Criteria for the selection of cell, tissue, and organ donors, list of precluding circumstances for the donation of cells, tissues, or organs, list of mandatory laboratory studies established for a donor, and the conditions and procedure for carrying out these studies

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The Regulation will be established in accordance with subsection 10 (2) and (5) of the Procurement, Handling and Transplantation of Cells, Tissues and Organs Act and subsection 15 (3) of the Communicable Diseases Prevention and Control Act.

§ 1. Scope of regulation

(1) This Regulation establishes the criteria for the selection of cell, tissue, and organ donors, the list of precluding circumstances for the donation of cells, tissues, or organs, the list of mandatory laboratory studies established for a donor, and the conditions and procedure for carrying out these studies.

(2) The requirements established with this Regulation are applied for the selection of germ cell donors, except in the case described in subsection 3 (3) of this Regulation.

§ 2. Definitions

(1) For the purposes of this Regulation, an allogenic donor is a person from whom cells, tissues, or organs are removed, and used for transplantation to another person.

(2) For the purposes of this Regulation, an autologous donor is a person from whom cells and tissues are removed, and used for transplantation to the same person.

(3) For the purposes of this Regulation, partner donation means the donation of germ cells between a man and a woman who disclose that they are in an intimate relationship.

(4) For the purposes of this Regulation, direct use means a situation in which cells or tissues are donated, and they are used for transplantation without preservation.

(5) For the purposes of this Regulation, indirect use means a situation in which cells or tissues are donated, and they are preserved before the transplantation.

(6) For the purposes of this Regulation, a transplant is the cell, tissue, or an organ intended to be transplanted.

§ 3. The basic criteria for donor selection

(1) The evaluation of circumstances which may endanger the health of the donor and recipient, and the quality and safety of the cells, tissues, and organs being donated shall be documented when selecting a donor.

(2) The suitability of a person for donation is determined on the basis of the form completed by the person, an interview, the physical examination of the person, their anamnesis, their prior risky behaviours, laboratory studies, a post-mortem examination in the case of a deceased donor, and any other relevant studies. In the case of a deceased donor, an interview is conducted with the persons established in subsection 17 (3) and subsection 18 (1) of the Procurement, Handling and Transplantation of Cells, Tissues and Organs Act.

(3) The criteria for the selection of donors is not applied for autologous donors and partner donations. In case the removed cells and tissues are to be preserved or processed, the studies established in section 7 of this Regulation (except genetic studies) shall be carried out.

(4) In the handling of cells and tissues from autologous donors and germ cells from partner donations, laboratory studies shall be carried out to identify the markers of infectious agents for informational purposes in order to avoid the risk of cross-contamination and threat to the handler personnel. Positive study results do not prevent the preservation, processing, and transplantation of tissues and cells or products derived therefrom if an existing separate preservation system has been developed, which assures the absence of threat of cross-contamination with other transplants, contamination with added substances, and the risk of confusion.

(5) Depending on the cells, tissues, or organs to be donated, and the person's physical state and state of health, a person shall be deemed to be a donor if consent has been obtained from them, or the alleged person's will has been established, and there are no criteria provided for in section 4, 5, and 6 of this Regulation.

(6) In a specific case, it is allowed to deviate from the criteria established in section 4, 5, and 6 of this Regulation on the basis of a documented risk analysis carried out by a competent person.

§ 4. List of criteria precluding circumstances for the donation of cells and tissues of a deceased person

A deceased person is excluded from the donation of cells and tissues if an autopsy does not provide information about the cause of their death and the cause of death is unknown, or one of the following criteria is valid:

1) former occurrence of a disease of unknown cause;

2) presence or former occurrence of a malignant tumour, with the exception of primary basal cell carcinoma, cervical carcinoma in situ, and some primary central nervous system tumours which should be evaluated based on scientific evidence. Donors with a malignant tumour may be evaluated and considered for corneal donation with the exception of those who have a retinal tumour, a hematologic tumour, or a malignant tumour in the anterior part of the eye;

3) risk of transmission of diseases caused by prions. The following people are in that risk group:

a) people who have been diagnosed with the Creutzfeldt-Jakob disease or a variant of the Creutzfeldt-Jakob disease, or people who have a family history of non-iatrogenic Creutzfeldt-Jakob disease;

b) people who have experienced rapidly evolving dementia or a disease which degenerates the nervous system, including diseases with an unknown origin;

c) recipients of hormones from the human pituitary gland, recipients of the cornea, sclera, and dura mater, and people who have undergone neurosurgical operations in which dura mater was used;

4) a systematic infection which is not under control during the donation, including bacterial diseases, systemic viral, fungal, or parasitic infections, or a significant local infection in the cells, tissues, and organs to be donated. Donors with bacterial septicaemia may be evaluated and considered for the donation of eye tissues and cells, but only if the cornea is preserved in an organic culture so that it would be possible to detect the possible bacterial contamination of the tissue;

5) persons with HIV, acute or chronic hepatitis B, except in the case of persons with proven immunity, prior occurrence of hepatitis C and HTVL I/II, clinical signs or the existence of laboratory evidence, risk of transmission of the mentioned infectious diseases, or the discovery of risk factors;

6) prior occurrence of a chronic and systemic autoimmune disease which may have a negative effect on the quality of the cells, tissues, or organs to be removed;

7) absence of a blood test which meets the requirements provided for in section 8 of this Regulation;

8) treatment with immunosuppressive agents if less than 90 calendar days have passed after the termination of the treatment at the moment of the donation of cells, tissues, or organs;

9) physical signs detected during the physical examination of the donor's body, which suggest the risk of transmission of infectious diseases;
10) exposure to cyanide, lead, mercury, gold, or any other substance which may be passed to the recipient in an amount which endangers their health;
11) recent vaccination with an attenuated live virus, for which the risk of transmission is considered;
12) transplantation, in which case xenotransplantation was used.

§ 5. List of criteria precluding the donation of cells, tissues, and organs of a live donor

(1) The criteria established in section 4 of this Regulation for the exclusion of a deceased person from the donation of cells and tissues are applied for the exclusion of a live person from the donation of cells, tissues, or organs.

(2) Depending on the cells, tissues, or organs being donated, the handler may establish additional criteria for the exclusion from live donation.

§ 6. List of criteria precluding from the donation of a person's germ cells

(1) A person is excluded from the donation of germ cells if they have one of the following:
1) HIV;
2) acute or chronic hepatitis B with the exception of persons with an identified immunity;
3) hepatitis C;
4) syphilis;
5) chlamydial infection;
6) HTLV I/II;
7) cystic fibrosis and other autosomal recessive diseases;
8) fragile-X Syndrome, and other X-linked recessive disorders;
9) other genetic diseases;
10) multifactorial congenital disorder or syndrome;
11) chromosome changes which might likely cause unbalanced chromosome changes.

(2) In the case of germ cell donors, a genetic screening of autosomal recessive genes causing hereditary diseases known in the donor's family history or hereditary diseases caused by the donor's ethnic background shall be carried out in order to evaluate the risk of transmission of diseases. All information about the risks associated with hereditary diseases and the measures to be taken to avoid these risks shall be communicated to the recipient.

§ 7. List of mandatory laboratory studies established for a donor

(1) The minimum requirements for the donor include laboratory studies for the detection of the following markers of infectious agents:
1) HIV-1, 2 antibodies to detect HIV-1 and HIV-2;
2) HBs antigen and HBc antibodies for the detection of hepatitis B;
3) HBV antibodies for the detection of hepatitis C;
4) Treponema pallidum antibodies for the detection of active syphilis;
5) a study of antibodies shall be carried out for the detection of HTVL I/II with donors who themselves or whose sexual partners live or originate from a high-prevalence area, or donors whose parents originate from the mentioned area.

(2) In the case of germ cell donors, studies for the detection of Neisseria gonorrhoeae, Trichomonas vaginalis, and Chlamydia trachomatis, a chromosomal study of peripheral blood, and a molecular-genetic testing for cystic fibrosis shall also be carried out in addition to the studies specified in subsection 1 of this section.

(3) In the case of egg cell donors, studies for the fragile X syndrome shall also be carried out in addition to the studies specified in subsections 1 and 2 of this section.

(4) If the HBc antibodies are positive and the HBs antigen is negative, further studies with a risk evaluation shall be carried out in order to determine whether the cells, tissues, or organs meet the requirements of clinical use.

(5) Depending on the risk analysis, the handler may carry out additional laboratory studies on the germ cell donor for pathogens and genetic diseases which may be transmitted.

§ 8. The conditions and procedure for carrying out laboratory studies

(1) If the donor has lost blood and there has been a transfer of blood, blood components, or colloids to them within 48 hours before the collection of a blood sample, or crystalloids have been transferred to them within an hour before taking the blood sample, the blood sample may be invalid due to the blood dilution. In that case, the dilution level of the blood samples shall be evaluated. Handlers may accept cells, tissues, and organs from donors with a plasma dilution level of more than 50% only if the used study method has been validated for the plasma dilution, or if there is a blood sample taken before the transfer.

