

No. 101/2001

Act on the Medical Use of Human Organs, Tissues and Cells
(Amendments up to 277/2013 included)

Issued in Helsinki on 2 February 2001

Chapter 1
General provisions

Section 1 (547/2007)
Scope of application

This Act lays down provisions on the following:

- 1) removal, storage and use of human organs, tissues and cells for the treatment of human disease or injury;
- 1a) donation, testing, retention, preservation and storage, transport, transplantation and traceability of organs intended for organ transplantation, characterisation of the donor and the organ, and reporting of serious adverse events and serious adverse reactions; (277/2013)
- 2) retention, storage and use for medical purposes of organs, tissues and cells removed during diagnosis and treatment of human disease;
- 3) donation, procurement, testing, processing, preservation, storage and distribution at a tissue establishment or commissioned by a tissue establishment of human tissues and cells intended for human applications and of products made of human tissues and cells and intended for human applications;
- 4) use of human embryos for a purpose other than fertility treatment or medical research;
- 5) use of human organs, tissues, cells and tissue samples for a purpose other than that for which they were removed or retained;
- 6) use of a cadaver for medical teaching and research.

For the purposes of this Act human tissues and cells mean any tissues and cells intended for human applications, including haematopoietic stem cells from peripheral blood, umbilical cord and bone marrow, gametes, embryonic tissues and cells and adult and embryonic stem cells.

In regard to pharmaceutical products and health care devices and equipment this Act is applied to donation, procurement and testing of tissues and cells.

The provisions of Chapter 6a of this Act are not applied to tissues and cells that are used as autologous transplants in connection with one and the same surgical measure without storing the tissues or cells in a tissue or cell bank, and neither to organs nor parts thereof if those are used for application in the human body for the original function of the organ.

Separate provisions will be laid down concerning removal of organs and tissues in connection with diagnosis and treatment of diseases or medical research or that are necessary to investigate the

cause of death. The tissues and cells to be used in medical research for human applications must however fulfil the quality and safety requirements laid down in this Act.

Separate provisions will also be laid down concerning the donation and examination of human blood and its components, and the processing, storage and distribution of the blood and its components intended for blood transfusion. The same applies to the use and storage of gametes for fertility treatment, and remuneration and charges regarding fertility treatments.

Section 1a (547/2007)

Definitions

For the purposes of this Act:

1) *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 a significant level of autonomy; (277/2013)

1a) *organ characterisation* means recording the information on the organ that is needed to evaluate its suitability for transplantation; (277/2013)

1b) *donor characterisation* means recording the health information regarding the donor that is needed to evaluate the person's suitability as a donor; (277/2013)

2) *tissue* means all constituent parts of the human body formed by cells;

3) *cells* means individual human cells or a collection of cells which are not bound by any form of connective tissue;

4) *tissue establishment* means a tissue bank, a health care unit or its part, or any other unit that processes, preserves, stores or distributes human tissues and cells or that is responsible for procurement or testing of tissues and cells;

5) *quality system* means the organisational structure and the division of responsibilities, procedures, methods and resources required for quality management, including all measures that indirectly or directly contribute to quality promotion;

6) *human application* means the application of tissues or cells in the person receiving them;

7) *autologous use* means tissues or cells removed from and applied to the same person without storing them in a tissue or cell bank;

8) *procurement* means a process by which the donated tissues or cells are made available;

8a) *retention* means a process by which the donated organs are made available; (277/2013)

9) *processing* means all measures involved in the preparation, manipulation, preservation or packaging of the organs, tissues or cells intended for human applications; (277/2013)

10) *preservation* means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physiological deterioration of organs, tissues or cells during the processing or in regard to organs from retention to transplantation; (277/2013)

11) *storage* means maintaining the product under appropriate controlled conditions until distribution;

12) *distribution* means transportation and delivery of tissues or cells intended for human applications;

12a) *traceability* means location and identification of the organ at any stage of the chain from donation to transplantation or disposal, including identification of the donor, organisation of retention, recipient or recipients, and location and identification of all relevant information relating to products and materials coming into contact with that organ; (277/2013)

13) *serious adverse event* means:

a) any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-

threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalization or morbidity;

b) any undesired occurrence associated with procurement, testing, processing, preservation, storage or distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalization or morbidity;

(277/2013)

14) *serious adverse reaction* means:

a) any unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation, which is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

b) any unintended response, including a communicable disease, associated with the procurement of tissues and cells or their use in the donor or the recipient, which might be fatal, life-threatening, disabling or incapacitating, or which might result in, or prolong, hospitalization or morbidity; (277/2013)

15) *standard routines* means written instructions that describe the different stages of each procedure, including the materials and methods used and the expected final product or final result; (277/2013)

16) *organ transplantation centre* means the university central hospital of the Helsinki region where transplantations are concentrated in accordance with the Government Decree on the provision and centralisation of highly specialised medical care (336/2011). (277/2013)

Chapter 2

Removal of organs, tissues and cells from living donors for transplantation (547/2007)

Section 2 (547/2007)

General preconditions

Organs, tissues or cells may be removed from donors who have given their consent in order to treat human disease or injury. Removed organs, tissues and cells may be stored for future use.

Organs, tissues or cells may only be removed if this does not cause the donor any major health hazard or serious harm, if there is no treatment available for the recipient as effective as transplantation, and if no suitable organ, tissue or cells from a dead donor are available, or the prognosis is expected to be appreciably better than the prognosis of transplantation from a deceased donor.

