   ID:

Other data:

4. Designation of human tissue or human cells to be exported outside the territory of Slovakia of the Republic:

3. A statement by the healthcare provider that he or she has not been referred for a transplant human tissue or human cells from any other healthcare provider in the territory

Slovak Republic.

6. Date of manufacture:

7. Name and surname of the person authorized to act on behalf of the healthcare provider:

8. Signature of the person authorized to act on behalf of the healthcare provider and imprint of the stamp healthcare provider:

9. Proof of a written request from a body of the State to which human tissue or human tissue is to be requested cells exported from the Slovak Republic.

317/2016 Coll. Collection of Laws of the Slovak Republic

Annex no. 8to Act no. 317/2016 Coll

ANNUAL NOTIFICATION OF SERIOUS ADVERSE REACTIONS AND SERIOUS ADVERSEEVENTS RELATING TO HUMAN TISSUE OR HUMAN CELLS

DynamicResources \ 5441767a-fb02-48ac-bdb1-c2216feee2b4_5.pdf

PART A

Annual notification of serious adverse reactions

Notifying State

Notification for the period
from 1 January to 31 December (year)

Number of serious adverse reactions by type of human tissue or human cells
(or product that has come in contact with tissue or cells)

Type of human tissue or human cells

Total number of human tissue distributed
or human cells (including human tissue type
or human cells for which they have not been reported no serious adverse reactions):

Number of human tissue recipients concerned; or human cells
(total number of human tissue recipients or human cells):

Nature of reported serious adverse reactions

Total number of serious adverse reactions	Transmission of bacterial infection
Transmission of viral infection	HBV HCV HIV-1/2 Other (specify) Malaria Other (specify)
Transmission of parasitic infection	
Transmission of malignant diseases	
Transmission of other diseases	
Other serious reactions (please specify)	

PART B

Annual notification of serious adverse events

Notifying State

Notification for the period
from 1 January to 31 December (year)

Total number of processed human tissue
or human cells

Total number of serious adverse events
events that may have affected
quality and safety of human tissue or
human cells for the deviation
at taken transportation testing processing
storage distribution materials other

(specify)

Annex no. 9to Act no. 317/2016 Coll

National Transplant Register

a) List of personal data processed
Name and surname, birth name, birth number, code of the municipality of permanent residence, address, telephone number,health insurance company, disease codes according to the International Classification of Diseases (ICD), incidence
risk factors in the patient, medical data related to collection and transplantationhuman organ, human tissue or human cells, date of disagreement
with the removal of human organs, human tissue or human cells after their death, date
death in the dead, pathological-anatomical disease according to MKCH, a unique number of donations assigned to the donor of a human organ, human tissue or human cells and a unique number
recipient of a human organ.

b) Purpose of the processing of personal data
The purpose of processing personal data is to register waiting for a human transplantorgan, human tissue or cells, donor registration of a human organ, human
tissue or human cells and registration of patients after human organ transplantation as well as
persons who, during their lifetime, have expressed their opposition to the removal of human organs, human tissue or human cells after his death.

c) Circle of persons concerned
People with the underlying disease for whom transplantation of a human organ, human tissueor human cells is an effective form of treatment, potential donors of the human organ,
human tissue or human cells who have undergone a human transplant
organ, human tissue or human cells, persons who have expressed during their lifetime disagreement with the removal of human organs, human tissue or human cells after death.

d) Purpose of providing personal data
Personal data from the register may be provided for the purpose of transplantation of a human organ, humantissue or human cells by the relevant healthcare provider and by
European and world registries of waiting for human organ transplantation, human tissue or human cells and registries of human organ, human tissue or donor donors;human cells.

e) List of personal data that can be provided
Name and surname, birth name, birth number, code of the municipality of permanent residence, address, telephone numbercontact, health insurance company, disease codes according to MKCH, occurrence of risk factors in the patient,
medical data related to the collection and transplantation of human organs, human tissueor human cells, the date of disagreement with the removal of human organs, human tissue or human cells after death, date of death in the deceased, pathological-anatomicalMKCH disease.

f) Third parties to whom personal data are providedRelevant healthcare providers.