(2) In the case of deceased donors, the blood sample shall be taken immediately before death or no later than within 24 hours after the person has died.

(3) In the case of live donors, with the exception of bone marrow stem cell and peripheral blood stem cell donors, blood samples for laboratory studies have to be collected during the procurement or within seven days after the procurement. If it possible to preserve the live donor's cells and tissues for a long time, a re-sample and study have to be performed after 180 days have passed. If the blood sample is further studied with a nucleic acid amplification technique for HIV, HBV, and HCV, the re-study does not have to be carried out. The re-study may also be omitted if the processing for the named viruses included a validated inactivation stage.
[RT I, 27.10.2015, 9 – entry into force. 30.10.2015]

(4) For the procurement of bone marrow and peripheral blood stem cells, the blood sample for the study has to be collected within 30 days before the procurement.

(5) For the donation of germ cells, the blood sample shall be collected for genetic studies during the donation, with the exception of partner donation.

(6) In the case of partner donation (indirect usage), the blood samples shall be collected within three months before the first donation. Regarding the following donations from the same donors, the blood samples shall be collected no later than within 24 months since the last sample was collected.

(7) Donations of spermatozoa, with the exception of partner donations, are quarantined for at least 180 days after which a re-study shall be carried out. If the blood sample is further studied with a nucleic acid amplification technique for HIV, HBV, and HCV, the re-study does not have to be carried out. The re-study may also be omitted if the processing for the named viruses included a validated inactivation stage.
[RT I, 27.10.2015, 9 – entry into force. 30.10.2015]

(8) The blood samples established in subsection 2, 3, 5, and 6 of this section are studied on the basis of the donor's serum or plasma, and these may not be replaced with studies made with other fluids or secretions, unless it is specifically clinically substantiated, and a laboratory study is used which is validated for that fluid.

(9) Transplantation of embryos created from donor egg cells is allowed without prior quarantine if the recipient has provided their consent in writing.

Procurement, Handling and Transplantation of Cells, Tissues and Organs Act[1]

Passed 29.01.2015
RT I, 26.02.2015, 1
Entry into force 01.03.2015

§ 1. Scope of application

(1) This Act establishes the conditions and organisation of procurement, handling and transplantation of cells, tissues and organs of human origin and the procedure for state supervision and liability.

(2) This Act applies to the cells, tissues and organs which are removed from a living or deceased human donor (hereinafter donor) and are or are not processed *in vitro* and which are intended for human use.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(3) This Act does not regulate:
1) the transplantation of gametes and embryos within the meaning of the Artificial Insemination and Embryo Protection Act;
2) the handling of blood within the meaning of the Blood Act;
3) the transplantation of cells, tissues and organs taken from a person to the person in the course of one surgical procedure;
4) the use of cells, tissues and organs in scientific research if used for purposes other than medical use on human beings.

(4) The provisions of the Administrative Procedure Act apply to the administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.

§ 2. Definitions

(1) For the purposes of this Act, the procurement of cells, tissues and organs means the process during which cells, tissues and organs are made accessible for handling and transplantation. The process of procurement of cells, tissues and organs for the purposes of this Act means above all the selection of a donor, removal of cells, tissues and organs and the coding, packaging, labelling and distribution of procured cells, tissues and organs to the handler or transplanter.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(2) For the purposes of this Act, the handling of cells, tissues and organs means the description, coding, labelling, testing, preservation and processing of cells, tissues and organs and the packaging, labelling, storage, release and distribution to the transplanter of handled cells, tissues and organs.

(3) For the purposes of this Act, the transplantation of cells, tissues and organs means the implantation of cells, tissues and organs removed from a donor for therapeutic purposes.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(4) For the purposes of this Act, cells mean individual human cells or a collection of human cells when not bound by any form of connective tissue.

(5) For the purposes of this Act, tissues mean all constituent parts of the human body formed by cells.

(6) For the purposes of this Act, an organ means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy after removal from the human body. An organ also means a part of an organ if the functioning thereof in the human body is used for the same purpose as a complete organ and it maintains its structure and vascularisation after removal from the human body.

(7) Donation means the voluntary donating of cells, tissues and organs for transplantation.

(8) A donor means a person from whom cells, tissues or organs are removed for transplantation.

(9) A recipient means a person to whom the cells, tissues or organs removed from a donor are transplanted.

(10) For the purposes of this Act, a procurer means a special medical care provider to whom an activity licence has been issued for the procurement of cells, tissues and organs.

(11) For the purposes of this Act, a handler means a legal person in private law to whom an activity licence has been issued for the handling of cells or tissues. Organs may be handled by a special medical care provider to whom an activity licence has been issued for the handling of organs.

(12) For the purposes of this Act, a transplanter means a special medical care provider who engages in the transplantation of cells, tissues or organs.

(13) For the purposes of this Act, human use means the use of cells, tissues and organs on or in a human recipient or *in vitro*.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(14) For the purposes of this Act, a third country supplier outside the European Union and the European Economic Area means the procurer or handler of cells and tissues founded in a third country outside the European Union and the European Economic Area or another person responsible for the export of such cells and tissues to the European Union and the European Economic Area, which the person supplies to the importing procurer of the handler of cells and tissues. A third country supplier may perform one or many operations outside the European Union and the European Economic Area relating to the donation, procurement, study, processing, preservation, storage and distribution of cells and tissues imported to the European Union and the European Economic Area.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 3. Seeking financial gain

The donation of cells, tissues and organs is voluntary and offering reward or seeking financial gain for the donation is prohibited, except in the cases provided for in the Artificial Insemination and Embryo Protection Act.

§ 4. Protection of personal data

The personal data of donors and recipients shall be processed according to the Personal Data Protection Act and Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 04.05.2016, p. 1–88) and the data may be disclosed only to the procurer, handler, transplanter and to the person who needs the data for the performance of his or her duties arising from the law.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

Chapter 2 ORGANISATION OF PROCUREMENT, HANDLING AND TRANSPLANTATION OF CELLS, TISSUE AND ORGANS

§ 5. Transplantation infrastructure

(1) The transplantation infrastructure means the national system of procurement, handling and transplantation of cells, tissues and organs, the purpose of which is to ensure the procurement, handling and transplantation of cells, tissues and organs according to the established legislation.

(2) The transplantation infrastructure shall be composed of:
1) transplantation council;
2) national transplantation agency;
3) transplantation centres;
4) the procurers and handlers of cells, tissues and organs;
5) Estonian Health Insurance Fund;
6) State Agency of Medicines;
7) Health Board;
8) Ministry of Social Affairs.

§ 6. Transplantation council

(1) The transplantation council is an independent advisory committee formed by the minister responsible for the area, the members of which are the procurers, handlers and transplanters of cells, tissues and organs and the representatives of the Estonian Health Insurance Fund, the Health Board, the State Agency of Medicines, the Ministry of Social Affairs, the representative organisations of patients and the relevant professional organisations.

(2) The function of the transplantation council is to submit proposals to the relevant organisations:
1) to determine and update the national need for the procurement, handling and transplantation of cells, tissues and organs;
2) to establish the strategic goals for the procurement, handling and transplantation of cells, tissues and organs;
3) to finance the procurement, handling and transplantation of cells, tissues and organs;
4) to promote the awareness on the donation of cells, tissues and organs.

§ 7. National transplantation agency

(1) Performance of the functions of national transplantation agency shall be ensured by the Estonian Health Insurance Fund who may enter an administrative contract with a transplantation centre therefore, based on the conditions provided for in the Administrative Co-operation Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) The national transplantation agency shall perform the following functions:
1) organises the subsequent observation of the medical status of live organ donors;
2) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]
3) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]
4) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]
5) organises activities, the purpose of which is to notify of the importance of the donation of cells, tissues and organs;
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]
6) carries out audits over the donation of cells, tissues and organs and establishes the reasons for non-donation;

7) organises the development of quality and safety instructions for the procurement, handling and transplantation of cells, tissues and organs;
8) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]
9) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 8. Transplantation centre

(1) A transplantation centre is Tartu University Hospital, provided that an activity licence has been issued thereto for the procurement, handling and transplantation of organs.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(1^1) The transplantation centre shall perform the following functions:
1) organises the traceability and biovigilance of the procurement, handling and transplantation of organs;
2) maintains the organ transplant waiting lists;
3) organises the distribution and international exchange of organs to be transplanted and enters into contracts therefor with the relevant organisations of the European Union and third countries;
4) organises the communication concerning the procurement, handling and transplantation of cells, tissues and organs with the procurers, handlers, transplanters and the State Agency of Medicines.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(1^2) The transplantation centre shall ensure the 24-hour performance of functions specified in clauses (1^1) 1)–3) of this section.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 3 PROCUREMENT, HANDLING AND TRANSPLANTATION OF CELLS, TISSUES AND ORGANS

Division 1Selection of Donor

§ 9. Notification obligation of potential deceased donor

(1) Regional and central hospitals shall be required to establish the death and notify the transplantation centre of a potential deceased donor.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) A person is a potential deceased donor if the person's death has been started to be established pursuant to the procedure provided for in § 16 of this Act.