After the donation the health state of the donor must be followed so as to be able to detect any serious adverse reactions that might be caused by the donation as well as any circumstances possibly affecting the quality and safety to the donated organ or the safety of the donor, so as to be able to inform about them in the way laid down in this Act and to undertake other necessary measures to ensure the safety of the donor and the recipient. (277/2013)

Doctors treating recipients may not be involved in decisions concerning the removal of organs or tissues, with the exception of removal of bone marrow tissue.

Section 3 (547/2007)

Consent of the donor

Donors must give informed written consent to the removal of an organ, tissue or cells. They are entitled to withdraw consent at any time before removal of the organ, tissue or cells, without being required to state any reason.

Before giving written consent, donors must be provided with an explanation of the significance of the removal and associated risks for themselves and the recipients, any analytical tests possibly performed on them and their results, the registration and protection of the data on the donors and safety measures to protect the donors, and be informed that their consent can be withdrawn at any time before the organ or tissue is removed. The donor's personal physician contributing to the decision to donate must personally make the explanation to the donor.

If the donor is under-age or, though of age, does not have the capacity to decide on his or her treatment because of disease, mental health disorder or some other reason (*incapacitated*), the written consent of his or her legal representative must be obtained before the removal takes place. However, no organ, tissue or cells may be removed if the person concerned objects. The donor's personal physician contributing to the decision to donate must personally make the explanation referred to in paragraph 2 to the donor's legal representative. The physician must also establish the views of an under-age or incapacitated donor in so far as the donor's age and developmental level permit.

Section 4

Removal of non-regenerative organs or tissues

Adult persons able to decide about their treatment may donate non-regenerative organs or tissues only to treat disease or injury in a near relative or other person close to them.

A permit from the National Supervisory Authority for Welfare and Health is required for all removals of organs or tissues. (778/2009)

Section 5

Under-age or incapacitated donors

Under-age or incapacitated persons may only donate regenerative tissue or part of a regenerative organ to treat disease or injury threatening the life of a sibling if no suitable tissue or organ is available from a deceased or legally competent donor. If the donor is under-age, but of an age and developmental level that allows him or her to decide about personal treatment, the recipient can be a near relative or other close person. Cells can also be donated in situations other than the above-mentioned if no suitable cells are available from a deceased or legally competent donor.

A permit from the National Supervisory Authority for Welfare and Health is required for the removal of tissue or part of an organ. (778/2009)

Chapter 3
Retention of organs, tissues and cells (547/2007)

Section 6
General preconditions and restrictions

Organs, tissues and cells removed from a patient during diagnosis or treatment can be retained and stored for medical use. (547/2007)

Embryos can only be used for fertility treatment or medical research.

Section 7 (547/2007)
Patient's consent and other preconditions for retention

The patient's informed written consent is required for the retention of organs, tissues or cells referred to in section 6 (1), and for subsequent storage and use. If patients are incapacitated or unable to understand the significance of the matter because of being under-age, the written consent of their legal representative is required for such retention. Patients or their legal representatives are entitled to withdraw consent at any time before ultimate use of an organ, tissue or cells, without stating any reason.

Before giving consent, patients must be provided with an explanation of the purpose and significance of the removal, any analytical tests possibly performed on them and their results, the registration and protection of data on the donors and appropriate safety measures undertaken to protect the donors, and informed that they can withdraw their consent before ultimate use of the organ, tissue or cells. The physician treating the patient must personally give an explanation to the patient or his or her legal representative. When retaining tissues or cells the explanation can also be given by some other health care professional.

If organs, tissues or cells are retained during termination of pregnancy or miscarriage, a permit from the National Supervisory Authority for Welfare and Health is required. (277/2013)

Chapter 4
Removal of organs, tissues and cells from a deceased donor (547/2007)

Section 8
General preconditions

Organs, tissues and cells may be removed from the deceased, and may be stored for later treatment of another person's disease or injury. (547/2007)

Death must be certified as laid down by Decree of the Ministry of Social Affairs and Health.

Physicians who certify death may not be involved in transplantation of organs, tissues and cells. (547/2007)

Section 9 (653/2010)
Consent

Organs, tissues and cells of a deceased person may be removed unless it is known or there is reason to assume that the person would have objected while still alive. If a person had, while still alive, forbidden the removal of his or her organs, tissues and cells, the measure may not be performed. Before removal of a deceased person's organs, tissues or cells for the purpose referred to in section 8 (1), the deceased person's opinion, while still alive, must be investigated as far as possible.

If the deceased person is under-age, and due to his or her age and developmental level while still alive was not able to form an opinion of removal of his or her organs, tissues or cells, the measure can be performed unless the person's guardian objects to it.

If an adult deceased person due to an illness, mental health disorder or for some other reason, while alive, was not able to form an opinion of removal of his or her organs, tissues or cells, the measure can be performed unless the person's near relative or other close person objects to it.

Section 9a (653/2010)

Explanation to a person close to the deceased person

The deceased person's near relative or other close person must be given an explanation of the removal of organs, tissues or cells and of its significance.

Section 10 (547/2007)

Restrictions on removal

Organs, tissues and cells may not be removed if this impedes investigation of the cause of death.

No action may be taken to remove organs, tissues or cells if the police have to carry out an investigation to establish the cause of death and object to such removal, or if removal would materially impede forensic investigation of the cause of death.