Annex no. 10to Act no. 317/2016 Coll

List of transposed legally binding acts of the European Union

1. Directive 2004/23 / EC of the European Parliament and of the Council of 31 March 2004 laying down standardsquality and safety in donation, collection, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004).
2. Commission Directive 2006/17 / EC of 8 February 2006 implementing Directive 2004/23 / EC of the European Parliament and of the Council as regards certain technical requirements for donation, procurementand testing of human tissues and cells (OJ L 38, 9.2.2006), as amended by Commission Directive 2012/39 / EU of 26 November 2012 (OJ L 327, 27.11.2012).
3. Commission Directive 2006/86 / EC of 24 October 2006 implementing Directive 2004/23 / EC of the European Parliament and of the Council as regards traceability, notification requirements serious adverse reactions and events and certain technical coding requirements, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006) as amended by Commission Directive (EU) 2015/565 of 8 April 2015 as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 9.4.2015).
4. Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on quality standardsand safety of human organs intended for transplantation (OJ L 207, 6.8.2010).
5. Commission Implementing Directive 2012/25 / EU of 9 October 2012 laying down information procedures for the exchange of human organs intended for transplantation between Member StatesStates (OJ L 275, 10.10.2012).
6. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23 / EC as regards procedures for verifying equivalent quality and safety standards for imported tissuesand cells (OJ L 93, 9.4.2015).

1) § 7 par. 3 letter h) of Act no. 578/2004 Coll. on healthcare providers, health professionals, professional organizations in health care and on the amendmentcertain laws as amended by Act no. 428/2015 Coll.

2) Section 11 of Act no. 578/2004 Coll. as amended.

3) § 7 par. 3 letter (a) second point and point b), § 7 par. 4 letter a) of Act no. 578/2004 Coll. as amendedlater regulations.

4) § 7 par. 13 of Act no. 578/2004 Coll. as amended by Act No. 317/2016 Coll.

5) § 7 par. 4 letter a) of Act no. 578/2004 Coll. as amended by Act No. 653/2007 Coll.

6) § 7 par. 3 letter f) of Act no. 578/2004 Coll. as amended by Act No. 653/2007 Coll.

7) Section 116 of the Civil Code.

8) Section 19 of Act no. 122/2013 Coll. on the protection of personal data and on the amendment of certainlaws as amended no. 84/2014 Coll.

9) § 8 of the Civil Code.

10) Section 6 of Act no. 576/2004 Coll. on health care, services related to the provision ofhealth care and on the amendment of certain laws as amended.

11) § 2 par. 5 of Act no. 576/2004 Coll. as amended by Act No. 220/2013 Coll.

12) § 43 par. 1 to 3 of Act no. 576/2004 Coll.

13) § 43 par. 3 to 6 of Act no. 576/2004 Coll. as amended by Act No. 350/2005 Coll.

14) Act of the Slovak National Council no. 323/1992 Coll. on notaries and notarial activities) order) as amended.
Act no. 599/2001 Coll. on the certification of documents and signatures on documents by district authorities and municipalitiesas amended.

15) Section 48 of Act no. 581/2004 Coll. on health insurance companies, health supervisioncare and on the amendment of certain laws as amended.

16) § 2 par. 19 of Act no. 362/2011 Coll. on medicines and medical devices and on changeand amendments to certain laws.

17) § 12 of the Decree of the Ministry of Health of the Slovak Republic no. 553/2007 Coll., Which lay down details of the requirements for the operation of medical facilities in terms of health protection.

18) Section 14 of Act no. 79/2015 Coll. on waste and on the amendment of certain laws.
19) § 20 par. 3 of Act no. 576/2004 Coll. as amended by Act No. 153/2013 Coll.

20) § 48 par. 8 of Act no. 581/2004 Coll. as amended.

21) Sections 19 to 21 of Act no. 576/2004 Coll. as amended.

22) Sections 18 to 25 of Act no. 576/2004 Coll. as amended.

23) Regulation of the Government of the Slovak Republic no. 387/2006 Coll. on reinsurance requirementssafety and health marking at work, as amended by Government Decree no. 104/2015 Coll.

24) Sections 79 and 79a of Act no. 578/2004 Coll. as amended.

25) Sections 13a and 25 of Act no. 578/2004 Coll. as amended.

26) The seventh part of Act no. 578/2004 Coll. as amended.

27) Section 26 of Act no. 578/2004 Coll. as amended.

28) § 2 letter f) of Act no. 540/2001 Coll. on state statistics as amended.
§ 9 of Act no. 122/2013 Coll.

29) § 4 par. 3 letter i) of Act no. 122/2013 Coll.

30) STN EN ISO 3166-1 Country name codes and their parts. Part 1: Country codes (ISO 3166-1: 2013)(01 0190).

Collection of Laws of the Slovak Republic 317/2016 Coll.

Publisher of the Collection of Laws of the Slovak Republic content administrator and legal and information operator of the Slow Lex portal available on the website www.slov-lex.sk is
Ministry of Justice of the Slovak Republic, Župné námestie 13, 813 11 Bratislava, phone: 02 888 91 137, fax: 02/52442853, e-mail: helpdesk@slov-lex.sk.