§ 10. Selection of donor

(1) A donor may be a person whom the doctor has declared, based on the person's state of health and the requirements provided for in this Act, to be medically suitable for the donation of cells, tissues or organs with the purpose of transplantation to another person.

(2) The criteria for the selection of cell, tissue and organ donors and the list of circumstances precluding the donation of cells, tissues and organs shall be established by a regulation of the minister responsible for the area.

(3) The procurer shall ensure that the laboratory testing specified in the regulation established under subsection (5) of this section is carried out on the donor upon the donation of cells, tissues or organ.

(4) Upon donation of an organ, laboratory testing shall be carried out on a donor in a laboratory accredited by an international accreditation institution to ascertain the tissue compatibility.

(5) The list of laboratory testing compulsory for donors and the conditions and procedure for the testing shall be established by a regulation of the minister responsible for the area.

(6) If necessary, a doctor has the right to carry out additional testing to ascertain the suitability of a donor.

(7) In addition to the requirements provided for in this Act, the special requirements provided for in the Artificial Insemination and Embryo Protection Act apply to the donors of gametes.

Division 2 Living Donor

§ 11. Conditions for removal of cells, tissues and organ from living donor

(1) Cells, tissues or an organ may be removed from a living donor if:
1) the donor has granted his or her consent for the removal of cells, tissues or an organ;
2) medical investigations performed on the living donor ascertain that the risk to the life or health of the living donor implied by the removal of cells, tissues or an organ is not higher than the risk implied by any other surgical operation of the same degree of complexity;
3) the purpose of removal of the organ is its transplantation for therapeutic purposes into a person with whom the donor has a genetic or emotional connection;
4) the donor has received psychological counselling before the removal of an organ.

(2) With the consent of the living donor, a removed organ may be used for transplantation into another recipient if it is impossible to transplant the organ into the person specified in clause (1) 3) of this section.

(3) In the case specified in subsection (2) of this section, the medical history of the living donor shall contain a written explanation concerning the circumstances which prevented the transplantation to the person specified in clause (1) 3) of this section.

§ 12. Consent of living donor

(1) For the purposes of this Act, the consent of a living donor means the consent granted by a donor for the removal of cells, tissues or an organ. The consent of a person with restricted active legal capacity shall be granted by his or her legal representative based on the requirements provided for in § 13 of this Act.

(2) Consent for the removal of cells, tissues or an organ shall be given by the persons specified in subsection (1) of this section expressly in writing for a specific donation.

(3) Consent granted by the persons specified in subsection (1) of this section is valid if they have been provided with information beforehand in writing or in a format which can be reproduced in writing:
1) as to the purpose and nature of the removal of cells, tissues or an organ;
2) as to the consequences and risks of the removal of cells, tissues or an organ;
3) as to the tests performed before the removal of cells, tissues or organs and the results thereof;
4) as to the registration and protection of the donor's personal data;
5) as to the purpose of transplantation and potential efficiency factors of the donated cells, tissues or organ;
6) as to the safety measures applied for the protection of the life and health of a donor.

(4) A consent may be withdrawn at any time until the removal of cells, tissues or an organ.

§ 13. Persons with restricted active legal capacity as living donors

(1) Persons with restricted active legal capacity may not be living donors, except on the conditions provided for in subsection (2) of this section.

(2) Persons with restricted active legal capacity may be living donors if:
1) regenerative cells or tissues are removed;

2) there is no compatible donor available who has active legal capacity;
3) the recipient is the sibling, child or biological parent of the person with restricted active legal capacity;
4) consent of the legal representative of the donor and permission of a court for removal of cells, tissues or organs has been obtained, and
5) the person with restricted active legal capacity does not object to the removal and transplantation.

(3) A county court shall decide on the grant of court permission provided for in clause (2) 4) of this section in proceedings on petition at the request of the legal representative of the donor or the procurer performing the removal of a cells or tissues, verifying that the person with restricted active legal capacity does not object to the removal and transplantation of cells or tissues.

§ 14. Rights and obligations of living donors

(1) A living donor has the rights and obligations of a patient as provided for in the Law of Obligations Act.

(2) A living donor has the right to:
1) obtain relevant information regarding the removal, handling and transplantation of cells, tissues or organ from a qualified person who is able to provide information appropriately by using definitions which are understandable to the living donor;
2) obtain information regarding the risks arising from the donation of cells, tissues or organs;
3) receive information on his or her state of health, on the results of the tests conducted on his or her cells, tissues and organs, and the suitability for treatment of the cells, tissues and organs donated by him or her accompanied by explanations understandable to the living donor and the measures applied for the protection of his or her health;
4) receive treatment arising from the state of health after removal of an organ regardless of being covered by health insurance;
5) the protection of personal data according to the Personal Data Protection Act.

(3) A living donor is required to:
1) submit his or her personal data and contact information to the procurer;
2) disclose all information and circumstances to the procurer which, to the donor's best understanding are relevant to the donation of cells, tissues or organs;
3) inform the procurer of circumstances, to his or her best understanding, which have become known to him or her after donation of cells, tissues or organs, and of any changes which occur in his or her state of health after donation which could affect the suitability for transplantation of the donated cells, tissues or organs;
4) confirm the correctness of the submitted information by his or her signature.

Division 3 Deceased Donor

§ 15. Conditions for removal of cells, tissues and organs from deceased donor

(1) Cells, tissues or organs may be removed from a deceased donor if:
1) the death of the person has been established pursuant to the procedure provided for in § 16 of this Act;
2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs after his or her death according to the provisions of § 17 of this Act, or if no information is available that the person had objected to it.

(2) The removal of cells, tissues or organs must not impede the conduct of forensic medical examination of a deceased person who died a violent death.

(3) The removal of cells, tissues or organs from a deceased person who had died a violent death shall be approved by a forensic pathologist or expert.

(4) A procurer who removes cells, tissues or organs from a deceased donor shall prepare a statement on the removal of the cells, tissues or organs.

(5) The standard format for statements on the removal of cells, tissues or organs from a deceased donor shall be established in the rules for procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.

§ 16. Establishment of death

(1) If cells, tissues or organs of a person will be used for transplantation after the death of the person, the death of the person shall be established by a committee of doctors with at least two members, who shall prepare a statement on the establishment of death.

(2) The death of a person shall not be established by a doctor who directly participates in the removal or transplantation of cells, tissues or organs of the deceased person or a doctor whose obligations involve care of the possible recipients of the cells, tissues or organs of the deceased person.

(3) The conditions and procedure for the establishment of death of a person and the standard format for statements on the establishment of death shall be established by a regulation of the minister responsible for the area.

§ 17. Declaration of intention of deceased donor expressed during his or her lifetime

(1) A person may express his or her intention to donate cells, tissues or organs for transplantation after death by confirming it through the health information system or in another clearly expressed manner.

(2) The procurer of cells, tissues and organs shall verify in the health information system the declaration of intention of a deceased person expressed during his or her lifetime to donate cells, tissues or organs for transplantation.

(3) If no information is available in the health information system on the declaration of intention of a deceased person expressed during his or her lifetime or if the deceased person had not expressed his or her intention in any other manner to donate his or her cells, tissues and organs for transplantation purposes, the procurer of cells, tissues and organs shall be required, if possible, to ascertain the declaration of intention of the deceased person expressed during his or her lifetime from the following persons in the following order:

1) spouse or cohabitee of the deceased person;
2) adult child of the deceased person;
3) parent of the deceased person;
4) adult sibling of the deceased person;
5) grandparent of the deceased person;
6) emotionally close person or another person with active legal capacity if the persons listed above are absent or unavailable.

(4) Other persons may not prohibit the removal of cells, tissues or organs if the deceased person has consented with the removal and transplantation in his or her lifetime. Other persons may not allow the removal of cells, tissue or organs if the deceased person has refused from the removal for transplantation during his or her lifetime.

§ 18. Person with restricted active legal capacity as deceased donor

(1) The consent of a deceased person with restricted active legal capacity for the removal of cells, tissues or organs shall be asked from the following persons in the following order:

1) the spouse or cohabitee of the deceased person;
2) adult child of the deceased person;
3) parent of the deceased person;
4) adult sibling of the deceased person;
5) grandparent of the deceased person;
6) emotionally close person or another person with active legal capacity if the persons listed above are absent or unavailable.