Chapter 5

Medical research and teaching in connection with post-mortem examination

Section 11(689/2012)

Preconditions for research and teaching

During post-mortem examinations, cadavers and organs, tissues, cells and other samples removed from them can also be used for medical research and teaching other than that related to investigation of the cause of death. Samples can also be transferred to a biobank referred to in the Biobank Act (688/2012). The preconditions for this are:

- 1) the competent ethics committee referred to in the Medical Research Act (488/1999) has given a favourable opinion on the use of cadavers and samples for medical research or on transfer of samples to a biobank; and
- 2) the National Supervisory Authority for Welfare and Health has given a permit to use the cadavers and samples for the purpose of teaching.

If the opinion of the ethics committee referred to in paragraph 1 (1) is negative, the National Supervisory Authority for Welfare and Health will, upon application, issue a decision on the matter.

Section 12

Restrictions on research and teaching

A cadaver may not be used, nor organs, tissues or cells removed, for research and teaching purposes if this impedes investigation of the cause of death or removal of organs, tissues and cells as laid down in this Act for treatment of human disease or injury. Research and teaching may not be

initiated if the police need to carry out an investigation to establish the cause of death and object to initiation of the said research and teaching. (547/2007)

All research and teaching must be carried out with respect for the deceased and in a way that does not materially change the deceased's appearance. Research and teaching may not be carried out if there is reason to assume that the deceased would have objected while still alive.

Section 13

Surrender of cadavers for teaching purposes

Cadavers may be donated to university departments of anatomy for medical teaching purposes if the deceased gave written consent for such surrender while still alive.

Chapter 6

General provisions concerning activities (277/2013)

Section 14 (547/2007)

Origin, quality and safety of organs, tissues and cells (277/2013)

Only human organs, tissues and cells, and products made from them, the quality and safety of which has been tested using appropriate methods, and whose origin can be traced, may be used to treat human disease or injury or otherwise for human application. (277/2013)

Imported organs, tissues and cells and products made from them may only be used to treat human disease or injury or otherwise for human application if the preconditions concerning the donor and the donation laid down in this Act are fulfilled.

Section 15 (547/2007)

Safeguarding the quality of activities

Health care units or other units engaging in removal, retention or storage as referred to in this Act, or using human organs, tissues and cells removed, retained or stored in accordance with this Act, must have appropriate facilities and equipment, and the necessary personnel.

Requirements for the activities of tissue establishments are laid down in Chapter 6a. Requirements for the activities of donation hospitals and the transplantation centre are laid down, in addition, in Chapter 6b. (277/2013)

Section 16 (547/2007)

Organ and tissue transplantation registers

A register shall be kept in order to supervise the safety and traceability of human organs, tissues and cells removed, retained and stored for the treatment of human disease or injury and the legality of said removal, retention, storage and use. The register shall be kept by a health care unit or other unit storing human organs, tissues and cells for the treatment of human disease or injury and using them for organ and tissue transplants. The register can also be kept by a tissue establishment that procures, tests, processes, preserves, stores or distributes tissues or cells. The Finnish Red Cross may keep a register of voluntary bone marrow donors.

The register shall contain the following information: the name and personal identity code or other identification code of the donor and recipient, the necessary contact data, test results on the organ, tissue or cells concerned, information on the donor and recipient related to safe use of organs, tissues and cells, information on the health care units involved in removing, storing and using the organs, tissues and cells, information on provision of organs, tissues or cells for a purpose other than that for which they were removed or retained, the number of the living and deceased donors, information on the type of the retained, transplanted or otherwise used organs and their number, and data on the permits for removal of organs, tissues and cells granted by the National Supervisory Authority for Welfare and Health, and on the donor's or patient's consent to removal or retention of organs, tissues and cells. (277/2013)

The information in the register shall be kept for 50 years from the death of a donor or, if there is no data on the death, for 100 years from the most recent register entry. If a donor withdraws consent, the register keeper must so inform the unit receiving the organ, tissue or cells. The information on the donor must then be removed from the organ or tissue transplantation register unless there is some other reason under the law to retain it.

The organ transplantation centre must annually draw up a report on the organ transplantations referred to in this section. The organ transplantation centre must send the report to the Finnish Medicines Agency, which publishes annually a report on organ transplantation activities. (277/2013)

Provisions on the registers kept by tissue establishments and on the information storage time deviating from what is provided for in paragraph 3 are laid down in section 20i.

Section 17

Provision of information from the register

Information deposited in the organ and tissue transplantation registers referred to in section 16 and the register of the tissue establishment referred to in section 20i, as well as other information concerning donors and recipients, and documents concerning them, shall be considered confidential. (547/2007)

Notwithstanding the confidentiality provisions, the register keeper shall provide another health care unit or other unit involved in the activities referred to in paragraph 1 with any information in the register needed to ensure safe use of an organ, tissues or cells. On request, the register keeper shall also provide an authority regulating and supervising the activities referred to in this Act with information from the register. What is provided in the Act on the Openness of Government Activities (621/1999) also applies to the provision of information. (547/2007)

Notwithstanding the confidentiality provisions, the register keeper is entitled to obtain information needed to ensure the safety and traceability of organs, tissues and cells from a health care unit or other unit removing, retaining, storing or using human organs, tissues and cells, or caring for a donor or recipient. (547/2007)

No charge may be made for provision of the information referred to in paragraphs 2 and 3 above.