(2) The consent of a person specified in subsection (1) of this section for the removal of cells, tissues and organs must be clearly expressed. The consent shall be documented by a health care professional.

(3) The consent of a person specified in subsection (1) of this section is valid if he or she has been previously provided with the information specified in clauses 12 (4) 1), 4) and 5) of this Act.

Division 4 Recipient

§ 19. Recipient's consent

(1) For the purposes of this Act, recipient's consent means the consent of the recipient or, in the cases provided for in the law, the consent of his or her legal representative which must be in written form, clearly expressed and for a specific donation.

(2) The recipient having granted his or her consent or, in the cases provided for in the law, his or her legal representative, may withdraw the consent at any time until the transplantation of cells, tissues or an organ.

(3) The consent granted by a person specified in subsection (1) of this section is valid if he or she has been provided with appropriate information beforehand as to the purpose and nature of the transplantation of cells, tissues or organs as well as on the potential risks and consequences thereof.

(4) The transplantation of cells, tissues or an organ into a recipient with restricted active legal capacity is allowed with the consent of the legal representative of the recipient. If the decision of the legal representative clearly damages the interests of the recipient, the health care provider may not comply with it.

(5) If a recipient with active legal capacity is not able, because of his or her state of health, to express consent, or if the legal representative of a recipient with restricted active legal capacity refuses to grant consent for the transplantation of cells, tissues or an organ, or if other circumstances prevent the obtaining of consent from the legal representative of the recipient, the transplantation of cells, tissues or an organ is permitted on the basis of a decision of a doctor on condition that transplantation is the only means of treatment that has the potential to be life-saving for the recipient.

(6) In the cases specified in subsection (4) and (5) of this section, the medical history of the recipient shall contain an explanation on how the decision of the legal representative of the recipient clearly damages the interests of the recipient as well as the circumstances which prevented the obtaining of consent, and a justification of the necessity of transplantation of cells, tissues or an organ to the recipient.

Division 5 Procurer, Handler and Transplanter

§ 20. Obligations of handlers and procurers

(1) Handlers and procurers shall be required to:
1) guarantee the existence of conditions for the procurement and handling of cells, tissues and organs in compliance with this Act and legislation established on the basis thereof and with the requirements of other legislation regulating the procurement and handling of cells, tissues and organs;
2) guarantee that the person responsible for procurement or the competent person, and in the absence thereof, his or her substitute, has necessary conditions and means for performing his or her duties;
3) guarantee that the procurement and handling of cells, tissues and organs comply with the internationally recognised or scientifically justified procedures, including the updating of procurement and handling procedures according to the development of science and technology;
4) guarantee that cells, tissues and organs are distributed, under the conditions and pursuant to the procedure provided by this Act and legislation established on the basis thereof, only to persons with the right to handle or transplant such cells, tissues and organs;
5) guarantee that the cells, tissues and organs intended for transplantation are of high quality and as safe as possible.

(2) Procurers and handlers shall maintain records on the procurement, handling and transplantation of cells and tissues and shall submit a report concerning the previous year to the State Agency of Medicines by 1 April each year. The State Agency of Medicines shall prepare and publish a consolidated report by 1 May of the calendar year.

(3) Procurers and handlers shall maintain records on the procurement, handling and transplantation of organs and shall submit a report concerning the previous year to the transplantation centre by 1 April each year. The transplantation centre shall prepare and publish a consolidated report by 1 May of the calendar year.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(4) The minister responsible for the area shall establish, by a regulation, the requirements for the preparation of reports on the procurement, handling and transplantation of cells, tissues and organs and the composition of data.

§ 21. Obligations of transplanters

(1) Transplanters shall be required to:
1) guarantee the existence of conditions for the transplantation of cells, tissues and organs in compliance with this Act and legislation established on the basis thereof and with the requirements of other legislation regulating the transplantation of cells, tissues and organs;
2) guarantee that the transplantation of cells, tissues and organs complies with the development of science and technology;
3) guarantee that cells, tissues and organs are transplanted only on the conditions and pursuant to the procedure provided for in this Act and in the legislation established on the basis thereof;
4) guarantee that the cells, tissues and organs to be transplanted are of high quality and that their purposeful use is safe for the recipient.

(2) Transplanters shall maintain records on the transplantation of organs and shall submit a report concerning the previous year to the transplantation centre by 1 April each year. The transplantation centre shall prepare and publish a consolidated report by 1 May of the calendar year.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) The minister responsible for the area shall establish, by a regulation, the requirements for preparation of reports on the transplantation of organs and the composition of data.

Division 6 Requirements for Procurement, Handling and Transplantation of Cells, Tissues and Organs

§ 22. Conditions for procurement and handling of cells, tissues and organs

(1) In order to ensure the safety and quality of cells, tissues and organs, the procurer and handler shall develop a quality assurance system which complies with the good practices of the European Union. The applied quality assurance system must be fully documented and continuously monitored in all its stages.

(2) In order to apply the quality assurance system, the necessary resources, such as competent personnel, suitable facilities, equipment and means must be ensured by the procurer and handler.

(3) The minister responsible for the area shall establish, by a regulation, the rules for the procurement and handling of cells, tissues and organs which provides for the requirements for the:
1) document management of procurers and handlers;
2) personnel of procurers and handlers;
3) procurement and handling facilities;
4) equipment and materials used upon procurement and handling;
5) procurement and handling procedures;
6) quality assurance upon procurement and handling;
7) biovigilance and withdrawal;
8) communication between procurers, handlers and transplanters;
9) traceability;
10) settlement of disputes having arisen upon procurement, handling or transplantation.
11) list of documents necessary for the application for the issue of an import certificate, composition of data and format of the import certificate.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(4) The procurer and handler shall preserve the necessary documents to ensure the traceability of cells, tissues and organs for 30 years and the documents reflecting the safety and quality for ten years after the clinical use or destruction of cells, tissues and organs.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

§ 23. Competent person and person responsible for procurement

(1) A competent person is a natural person designated by the handler, who is responsible for the handling of a type of cells, tissues and organs and who shall ensure that the cells, tissues or organs intended for transplantation into recipient have been handled according to the requirements of the legislation and the instructions established by the handler and they are as safe as possible for the recipient.

(2) A person responsible for procurement is a natural person designated by the procurer who shall ensure the compliance of the entire process of procurement of cells, tissues and organs with the requirements provided for in this Act.

(3) A person may be designated as a competent person or a person responsible for procurement by one handler or procurer at a time.

(4) The substitute for a competent person or a person responsible for procurement must comply with the requirements established for a competent person or a person responsible for procurement.

§ 24. Qualification requirements for competent person and person responsible for procurement

(1) The competent person designated by the handler of cells or tissues shall have an academic degree in medicine, biology or in a specialty related to biology acquired in a university or a corresponding foreign qualification and at least two years of work experience in the field of handling cells and tissues.

(2) A person responsible for the procurement of cells or tissues shall have an education acquired in a university or an institution of professional higher education in medicine, biology, nursing or midwifery or a corresponding foreign qualification and work experience in the field of procurement of cells and tissues or a special training ensured by the procurer.

(3) A competent person designated by the handler of organs must have completed the residency curriculum in full or acquired the specialty of a medical specialist or a corresponding foreign qualification and at least two years of work experience in the field of handling of organs.

(4) A person responsible for the procurement of organs must have completed the residency curriculum in full or acquired the specialty of a medical specialist or a corresponding foreign qualification.

§ 25. Conditions for transplantation of cells, tissues and organs

(1) Cells, tissues or organs may be transplanted if the medical investigations performed to the recipient and the results of such investigations give reason to expect successful transplantation, and improvement of the recipient's quality of life after transplantation.

(2) Cells, tissues and an organ may be transplanted into a recipient with the consent of the recipient.

(3) An organ may be transplanted into a recipient who has been registered on the organ transplant waiting list pursuant to the procedure provided for in this Act.

Chapter 4: ACTIVITY LICENCE

§ 26. Activity licence obligation

(1) Based on this Act, an activity licence must be present for:
1) the procurement of cells, tissues and organs;
2) the handling of cells, tissues and organs.

(2) An activity licence for the provision of special medical care must also be issued on the basis of the Health Services Organisation Act to the person who simultaneously applies for an activity licence for the procurement and handling of cells, tissues and organs.

(3) An activity licence for the provision of special medical care must be issued on the basis of the Health Services Organisation Act to a health care provider for the transplantation of cells, tissues and organs. An activity licence for the provision of special medical care, with the appropriate secondary condition, must be issued to a manager of regional hospital who transplants organs.

(4) An activity licence grants the right to commence and perform economic activities in the place of business specified in the activity licence.

(5) Activity licences for the procurement and handling of cells, tissues and organs shall be registered in the register of activity licences of the State Agency of Medicines on the basis of subsection 39 (1) of the Medicinal Products Act.

(6) The State Agency of Medicines shall enter the data on the activity licence for the procurement or handling of cells and tissues in the EU Tissue Establishments Registry founded by the European Commission where all the activity licences issued by the EU Member States for the handling and procurement of cells

and tissues are entered. The State Agency of Medicines shall also enter in the EU Tissue Establishments Registry the data specified in the Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells(OJ L 294, 25.10.2006, p 32–50), and in Annex VIII to the Commission Directive (EU) 2015/565 amending directive 2006/86/EC as regards certain technical requirements for the coding of human cells and tissues (OJT L 93, 09.04.2015, p 43–55), and in case of changes in the data, shall update the data according to Article 10b (2) d–f of Directive (EU) 2015/565 amending directive 2006/86/EC as regards certain technical requirements for the coding of human cells and tissues (OJ L 93, 09.04.2015, p 43–55) without undue delay but not later than after ten working days.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(7) A unique identification number shall be given in the EU Tissue Establishments Registry to the holder of an activity licence for the handling or procurement of cells and tissues. The State Agency of Medicines shall enter the unique identification number in the register of activity licences of the State Agency of Medicines.
[RT I, 09.03.2017, 1 – entry into force. 19.03.2017, implemented since 29 April 2017]

(8) If the holder of an activity licence for the procurement or handling of cells and tissues wishes to import cells and tissues from a third country outside the European Union or the European Economic Area, the data and documents, the composition and format of which has been provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act, shall be submitted additionally upon application for an import certificate.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

§ 27. Application for activity licence

(1) The State Agency of Medicines shall decide the issue or refusal to issue an activity licence for the procurement of cells, tissues and organs or for the handling of cells, tissues and organs (hereinafter the activity licence) within 60 days after the submission of an application.

(2) In addition to the data provided for in the General Part of the Economic Activities Code Act, an application for activity licence shall set out the following data and documents:
1) documents certifying the right of use of the facilities;
2) layout and description of facilities of the place of business;
3) organisation chart reflecting the composition and structure of the staff;
4) in case a quality manager is present, his or her name, personal identification code, a copy of a document certifying qualification, a copy of an identity document and, if necessary, a copy of a document certifying a change of name and data on professional work experience and training;
5) movement plans of the staff and materials;
6) the procedure for cleaning, maintenance and sterilisation of the facilities and equipment;
7) description of the procedure for the procurement of cells, tissues and organs, including the procedure for the selection of donors and the laboratory testing carried out on donors;
8) the list of third parties performing contract works and the description of the content of contract works;
9) contract entered into with a laboratory accredited by an international accreditation institution in which necessary laboratory testing is carried out on a living donor to ascertain tissue compatibility;
10) description of the biovigilance system;
11) description of the organisation of waste management.

(3) In addition to the data provided for in the General Part of the Economic Activities Code Act and the provisions of subsection (2) of this section, an application for activity licence for the handling of cells, tissues and organs shall separately set out the following data and documents for each type of cell, tissue or organ:

1) description of the handler's quality system;
2) description of the handler's document management system;
3) the name of the competent person of the handler, his or her personal identification code, a copy of a document certifying qualification, a copy of an identity document and a copy of a document certifying change of name, if necessary, data on professional work experience and training and the areas of responsibility and the procedure for substitution;
4) simplified plan and description of the ventilation system of the handling facilities and types of filters;
5) simplified plan and description of the water system of the handling facilities and quality classes of water;
6) the list of equipment used in the handling process and quality control and the purpose of each equipment;
7) the plan and short description of the procurement and handling procedure;
8) the description of critical equipment and materials used upon handling;
9) description of the procedure for the release of cells, tissues and organs;
10) critical quality requirements for the cells, tissues and organs to be procured and handled;
11) a copy of radiation practice licence if radiation is involved in handling.

(4) In addition to the data provided for in the General Part of the Economic Activities Code Act and the provisions of subsection (2) of this section, an application for the activity licence for the procurement of cells, tissues and organs shall set out the name of the person responsible for procurement, his or her personal identification code, a copy of a document certifying qualification, a copy of an identity document and a copy of a document certifying change of name, if necessary, data on professional work experience and training and the areas of responsibility and the procedure for substitution.

§ 28. Subject of review of activity licence

An activity licence shall be granted if the applicant complies with the requirements provided for in this Act and the legislation established on the basis thereof and other legislation regulating the procurement, handling and transplantation of cells, tissues and organs.

§ 29. Secondary conditions of activity licence

The following secondary conditions may be added to an activity licence:
1) particular type of cell, tissue or organ allowed upon procurement or handling;
2) particular type of handling operation allowed upon handling;
3) additional requirements for the measures applied upon procurement or handling;
4) additional requirements for the health protection measures applied upon commencement and termination of activities.

§ 30. Specifications for revocation of activity licence

Upon revocation of an activity licence in part or in full or upon prohibition of economic activities, the State Agency of Medicines may set a term and conditions for the holder of an activity licence for the sale or destruction of the procured and handled materials and submission of reports.

Chapter 5: ORGAN TRANSPLANT WAITING LIST

§ 31. Obligations of manager of organ transplant waiting list

(1) For the purpose of this Act, an organ transplant waiting list (hereinafter the waiting list) means a list of persons, accompanied by their health data, who are waiting for an organ transplantation due to medical indications. The waiting list is maintained nationally by organs to be transplanted.

(2) The waiting list manager is the transplantation centre.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) The waiting list manager shall establish the conditions of and procedure for the registration of persons on the waiting list based on the medical indications pursuant to the provisions of § 32 of this Act.

(4) The waiting list manager shall ensure that the persons registered on the waiting list comply with the conditions for registration on the waiting list specified in subsection (3) of this section.

(5) The waiting list manager shall publish on its website each year by 1 April the unpersonified statistical data for the previous calendar year concerning the maintenance of the waiting list.

§ 32. Registration on and removal from waiting list

(1) Estonian citizens residing in Estonia or foreigners residing in Estonia holding a residence permit of a long-term resident or citizens of the European Union holding a permanent right of residence may be registered on the waiting list.

(2) Citizens of another EU Member State, a country of the European Economic Area or a third country or persons without citizenship may also be registered on the waiting list on the condition that the waiting list manager shall be submitted a guarantee concerning the financing of the organ transplantation and a written confirmation by the person, bearing his or her handwritten signature, on the fact that he or she has not been registered on the organ transplant waiting list of another state. If a person is registered on the organ transplant waiting list of another state, he or she shall be required to notify the waiting list manager thereof immediately in writing.

(3) In case of recipients with similar compatibility for organ transplantation, the organ shall be transplanted:
1) as the first preference to the person specified in subsection (1) of this section who has been registered on the waiting list;
2) as the second preference to a citizen of another EU Member State or a country of the European Economic Area who has been registered on the waiting list;
3) as the third preference to a citizen of a third country or to a person without citizenship who has been registered on the waiting list.

(4) The equal treatment of persons must be ensured upon the registration of persons on the waiting list and the discrimination due to ethnical, religious, moral or other non-medical reasons is not allowed.

(5) A person may be registered on the waiting list of one waiting list manager only.

(6) The registration of a person on the waiting list and removal from the waiting list shall be decided by the waiting list manager based on the medical reasons on the proposal of the transplantation centre.

(7) The waiting list manager shall be required to notify a person, in a format which can be reproduced in writing, of the registration of the person on the waiting list and removal from the waiting list, except in case of death of the person registered on the waiting list.

Chapter 6: TRACEABILITY OF CELLS, TISSUES AND ORGANS AND BIOVIGILANCE

§ 33. Traceability of cells, tissues and organs

(1) Traceability means the possibility to identify cells, tissues and organs and to ascertain the location thereof during any step of the process from the procurement of cells, tissues and organs to distribution to the transplanter or disposal, including the possibility to ascertain the donor and the handler receiving, handling or storing the cells, tissues and organs or another agency, also the possibility to ascertain to whom the transplanter has transplanted the cells, tissues and organs. Traceability also covers the possibility to ascertain all the relevant information relating to the products, equipment, employees and materials which come into contact with the cells, tissues and organs. Information relating to cells and tissues used for an innovative medicinal product must be traceable at least until it reaches the producer of an innovative medicinal product.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(2) The procurer, handler and transplanter shall ensure the traceability of cells, tissues and organs from the donor to the recipient or to destruction and vice versa.

(3) The procurer, handler and transplanter shall preserve the information necessary to ensure traceability for at least thirty years as of transplantation of cells, tissues or organs into a recipient or as of the disposal.