Section 18 (547/2007)

Remuneration and prohibition on commercialization

No donor or assignee of a donor may be promised or paid a fee for the removal and use of an organ, tissue or cells or for the donation of a cadaver, as laid down in this Act. It is prohibited to advertise for the need or availability of organs for the purpose of offering or seeking financial gain or comparable benefit. (277/2013)

The donor of an organ, tissue or cells who suffers loss of income because of removal of an organ, tissue or cells as referred to in this Act to meet a vital transplantation need or for essential related tests and examinations, is entitled to a daily allowance as provided in the Health Insurance Act (1224/2004). The daily allowance will be paid for every weekday notwithstanding Chapter 8, section 7 of the said Act. If the employer pays salary for the period of incapacity for work, the entitlement to daily allowance is transferred as laid down in Chapter 7, section 4 (2) of the Health Insurance Act. (653/2010)

A health care unit or other unit involved in removing, retaining, storing or using organs, tissues and cells may not pursue financial gain from the activities provided for in this Act. However, the health care unit or other unit or tissue establishment may charge another health care unit or tissue establishment for handling and transporting organs, tissues or cells, and for carrying out the tests needed to ensure safety and for providing storage. The charge made may not exceed the total cost of producing the service.

Section 19 (778/2009)

Change of purpose for which organs, tissue and cells will be used

An organ, tissues or cells from a living person which are removed, retained or stored, and cannot for some medical reason be used for the purpose originally planned, may be used for some other justifiable medical purpose with the donor's consent. If the organ, tissues or cells have been removed from an under-age or incapacitated person, the consent of his or her legal representative is required.

If the removal or retention of an organ, tissue or cells requires a permit from the National Supervisory Authority for Welfare and Health, a change of purpose requires not only the consent referred to in paragraph 1 but also a permit from the aforesaid National Authority or, if it is question of medical research or transfer of samples to a biobank referred to in the Biobank Act, an opinion in favour of the matter from the competent ethics committee referred to on the Medical Research Act. (689/2012)

An organ, tissues or cells removed or retained from a cadaver that cannot, for a medical reason, be used for the purpose for which they were originally removed may be used for medical research and transferred to a biobank if a favourable opinion on the planned use has been received from the ethics committee referred to in paragraph 2, or for some other justifiable medical purpose with a permit from the National Supervisory Authority for Welfare and Health. (689/2012)

If the opinion of the ethics committee referred to in paragraph 2 or 3 is negative, the National Supervisory Authority for Welfare and Health will, upon application, issue a decision on the matter. (689/2012)

Section 20 (689/2012)

Change in purpose for which tissue samples will be used

Tissue samples taken for therapeutic or diagnostic purposes may be surrendered and used for medical research with the patient's consent. If the person is under-age or incapacitated, consent must be obtained from his or her legal representative. If it is impossible to obtain the person's consent because the person has died, the samples can be used for medical research or transferred to a biobank referred to in the Biobank Act after the ethics committee referred to in the Medical Research Act has issued a favourable opinion on the matter. If the opinion of the ethics committee is negative, the National Supervisory Authority for Welfare and Health shall issue a decision on the matter upon application. If there is reason to assume that the person while alive would have objected to use of his samples for research purposes, the sample may not be transferred to a biobank. Further preconditions for transfer and handling of samples are laid down in the Biobank Act.

Tissue samples taken for therapeutic or diagnostic purposes, or to establish the cause of death, may be surrendered and used for medical research, method development, quality management and teaching purposes with permission from the health care unit or other unit for whose activities the sample was taken, as long as no personal data are used in the surrender or use situation.

Tissue samples taken for therapeutic, diagnostic or medical research purposes may be surrendered and used to establish the hereditary character of a disease diagnosed in another person only if the person from whom the sample was taken gives his or her consent. If the person is under-age or incapacitated, consent must be obtained from his or her legal representative. If the person has died or the tissue sample was taken in order to establish the cause of death, the health care unit or other unit for whose activities the sample was taken shall decide whether to surrender the tissue sample, unless the deceased specifically prohibited this while alive.

Samples taken for therapeutic or diagnostic purposes, to establish the cause of death, or for medical research can be surrendered in order to establish the identity of biological parents to a research institution specified by a court of law or some other authority or to identify a deceased person to the police.

Tissue samples taken for therapeutic or diagnostic purposes, or to establish the cause of death, may not be surrendered or used for any purpose other than that for which they were taken if this will hamper their use for the original purpose.

Chapter 6a (547/2007)
Provisions on the activities of tissue establishments

Section 20a (547/2007)
Tasks of tissue establishments

The procurement, testing, processing, preservation, storage and distribution of tissues and cells takes place at a tissue establishment or commissioned by it. The tissue establishment must ensure that the quality and safety of the tissues and cells are appropriate, including examination of all donated tissues and cells to ensure their safety. The tissue establishment must also ensure that the conditions of procurement, testing, processing, preservation, storage and distribution are appropriate.

Section 20b (778/2009)
Authorisation and notification

The tissue establishment must have an authorisation granted by the Finnish Medicines Agency. Conditions regarding the scope of activities of the tissue establishment can be appended to the authorisation. The tissue establishment must notify any essential changes in its operations to the Finnish Medicines Agency that will decide if the change requires modification of the authorisation.

The Finnish Medicines Agency must, upon written application, grant authorisation for tissue establishment activities to a municipality, joint municipal authority, association or corresponding community or company, if the tissue establishment fulfils the requirements according to 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, the 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 and 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. The authorisation application must include information on the personnel, facilities, equipment and materials of the tissue establishment as well as information on the procedures regarding donation, procurement, testing, processing, storage, preservation and distribution of tissues and cells. Furthermore, the authorisation application must include information on the tissue establishment's quality system and procedures regarding the safety and traceability of tissues and cells as well as adverse events and adverse reactions.