(4) The requirements for the transmission of information between the procurer, handler, transplanter, transplantation centre and State Agency of Medicines in order to ensure the traceability of cells, tissues and organs shall be provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 34. Subsequent observation of living organ donors

(1) In order to maintain the health of a living organ donor at the best possible level and to ensure the quality of handling of the donated organ, the transplantation centre shall organise the observation of the state of health of a living organ donor until the end of his or her life.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) The national transplantation agency which has the duty to maintain confidentiality arising from the law shall have the right to process the personal data of a living organ donor in order to observe his or her state of health, including personal data of special categories and, if necessary, to make inquiries therefor to the appropriate state registers and databases.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

§ 35. Biovigilance

(1) Biovigilance means the provision of information concerning any serious adverse event associated with the handling of cells, tissues and organs and any serious adverse reaction occurring at the time or after transplantation of cells, tissues or organs into a recipient, and the procedure for establishing the reasons thereof.

(2) For the purposes of this Act, a serious adverse reaction means an unintended response in the living donor or in the recipient which may be associated with any step of the process from the removal of cells, tissues or organs to the transplantation and which is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalisation or morbidity.

(3) For the purposes of this Act, a serious adverse event means an unwanted and unexpected event associated with any step of the process from the removal of cells, tissues or organs to the transplantation and which may lead to the transmission of infectious agents of communicable diseases, to death, be life-threatening for living donors or recipients, cause disability or incapacity or which may result in, or prolong, hospitalisation or morbidity.

(4) In the case of procurement and handling of gametes and embryos, a serious adverse event shall be deemed to be, in addition to the previous, an unwanted and unexpected event associated with any step of the process from the removal of gametes to the transplantation, the consequence of which is the formation of an unsuitable embryo, loss of biological material or transplantation into a person not intended therefor and if the child born as a result of application of the gametes or embryo of a donor suffers from a serious or life-threatening genetic disease.

(5) The transplanter shall without undue delay notify the procurer or handler which issued to the transplanter the cells, tissues and organs transplanted into the recipient of any occurred serious adverse event or reaction.

(6) The procurer or handler shall without undue delay notify the State Agency of Medicines and the transplantation centre of serious adverse events and serious adverse reactions which have become evident upon the handling of cells, tissues and organs or after the handling.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(7) The procurers and handlers of cells, tissues and organs must have procedures prepared and in place which enable to assess the need to withdraw cells, tissues and organs immediately after a serious adverse event or reaction has been ascertained and, if possible, to withdraw the cells, tissues or organs.

(8) The conditions and procedure for biovigilance and withdrawal applied in respect of cells, tissues and organs and the forms of giving notification of serious adverse events and serious adverse reactions shall be provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.

(9) Based on the information submitted to the State Agency of Medicines, an annual consolidated report concerning the serious adverse events and the serious adverse reactions shall be prepared and submitted to the European Commission by the State Agency of Medicines.

Chapter 7: INTERNATIONAL EXCHANGE OF CELLS, TISSUES AND ORGANS

§ 36. Use of organ removed from donor in international exchange

[RT I, 09.03.2017, 1 – entry into force 19.03.2017]
The transplantation centre may enter into agreements for the exchange of organs removed from donors with the organ exchange organisations of the European Economic Area or third countries on the condition that it is possible to trace the organs intended for transplantation from the donor to the recipient and vice versa and that the organs comply with the quality requirements provided for in the rules of procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 37. Maintenance of organ transplant waiting list upon joining international organ exchange organisation

(1) The persons registered on the national waiting list may be registered on the organ transplant waiting list maintained by the international organ exchange organisation according to the contract entered into with the international organ exchange organisation.

(2) If the waiting list is maintained by the international organ exchange organisation, the procedure for transmission of information related to the maintenance of the waiting list shall be provided for in the contract.

§ 38. Import and export of cells, tissues and organs

(1) The import and export of cells, tissues and organs shall take place on the conditions and pursuant to the procedure provided for in the Medicinal Products Act.

(1^1) The import of cells and tissues from third countries outside the European Union and the European Economic Area is only allowed based on the import certificate issued by the State Agency of Medicines. The list of documents, composition of data and format of documents necessary for the application for an import certificate, have been provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^2) In case of changes or a request to make changes in the data and documents forming the basis of the import certificate issued to the procurer or handler of cells and tissues, an application for the issue of a new certificate must be submitted, except in the cases provided for in subsection (1^3) of this section.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^3) The requirements of the import certificate may be deviated from if:
1) there is no other possibility to quickly import cells and tissues which are used immediately for a known recipient whose health would be in threat without such import;
2) specific type of cells or tissues are imported which are intended for the individual use of the handler or procurer and for a third country supplier outside the European Union and the European Economic Area for a recipient which was known before the import.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^4) In the cases specified in subsection (1^3) of this Act specific type of cells and tissues are imported from third countries outside the European Union and the European Economic Area for the same recipient usually only once. Regular or recurrent import from a third country supplier is not deemed to be single import.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^5) The State Agency of Medicines shall issue the import certificate within 30 days after the submission of all the required data and documents.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^6) Upon exercising supervision, the State Agency of Medicines shall have the right to suspend the validity of an import certificate with an administrative act until compliance with the precept.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^7) The State Agency of Medicines shall revoke an import certificate if:
1) the holder of an activity licence has submitted an application for the revocation of certificate;
2) the validity of an import certificate of the holder of an activity licence has been suspended and the precept issued by the State Agency of Medicines has not been complied with regardless of the imposition of a coercive measure;

3) the activity licence expires.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(2) The handlers shall ensure the compliance of cells, tissues and organs to be imported and exported with the quality requirements provided for in the rules for procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.

Chapter 8: FINANCING

§ 39. Financing of procurement, handling and transplantation of cells, tissues and organs

The procurement, handling and transplantation of cells, tissues and organs shall be financed by the recipient unless the payment obligation for health services is assumed by the Estonian Health Insurance Fund.

§ 40. Compensation of expenses by Estonian Health Insurance Fund

(1) The Estonian Health Insurance Fund shall assume the obligation to pay a fee to the health care provider for the procurement and handling of cells, tissues and organs in the extent provided for in the Health Insurance Act if the donor and potential deceased donor is an insured person for the purposes of § 5 of the Health Insurance Act.

(2) The Estonian Health Insurance Fund shall assume the obligation to pay a fee to the health care provider for the transplantation of cells, tissues and organs in the extent provided for in the Health Insurance Act if the recipient is an insured person for the purposes of § 5 of the Health Insurance Act.

(3) Performance of functions of a national transplantation agency specified in subsection 7 (2) of this Act shall be financed from the budget of the Estonian Health Insurance Fund.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(4) Performance of functions of transplantation centre specified in subsection 8 (1^1) of this Act shall be financed from the budget of the Estonian Health Insurance Fund pursuant to the procedure provided for in the Health Insurance Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 41. Compensation of expenses of health services of persons not covered by health insurance

[RT I, 21.12.2018, 1 – entry into force 01.01.2020]

(1) The expenses of health services provided to a living donor not covered by health insurance which are connected with the procurement and handling of cells, tissues and organs and treatment due to a state of health having occurred after removal of an organ shall be paid for from the budget of the Estonian Health Insurance Fund on the bases, conditions and pursuant to the procedure provided for in the list of health services of the Estonian Health Insurance Fund.
[RT I, 21.12.2018, 1 – entry into force 01.01.2019]

(2) The expenses of health services provided to a deceased donor and potential deceased donor not covered by health insurance which are connected with the procurement and handling of cells, tissues and organs shall be paid for from the budget of the Estonian Health Insurance Fund on the bases, conditions and pursuant to the procedure provided for in the list of health services of the Estonian Health Insurance Fund.
[RT I, 21.12.2018, 1 – entry into force 01.01.2019]

(3) [Repealed - RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 9: STATE SUPERVISION

§ 42. State supervision

(1) State supervision over compliance with this Act and the requirements of legislation established on the basis thereof shall be exercised by the State Agency of Medicines and the Health Board.

(2) The State Agency of Medicines exercises supervision over compliance with the requirements for the procurement and handling of cells, tissues and organs provided for in this Act and legislation established on the basis thereof, including supervision over the quality and safety requirements of cells, tissues and organs.

(3) The Health Board exercises supervision over compliance of the specialised medical care providers whose practice involves the transplantation of cells, tissues and organs with the requirements for the transplantation of cells, tissues and organs provided for in this Act and legislation established on the basis thereof.

(4) State supervision shall be exercised at least once in every two years.

(5) The State Agency of Medicines may inspect a third state supplier outside the European Union and the European Economic Area in connection with the importing activity of a holder of an activity licence for the handling and procurement of cells and tissues in Estonia in case of suspicion that the aforesaid supplier does not comply with the requirements established under this Act. An inspection can also be commenced upon the request of a Member State, European Commission, European Council or the European Medicines Agency.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 43. Special state supervision measures

For the execution of state supervision provided for in this Act, the law enforcement agency may apply the special state supervision measures provided for in §§ 30, 31, 32, 50, 51 and 52 of the Law Enforcement Act on the basis of and pursuant to the procedure provided for in the Law Enforcement Act.