Section 20c (778/2009)

Responsible person

The tissue establishment must designate a person who is responsible for ensuring that the processing of tissues and cells takes place in compliance with the provisions of this Act and the quality system in use in the tissue establishment, making the notification referred to in section 20g and providing the Finnish Medicines Agency with the information referred to in section 20b that is needed for granting authorisation. The responsible person must fulfil the qualification requirements referred to in Article 17 of 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.

The tissue establishment must inform the Finnish Medicines Agency of the responsible person referred to in paragraph 1 and his or her substitute and any change of them.

Section 20d (547/2007)

Personnel

The personnel of the tissue establishment must have appropriate qualifications for performing their duties, and the personnel must be provided with regular and appropriate training.

Section 20e (547/2007)

The quality system

The tissue establishment must have an updated quality system based on the principles of good practice. The quality system must include at least standard operating procedures and other guidelines, training and reference manuals, reporting forms, donor records and information on the final destination of tissues and cells.

Section 20f (547/2007)

Traceability

The tissue establishment must have a system by means of which all the tissues and cells procured, processed, stored or distributed can be traced from donor to recipient and vice versa. The requirements for traceability also apply to all appropriate information on products and material that come into contact with such tissues and cells.

The tissue establishment must assign a unique code to each donation and to each of the products associated with it.

Section 20g (547/2007)

Notification of adverse events and adverse reactions

The tissue establishment must keep a list of all the adverse events and adverse reactions linked to tissues and cells that have come to its knowledge.

The tissue establishment must immediately notify the Finnish Medicines Agency of any potential serious adverse events and serious adverse reactions related to its activities and the procurement, testing, processing, preservation, storage and distribution of tissues or cells that may influence the quality and safety of the tissues and cells. The notification duty also concerns serious adverse reactions that have been observed during the clinical use or thereafter and that may concern the quality and safety of the tissues and cells. (778/2009)

The tissues and cells that have been notified as referred to in paragraph 2 may not be used, and they must be withdrawn from distribution. Such tissues and cells can be taken into use if it can be proved by means of a particular examination that they meet the safety and quality requirements laid down in this Act.

Section 20h (547/2007)

Agreement between a tissue establishment and a third party

The tissue establishment may due to technical, financial or productive circumstances and by permission of the Finnish Medicines Agency commission certain functions from a third party. (778/2009)

The tissue establishment must establish written agreements with a third party each time an external measure takes place which influences the quality and safety of tissues or cells processed in cooperation with a third party.

The agreement referred to in paragraph 2 must be concluded in particular if:

- a) a third party manages the processing of tissue or cells or some stage of it;
- b) a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution;
- c) the tissue establishment provides services to a party other than another tissue establishment; or

d) the tissue establishment distributes tissues or cells processed by third parties.

The responsibilities of the third parties and the procedures to be followed must be specified in the agreement.

The tissue establishment must keep a list of the agreements it has established and at request provide copies of the agreements to the Finnish Medicines Agency. (778/2009)

Section 20i (547/2007)
Registers and retaining of information

The tissue establishment must keep a record of its activities. In addition to what is laid down in section 16 (2) also the types and quantities of tissues and cells procured, tested, processed, preserved, stored and distributed or otherwise disposed of must be entered in the record. Also, information on any products and materials that influence the quality of tissues and cells and on products that may come into contact with them must be entered in the register.

The tissue establishment must submit an annual report of its activities to the Finnish Medicines Agency. (778/2009)

The tissue establishment must keep the data required for full traceability for a minimum of 30 years after clinical use. The data can also be stored in an electronic form.

What is provided in section 17 correspondingly applies to submitting information from the register referred to in paragraph 1.

The Finnish Medicines Agency maintains a register of tissue establishments specifying the activities for which each tissue establishment has been authorised. The register is publicly accessible. (778/2009)

Section 20j (778/2009)
Guidance and supervision of tissue establishments

The guidance and supervision of tissue establishments in regard to the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells as well as in regard to the quality and safety requirements concerning them is the duty of the Finnish Medicines Agency under the Ministry of Social Affairs and Health.

The Finnish Medicines Agency must inspect the tissue establishments regularly, at least every second year. The Agency can also, as necessary, inspect a tissue establishment if an adverse event or a serious adverse reaction is observed in regard to the quality and safety of tissues or cells or if it is suspected that there has been such an adverse event or reaction.

The inspector must be given access to all facilities and premises of the tissue establishment as well as to the facilities and premises of the third party that has made an agreement referred to in section 20h (2) with the tissue establishment. An inspection may not be performed in facilities used for permanent housing. All documents requested by the inspector at the inspection that are necessary for carrying out the inspection must be presented to the inspector notwithstanding confidentiality provisions. The inspector must be provided with free copies of the documents necessary for carrying out the inspection as well as samples of the substances and products at the establishment

for further inspection. The inspector has also the right to take photographs during the inspection. The inspector keeps minutes of the inspection.

Section 20k (547/2007)
Orders issued at the inspection

The inspector carrying out the inspection referred to in section 20j may order that the defects that have been observed shall be remedied. The measures required on account of the order issued at the inspection must be undertaken immediately.

Section 20l (778/2009)
Charges

The Finnish Medicines Agency can charge a fee for the authorisation referred to in section 20b and the supervision referred to in section 20j.

Section 20m (778/2009)
Cancelling of authorisation and imposing a conditional fine

The Finnish Medicines Agency can cancel the authorisation of the tissue establishment for a fixed period or wholly if it can be judged from the inspections or control measures that the establishment or quality system does not fulfil the requirements laid down in the law.

The decision on cancelling the authorisation must be observed notwithstanding appeal.

The Finnish Medicines Agency may impose a conditional fine as laid down in the Act on Conditional Fines (1113/1990), if:

- 1) the conditions for granting authorisation are no longer met;
- 2) the tissue establishment has essentially acted against the provisions of this Act or the conditions linked to the authorisation or its activities otherwise seriously jeopardise the safety of tissues or cells: or
- 3) the measures referred to in section 20k have not been undertaken.

Chapter 6b (277/2013)
Provisions regarding the activities of donation hospitals and the transplantation centre

Section 20n (277/2013)
Donation hospitals and the organ transplantation centre

Provisions on the requirements set for the donation hospitals and the organ transplantation centre are laid down, besides this Act, in the Health Care Act (1326/2010) and the Specialised Medical Care Act (1062/1989).

The Finnish Medicines Agency keeps an updated list of the donation hospitals and the organ transplantation centre.

Provisions on organising and centralising the organ transplantations within highly specialised medical care are laid down by Government Decree.

Section 20o (277/2013)

Duties of the donation hospitals and the organ transplantation centre

The donation hospital must identify a potential donor of an organ, establish death, find out and record the deceased person's possible view, while living, on removal of his or her organs, see to it that the explanation referred to in section 9a is given to a near relative or other close person to the deceased person, assume responsibility for the care of the donor and perform the necessary further examinations regarding the organ's suitability for transplantation.

The organ transplantation centre must ensure that the quality and safety of the organ are appropriate. The centre is responsible for removing and transplanting the organ, and it accepts the donor and chooses the recipient. The centre must check before performing an organ transplantation that the organ and donor characterisation is appropriate and that the conditions of preservation, storage and transportation of the transported organs have been appropriate.

The organ transplantation centre must ensure the integrity of the organs during transport and a suitable transport time.

The Finnish Medicines Agency will issue further regulations on quality and safety requirements regarding the transport of organs.

Section 20p (277/2013)

Good practices regarding quality and safety

The activities of the donation hospitals and the organ transplantation centre must comply with updated and good operational principles and guidelines covering all stages of the chain from the donation of an organ to its transplantation or disposal in order to ensure:

- 1) the identity of the donor;
- 2) recording of the investigation of the donor's consent in accordance with section 3 or 9;
- 3) organ and donor characterisation;
- 4) that the personnel fulfils the requirements laid down in section 20q;
- 5) appropriate retention, preservation, storage, packaging, transport and labelling of the organ;
- 6) traceability of the organ;
- 7) complying with the provisions on protection of personal data;
- 8) exact, fast and reliable reporting of serious adverse events and adverse reactions;
- 9) control of serious adverse events and adverse reactions.

The Finnish Medicines Agency will issue further regulations on the good operational principles and guidelines as referred to in paragraph 1.

Section 20q (277/2013)

Personnel

The personnel involved in donation and transplantation activities must have adequate competence, training and expertise in view of the quality and scope of the activities needed for performing their duties. The donation hospitals and the organ transplantation centre must organise appropriate training for their personnel on a regular basis.

Section 20r (277/2013)

Quality requirements for the retention of organs

The person responsible for the medical procedures related to the retention of organs must be a physician.

The retention must be performed in operating theatres that have been designed and built and are maintained and used in accordance with appropriate requirements and the best medical practices.

The material and equipment used in retention must be managed in accordance with the relevant international, European Union and national legislation, standards and guidelines on sterilisation and medical devices.

Section 20s (277/2013)
Characterisation of the organ and the donor

There must be necessary information on the donor and the organ regarding suitability for donation prior to the transplantation.

The tests to obtain the information must be performed in a laboratory with adequate qualified, trained and competent personnel and appropriate facilities and devices.

Provisions on the required minimum data on donors and organs are laid down by Decree of the Ministry of Social Affairs and Health. Transplantations can be performed even where not all of the minimum data specified in the Decree is available if the expected benefits for the recipient outweigh the risks posed by incomplete data.

The Finnish Medicines Agency will issue further regulations regarding what data that is essential for the characterisation of the organ and donor should also be obtained.

Section 20t (277/2013)
Traceability

The organ transplantation centre must be able to specify each donation and the organ and recipient related to it and to trace all organs retained, distributed and transplanted in Finland from donor to recipient and vice versa.

The requirement for traceability also applies to all adequate information about products and materials that come into contact with such an organ.

Section 20u (277/2013)
Notifying of adverse events and adverse reactions

The organ transplantation centre must keep a list of all potential adverse events related to organs that may affect the quality and safety of the organs as well as of any serious adverse reactions that have come to its knowledge.

The donation hospitals must without delay notify the organ transplantation centre of all potential adverse events related to organs that may affect the quality and safety of the organs as well as of any serious adverse reactions that have come to its knowledge.

The organ transplantation centre must notify the Finnish Medicines Agency of any potential serious adverse events and serious adverse reactions related to the testing, characterisation, retention, preservation, storage and transport of organs that may affect the quality and safety of organs.

An organ that has been notified as referred to in this section may not be used until a written risk assessment has been made of it. Such an organ may be used if it can be assumed on the basis of the risk assessment that the benefits for the patient outweigh the harm caused by the transplantation to the patient.

Section 20v (277/2013)

Guidance and supervision of the donation hospitals and the organ transplantation centre

The general guidance and supervision of the organ transplantations of the donation hospitals and the organ transplantation centre are the duty of the National Supervisory Authority for Welfare and Health under the Ministry of Social Affairs and Health and the Regional State Administrative Agencies, as laid down in this Act or in any other law.