§ 44. Limit of penalty payment

In the event of failure to comply with a precept, the upper limit of penalty payment imposed pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act shall be 9600 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

Chapter 10: REPORTING OBLIGATION

§ 45. Reporting obligation

(1) The State Agency of Medicines shall submit to the European Commission a report regarding the handling of cells, tissues and organs and the results of state supervision by 1 April 2016 and after that, once in every three years by the same term.

(2) If the State Agency of Medicines is notified of a serious adverse event or serious adverse reaction related with a donor whose organ was sent to another country of the European Economic Area or to a third country, the State Agency of Medicines shall immediately notify the competent authority of the relevant country thereof and shall, within three months as of the submission of the initial report, submit a report thereto which contains the data provided for in the rules for procurement and handling of cells, tissues and organs established under subsection 22 (3) of this Act.

(3) The transplantation centre shall submit to the European Commission a report regarding the activities related to the transplantation of organs and the acquired experiences by 1 August 2016 and after that, once in every three years by the same term.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 11: LIABILITY

§ 46. Derivation of financial gain for donation of cells, tissues and organs

Donation of cells, tissues and organs, if the donor or his or her legal representative has derived financial gain for it, is punishable by a fine of up to 300 fine units.

§ 47. Violation of requirements for procurement and handling of cells, tissues and organs

(1) Violation of the requirements for the procurement and handling of cells, tissues and organs is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 48. Violation of requirements for transplantation of cells, tissues and organs

(1) Violation of the requirements for the transplantation of cells, tissues and organs is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 49. Procedure

(1) [Repealed - RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(2) Extra-judicial proceedings concerning the misdemeanour provided for in § 46 of this Act shall be conducted by the Police and Border Guard Board.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(3) Extra-judicial proceedings concerning the misdemeanour provided for in § 47 of this Act shall be conducted by the State Agency of Medicines.

(4) Extra-judicial proceedings concerning the misdemeanour provided for in § 48 of this Act shall be conducted by the Health Board.

Chapter 12: IMPLEMENTING PROVISIONS

§ 50. Implementation of activity licence obligation

(1) Activity licences issued for the handling, including procurement of cells, tissues and organs before the entry into force of this Act shall be valid.

(2) The procurers of cells, tissues and organs shall apply for an activity licence for the procurement of cells, tissues and organs no later than by 1 January 2016, except in the case provided for in subsection (1) of this section.

(3) Specialised medical care providers engaged in the transplantation of organs shall apply for an activity licence for the provision of specialised medical care no later than by 1 January 2016.

§ 50[1]. Implementation of subsections 26 (6)–(8) and subsections 38 (1[1])–(1[7]) of this Act

(1) The requirements established in subsections 26 (6)–(8) and subsections 38 (1[1])–(1[7]) shall be implemented since 29 April 2017.

(2) The holders of an activity licence for the handling or procurement of cells and tissues who import cells and tissues from third countries outside the European Union and the European Economic Area and to whom a respective activity licence has been issued before the implementation of subsection 38 (1[1]) of this Act, shall submit an application with the data and documents necessary for the issue of an import certificate no later than by the term specified in subsection (1) of this section.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 51. - § 52. The amendment provisions of other Acts omitted from this translation.

§ 53. Repeal of Handling and Transplantation of Cells, Tissues and Organs Act

The Handling and Transplantation of Cells, Tissues and Organs Act shall be repealed.

§ 54. - § 59. The amendment provisions of other Acts omitted from this translation.

§ 60. Entry into force of Act

This Act enters into force on 1 March 2015.

[1]Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.04.2004, p. 48–58); Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ L 38, 9.02.2006, p. 40–52) amended with Commission Directive 2012/39/EU amending Directive 2006/17/EC as regards certain technical requirements for the testing of human cells and tissues (OJ L 327, 27.11.2012, p 24–25); Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32–50) amended with Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 09.04.2015, p 43–55); Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (OJ L 207, 06.08.2010, p. 14–29); Commission implementing directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (OJ L 275, 10.10.2012, p. 27–32); Commission Directive (EU) 2015/566 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (OJ L 93, 09.04.2015, p 56–68). [RT I, 09.03.2017, 1 – entry into force 19.03.2017]

Act amending the Law on the procurement, handling and transplantation of cells, tissues and organs and the State Fees Act

Adopted on 22.02.2017

Paragraph 1 of the Act of 1 January 199 Amendment of the Law on the procurement, handling and transplantation of cells, tissues and organs

The Law on the procurement, handling and transplantation of cells, tissues and organs is amended as follows:

1) subsection 1 (2) is amended and worded as follows:

"(2) This Act shall apply to the human use of cells, tissues and organs removed from living or dead human donors (hereinafter referred to as *donors)*and processed or unprocessed outside the body.";

2) subsection 2 (1) is amended and worded as follows:

"(1) Procurement of cells, tissues and organs within the meaning of this Act is the process by which donated cells, tissues and organs are made available for handling and transplantation. The process of procuring cells, tissues and organs shall be in particular the selection of the donor, the removal of cells, tissues and organs and the coding, packaging, labelling and dispensing of the procured cells, tissues and organs to the handler or transplanter.';

3) in subsection 2 (3), the words "to another person" are omitted;

4) subsections (13) and (14) are added to § 2 worded as follows:

"(13) Human use within the meaning of this Act is the use of cells, tissues or organs in a human recipient or recipient or outside the body.

(14) A supplier from a third country outside the European Union and the European Economic Area for the purposes of this Act is the procuring entity or operator of cells and tissues established in a third country outside the European Union and the European Economic Area or any other person responsible for exporting cells and tissues to the European Union and the European Economic Area which it supplies to the importing cell and tissue vendor or handler. A supplier from a third country may carry out one or more operations outside the European Union and the European Economic Area in connection with the donation, procurement, testing, processing, storage, storage or dispensing of cells and tissues imported into the European Union and the European Economic Area.';

5) subsection 9 (1) is amended and worded as follows:

"(1) The regional and central hospitals shall be obliged to identify and inform the national transplant institution of a potential deceased donor.";

6) subsection 22 (3) is added to clause 11) worded as follows:

"11) the list of documents necessary for application for the issue of an import certificate, the data set and the form of the import certificate.";

7) subsections 6\u20128 are added to § 26 worded as follows:

"(6) The Agency shall enter the details of the activity licence for the procurement or handling of cells and tissues in the European Union tissue register established by the European Commission, in which all authorisations issued by the Member States of the European Union for the procurement or handling of cells and tissues are entered. The Agency shall also enter in the European Union tissue banking register the european Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council on traceability requirements, reporting of serious adverse reactions and events and certain technical requirements for the coding, processing, storage, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, pp. 32-50) and Directive (EU) 2015/565 of the European Commission, amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 09.04.2015, pp. 43-55), and updating them accordingly in the light of changes in data in accordance with Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 09.04.2015, pp. 43-55), article 10b(2)(d) to (f) without undue delay, but no later than 10 working days.

(7) The European Union Tissue Bank Register shall establish a unique identification number for the holder of an activity licence for the procurement or handling of cells and tissues. The Agency shall enter a unique identification number in the register of authorisations of the Agency.

(8) If the holder of an activity licence for the procurement or handling of cells and tissues wishes to import cells or tissues from third countries outside the European Union and the European Economic Area, additional data and documents, the composition and format of which are laid down in the rules for the procurement and handling of cells, tissues and organs established on the basis of subsection 22 (3) of this Act, must be submitted in order to apply for an import certificate.";

8) subsection 33 (1) is amended and worded as follows:

"(1) Traceability is an ability to identify cells, tissues and organs and to determine their location at every stage of the process, from the procurement of cells, tissues and organs to the transfer or destruction of the transplantor, including the possibility of identifying the donor and the operator or other authority receiving, handling or storing cells, tissues and organs, as well as the possibility of identifying to whom the transplanter has transplanted cells, tissues and organs. Traceability shall also include the possibility of identifying all relevant data on products, equipment, personnel and materials in contact with cells, tissues and organs. Information on cells and tissues used for an advanced therapy medicinal product shall be traceable at least until it reaches the manufacturer of the advanced therapy medicinal product.';

9) the word "dead" is omitted from the title and text of § 36;

10) subsection 1 1 \u20121^{7}is added to §^{38} worded as follows:

"$^{(11)}$) Imports of cells and tissues from third countries outside the European Union and the European Economic Area shall be permitted only if an import certificate issued by the Agency is available. The list of documents, data composition and format required for applying for an import certificate are laid down in the rules for the procurement and handling of cells, tissues and organs established on the basis of subsection 22 (3) of this Act.

$^{(12)}$) Except as provided in paragraph 1(3) of this section, where changes have been or are requested to be made to the particulars and documents on which the import certificate is based issued to the procuring entity or handler of cells and tissues, an application for the issue of a new certificate shall be submitted.