The guidance and supervision of the donation hospitals and the organ transplantation centre in regard to the testing, preservation, storage, packaging, transport and other processing of organs and the quality and safety requirements for these measures, reporting and control of serious adverse events and serious adverse reactions and the traceability requirements is the duty of the Finnish Medicines Agency under the Ministry of Social Affairs and Health.

The National Supervisory Authority for Welfare and Health, the Regional State Administrative Agencies and the Finnish Medicines Agency are entitled to obtain free of charge and notwithstanding confidentiality provisions such information from the donation hospitals and the organ transplantation centre, central and local government authorities, other public corporations, and corporations or institutions providing health and medical care services as is necessary for the supervision.

Section 20x (277/2013)

Inspection of the donation hospitals and the organ transplantation centre

For the supervision of compliance with this Act and the provisions and regulations issued in virtue of it the National Supervisory Authority for Welfare and Health, the Regional State Administrative Agencies and the Finnish Medicines Agency have the right to inspect the facilities and activities of the donation hospitals and the organ transplantation centre as well as the necessary documents.

The inspector must be allowed access to all facilities of the donation hospital and the organ transplantation centre, and notwithstanding confidentiality provisions to all the documents requested by the inspector that are necessary for carrying out the inspection. The inspector must be given free copies of the documents requested by him or her that are necessary for carrying out the inspection, as well as samples of the substances and products in the facilities for a more detailed separate inspection. The inspector has the right to take photographs during the inspection. No inspection may be carried out in facilities that are used for permanent housing.

The National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency or the Finnish Medicines Agency must deliver a copy of the minutes of the inspection within 30 days to the donation hospital and the organ transplantation centre. The inspection is

considered to have been concluded when a copy of the minutes has been communicated to those concerned.

The donation hospital and the organ transplantation centre must without delay initiate measures to remedy the defects observed during the inspection and notify the National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency or the Finnish Medicines Agency of the measures to be undertaken, the time schedule and details of them within 30 days from the date when the inspection report was communicated to the establishment.

Section 20y (277/2013)
Orders and coercive measures

The National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency or the Finnish Medicines Agency must forbid the donation hospital or the organ transplantation centre to pursue their activities if it can be judged from the inspection or some other supervisory measure that the establishment does not fulfil the requirements laid down in this Act.

The decision on prohibition must be observed notwithstanding appeal, unless the appeal authority otherwise orders.

The National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency or the Finnish Medicines Agency can give notice of a conditional fine as laid down in the Conditional Fine Act (1113/1990), if:

- 1) the donation hospital or the organ transplantation centre has essentially acted against the provisions of this Act or its activity otherwise seriously jeopardises the quality and safety of organs; or
- 2) the measures in accordance with the orders imposed in virtue of section 20x have not been undertaken.

Chapter 7
Miscellaneous provisions

Section 21
Definition of death

A person is considered to be dead when brain function has totally ceased.

Section 21a (689/2012)
Use of tissue samples for medical research

The National Supervisory Authority for Welfare and Health may grant a permit for use of tissue samples taken for therapeutic and diagnostic purposes for medical research. The preconditions are as follows:

- 1) the research is medically and socially significant;
- 2) the ethics committee referred to in the Medical Research Act has issued a favourable opinion on the matter;
- 3) the samples needed are not available from a biobank;
- 4) there are appropriate facilities, equipment and personnel for carrying out the research;
- 5) a physician responsible for the research has been designated;

6) the protection of privacy of the persons concerned is not endangered.

Detailed conditions to ensure the protection of privacy of the persons concerned can be appended to the permit.

The health care unit may surrender the samples referred to in the decision of the National Supervisory Authority for Welfare and Health to the physician responsible for the research if there is no reason to assume that the person would have objected to use of his or her samples for medical research.

Section 22 (778/2009)

Permits granted by the National Supervisory Authority for Welfare and Health

The National Supervisory Authority for Welfare and Health can grant the permit referred to in section 4(2) and section 5(2), if the preconditions for removal laid down in this Act have been met and removal of the organ, tissue or cells is justified in terms of the recipient's treatment.

The National Supervisory Authority for Welfare and Health grants the permit referred to in section 7(3), section 11 (1)(2), and section 19 (2) and (3), if the activity can be considered medically justified, there are appropriate facilities, equipment and personnel, and a responsible physician has been appointed for the activity. The National Supervisory Authority can grant a permit for a fixed or indefinite period, and more detailed conditions concerning how the activity is arranged can be appended to the permit. (689/2012)

Section 23 (778/2009)

Supervision of activities and withdrawal of permits granted by the National Supervisory Authority for Welfare and Health

The National Supervisory Authority for Welfare and Health can order the activities referred to in section 7(3), section 11, section 19(2) and (3), section 20(1), and section 21a to be suspended, or withdraw a permit granted for the activities referred to in the above provisions, if current provisions or permit conditions are not being observed in the activities. (689/1012)

If necessary, the National Supervisory Authority for Welfare and Health can order performance of an inspection of the facilities of an establishment that has been granted a permit, and of its activities referred to in paragraph 1 and of documents needed for supervisory purposes.

A decision to withdraw a permit must be complied with even if it has been appealed.

Section 23a (778/2012)

Import and export of tissues and cells

Tissues and cells may only be imported to Finland and exported from Finland by a tissue establishment that has been granted authorisation by the Finnish Medicines Agency. The cells to be imported or exported must comply with the requirements for quality, safety and traceability laid down in this Act.