(13) The requirement for an import certificate
may be waived if: (1) there is no other way to import rapidly cells and tissues used immediately for a known recipient whose health would be at high risk without such imports;
2) specific types of cells or tissues are imported which are intended for individual use by the contracting authority or handler and by a supplier of a third country outside the European Union and the European Economic Area for a recipient known prior to import.

(14) In the cases provided for in paragraph 1 3 of this section, cells or tissues of a specific type shall normally be imported once for the same recipient from third countries outside the European Union and the European Economic Area. Regular or recurrent imports from the same supplier in a third country outside the European Union and the European Economic Area shall not be considered as one-off imports.

(15) The Agency shall issue an import certificate within 30 days of the submission of all the required data and documents.

(16) In carrying out supervision, the Agency shall have the right to suspend the validity of the import certificate by its administrative act until the prescription has been complied with.

(17) The Agency shall revoke the
import certificate if: (1) the holder of the activity licence has submitted an application for revocation of the certificate;
2) the validity of the import certificate of the holder of the activity licence has been suspended and the precept of the State Agency of Medicines remains unfulfilled despite the application of the coercive measure;
3) the activity licence expires.";

11) subsection (5) is added to § 42 worded as follows:

"(5) The Agency may inspect a supplier from a third country outside the European Union and the European Economic Area in connection with the import activities of the holder of an activity licence for the procurement or handling of Estonian cells and tissues or if there is a suspicion that the said supplier does not comply with the requirements established on the basis of this Act. An inspection may also be initiated at the request of a Member State, the European Commission, the Council of the European Union or the European Medicines Agency.';

12) in § 44, the figure "1800" is replaced by "9600";

13) in subsection 47 (2), the figure "3200" is replaced by "32 000";

14) in subsection 48 (2), the figure "3200" is replaced by "32 000";

15) subsection 49 (1) is repealed;

16) in subsection 49 (2), the words "police authority" are substituted by the words "Police and Border Guard Board";

17) section 50[1] is added to the Act worded as follows:

«**§ 50[1]. Implementation of paragraphs 26 (6) to (8) and 38 (1)to (1)7) of this Act**

(1) The requirements established in subsections 26 (6) to (8) and 38(1)to (1)7) of this Act shall apply from 29 April 2017.

(2) Holder of an activity licence for the procurement or handling of cells and tissues who import cells or tissues from third countries outside the European Union and the European Economic Area and who have been granted such an activity licence before the implementation of subsection 38 (1)[1)] of this Act shall submit an application for an import certificate together with the required information and documents by the deadline provided for in subsection (1) of this section at the latest.";

18) the normative technical note of the Act is amended and worded as follows:

"[1] Directive 2004/23/EC of the European Parliament and of the Council establishing quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 07.04.2004, pp. 48-58);
European Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ L 38, 09.02.2006, pp. 40-52), as amended by European Commission Directive 2012/39/EU amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells (OJ L 327, 27.11.2012, pp. 24-25);
European Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, the reporting of serious adverse reactions and events and certain technical requirements for the coding, processing, storage, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, pp. 32-50), as amended by European Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 09.04.2015, pp. 43-55);
Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (OJ L 207, 06.08.2010, pp. 14-29);
European Commission Implementing Directive 2012/25/EU laying down a procedure for the provision of information on the exchange of human organs intended for transplantation between Member States (OJ L 275, 10.10.2012, pp. 27-32);
European Commission Directive (EU) 2015/566 implementing Directive 2004/23/EC as regards procedures for checking equivalence of quality and safety standards for imported tissues and cells (OJ L 93, 09.04.2015, pp. 56-68).'.

Paragraph 2 of the Act of 2 December 200 Amendment of the State Fees Act

Section 3 of Section 1 of Chapter 12 of the State Fees Act is supplemented by § 285[2,] worded as follows:

"**§ 285[2]. Examination of an application for a certificate of import of cells and tissues**

A state fee of EUR 340 shall be paid for the examination of an application for the issue of a certificate for the import of cells and tissues.';

Enn Eesmaa
Vice-Chairman of the Riigikogu

Communicable Diseases Prevention and Control Act

Passed 12.02.2003
RT I 2003, 26, 160
entry into force in accordance with § 54.

Chapter 1: GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act regulates the way in which the control of communicable diseases is organised and the procedure for the provision of health care services to infected persons (hereinafter provision of medical care), and sets out the obligations of the state, local governments, legal persons and natural persons in the prevention and control of communicable diseases.

(2) This Act applies to all natural persons in the territory of the Republic of Estonia and to legal persons located in the territory of the Republic of Estonia unless otherwise provided by an international agreement or international convention.

(3) The provisions of the Administrative Procedure Act apply to administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.

§ 2. Definitions

In this Act, the following definitions are used:
1) “infectious agent” means a prion, virus, bacterium, microscopic fungus, protozoan, helminth or arthropod, and their components and toxins capable of causing communicable diseases;
2) “communicable disease” means a disease, or carrier state with no signs of disease, which is caused by the entry of an infectious agent into the human body which is transmitted or with regard to which there is reason to believe that it may be transmitted directly or indirectly person-to-person or animal-to-person;
3) “extremely dangerous communicable disease” means a disease with a high level of infectiousness which spreads rapidly and extensively or which is serious or life-threatening. For the purposes of this Act, the plague, cholera, yellow fever, viral hemorrhagic fevers and tuberculosis are extremely dangerous communicable diseases;
4) “person suffering from a communicable disease” means a person who has been diagnosed as having a communicable disease using methods accepted by medical science;
5) “ person suspected of being infected” means a person who has been exposed to similar conditions as a person suffering from a communicable disease or who may have been infected by a person suffering from a communicable disease but who has not developed any symptoms of disease by the time he or she undergoes a medical examination;
6) “control of communicable diseases” means the application of health protection measures which enable the early detection and consequent testing and treatment of persons suffering from communicable diseases and of persons suspected of being infected in order to ascertain the causes and mode of their infection, prevent the spread of the communicable disease and prevent healthy persons from being infected;
7) “epidemic” means an outbreak of a communicable disease which calls for infection control measures to be applied extensively;
8) “surveillance” means systematic collection, analysis, interpretation and dissemination of health data, including epidemiological studies of communicable diseases and risk factors for contracting communicable diseases for the purpose of prevention of the spread and control of communicable diseases;
[RT I 2009, 49, 331 – entry into force 01.01.2010]

9) “disease outbreak” means the occurrence of cases of communicable disease connected with the same source of infection or spread factor in excess of what would normally be expected within a certain period.
[RT I 2009, 49, 331 – entry into force 01.01.2010]
10) “retention sample of donor blood” – sample of donor blood taken from a dose of blood.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(2) A dangerous novel communicable disease for the purposes of this Act is a communicable disease:
1) that has the features of an extremely dangerous communicable disease provided for in clause (1) 3) of this section;
2) that has no effective treatment or for which no effective treatment is available or the spread of which may exceed the hospital treatment capacity.
[RT I, 17.05.2020, 1 – entry into force 18.05.2020]

Chapter 3: PREVENTION OF SPREAD OF COMMUNICABLE DISEASES

§ 14. Ensuring safety of blood donation from infection

(1) In order to protect donors and recipients, the Blood Centre and health care providers shall apply measures to ensure safety from infection.

(2) The Blood Centre or the health care provider shall prepare a document recording the preparation and use of blood products, in compliance with the requirements provided for in the Blood Act (RT I 2005, 13, 63) and in the legislation established on the basis thereof.

(3) The procedure for screening donated blood and blood components for infectious agents shall be established by a regulation of the minister responsible for the area.
[RT I 2005, 13, 63 – entry into force 01.05.2005]

(4) A retention sample of donor blood shall be preserved for five years according to the procedure provided for in subsection (3) of this section. The documents on laboratory testing procedures and the testing results received in the course thereof shall be preserved for 15 years.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

§ 15. Ensuring safety of procurement, handling and transplantation of cells, tissues and organs from infection

[RT I, 26.02.2015, 1 - entry into force 01.03.2015]

(1) In order to protect recipients and live donors, health care providers shall apply measures to ensure safety from infection.

(2) A health care provider shall prepare a document recording the use of cells, tissues and organs.

(3) The conditions of and procedure for screening donors for infectious agents shall be established by a regulation of the minister responsible for the area.
[RT I, 26.02.2015, 1 - entry into force 01.03.2015]

§ 54. Entry into force of Act

This Act enters into force on 1 November 2003, except for:

1) subsections 20 (1) and (2) of this Act which enter into force on 1 July 2004;

2) subsection 9 (2) of this Act which enters into force on 1 November 2004;

3) section 11 of this Act which enters into force on 1 May 2005;

4) subsection 21 (9) of this Act which enters into force as of Estonia's accession to the European Union.