In exceptional cases the Finnish Medicines Agency may grant a tissue establishment or other health care unit a permit to import or export certain tissues and cells.

Section 23b (277/2013)

Import and export of organs for the purpose of transplantation

Organs intended for transplantation may be imported to Finland and exported from Finland only by the organ transplantation centre referred to in this Act and a health care actor authorised by it.

Import of organs from countries outside the European Union and export to countries outside the European Union is allowed only if the organs can be traced from donor to recipient and vice versa, if they comply with the quality and safety requirements equivalent to those laid down in this Act and if the requirements laid down in section 14 (2) are being observed.

Section 24 (778/2013)

Further provisions and regulations (277/2013)

Further provisions on the preconditions for grant of the permits referred to in this Act and on enforcement of the Act will be issued by Government Decree.

The Ministry of Social Affairs and Health will issue further provisions and instructions by Decree, as necessary, concerning the following:

- 1) the arrangement of removal, retention, storage and use of organs, tissues and cells and tissue samples at health care units and other units;
- 2) compensation for the costs of health care units, other units and tissue establishments;
- 3) entries to be made in the organ and tissue transplantation registers referred to in section 16, the register of tissue establishments referred to in section 20i (1), the tissue establishment register of the Finnish Medicines Agency referred to in section 20i (5) and in patients' medical records;
- 4) any essential changes in activities that require modifying the authorisation granted by the Finnish Medicines Agency;
- 5) charges for the authorisation granted by the Finnish Medicines Agency and for the supervision carried out by the Agency, taking into account what is provided in the Act on Criteria for Charges Payable to the State (150/1992) and in virtue of it;
- 6) information on the traceability of organs, tissues and cells; (277/2013)
- 7) procedure for notification of adverse events and adverse reactions;
- 8) matters to be taken into account in particular in the inspection of donation hospitals, the transplantation centre and tissue establishments, more detailed content of the inspection procedure and its minutes, period of storage of the minutes and informing thereof; (277/2013)
- 9) exceptional situations in which the Finnish Medicines Agency may grant permit to import or export certain tissues or cells.

The Finnish Medicines Agency confirms by its regulation the format of the forms needed in the activities under the scope of application of this Act (277/2013):

The Finnish Medicines Agency may issue further regulations, as necessary, concerning the following:

- 1) the content of the quality system of tissue establishments and its implementation;
- 2) the criteria for selection of donors of tissues and cells;
- 3) tests required for examining the quality and safety of tissues and cells, and concerning acceptable results of them;

4) requirements for the quality and safety of tissues and cells, procurement and processing procedures, conditions and period of storage and conditions of distribution regarding tissues and cells.

Section 25 (547/2007)

Penal provisions

Whosoever knowingly

- 1) removes, retains or stores organs, tissues or cells without the consent or permit laid down in this Act;
- 2) surrenders removed, retained or stored organs, tissues, cells or tissue samples or uses them without the consent, permit or request laid down in this Act;
- 3) procures, tests, processes, preserves, stores or distributes tissues or cells without an authorisation or agreement with a tissue establishment as laid down in this Act;
- 4) fails to inform about serious adverse events and adverse reactions regarding organs, tissues and cells; (277/2013)
- 5) fails to keep the personal register needed to supervise the traceability and safety of organs, tissues and cells or activities as laid down in this Act;
- 6) uses for human treatment or otherwise for human application organs, tissues or cells or products made of them whose origin is unknown or whose safety has not been established;
- 7) imports into Finland organs, tissues or cells that have been removed or retained contrary to the preconditions on donors laid down in this Act, or imports into Finland organs, tissues or cells from states whose legislation does not meet the preconditions laid down in this Act regarding the removal and traceability of organs, tissues and cells; or
- 8) promises or pays an organ donor or his or her assignee a fee for removal of organs, tissues or cells, shall be sentenced to a fine *for violation of the provisions on medical use of human organs, tissues and cells*, unless more severe punishment is provided for the act elsewhere in the law. The act referred to in paragraph 1 (5) above is also punishable if it occurred through gross negligence.

Section 26 (778/2009)

Appeal

Decisions by an inspector referred to in section 20k cannot be appealed. The party concerned may submit a written claim for rectification to the Finnish Medicines Agency within 30 days of service of the decision. The processing of the claim for rectification is otherwise subject to the provisions of the Administrative Procedure Act (434/2003). Bringing a claim for rectification does not hinder the implementation of the inspector's decision.

Decisions by the National Supervisory Authority for Welfare and Health and the Finnish Medicines Agency can be appealed as provided in the Administrative Judicial Procedure Act (586/1996).

Decisions by the National Supervisory Authority for Welfare and Health referred to in sections 4 and 5 of this Act cannot be appealed.

Chapter 8

Entry into force

Section 27

22

Implementing and transitional provisions

This Act enters into force on 1 September 2001.

This Act repeals the Act of 26 April 1985 on the removal of human organs and tissues for medical purposes (355/1985) with later amendments.

The authorisations required in this Act must be applied for within one year of the Act's entry into force.

Measures necessary for the implementation of this Act can be undertaken before its entry into force.

Entry into force and application of the latest amended Acts:

689/2012:

This Act enters into force on 1 September 2013.

In virtue of section 20 (1) that was in force at the entry into force of this Act, the National Supervisory Authority for Welfare and Health can grant a permit to surrender and use tissue samples on the conditions referred to in the Act until 1 January 2018, if samples needed for medical research are not available from a biobank.

277/2013:

This Act enters into force on 1 May 2013.

Directive 2010/53/EU of the European Parliament and of the Council (32010L0053)