

THE CELL, TISSUE AND ORGAN RECOVERY, STORAGE AND TRANSPLANTATION ACT ¹⁾²⁾

of July 1st, 2005

(the Official Journal of Acts *Dziennik Ustaw* 05.169.1411, as amended)

Chapter 1 General Regulations

Article 1

1. This Act defines rules of:

1) the recovery, storage and transplantation of cells, including bone-marrow haematopoietic cells, peripheral blood and umbilical cord blood cells, tissues and organs from living donors or cadavers;

2) the testing, processing, storage and distribution of human cells and tissues.

2. The regulations of the present Act shall not apply to:

1) a recovery, transplantation of gametes, gonads, embryonal and fetal tissues, and reproductive organs or parts of these;

2) a recovery, storage and distribution of blood for transfusion purposes, its components separation or processing into medicines.

3. The regulations of the Code of Administrative Procedure shall apply to all permits referred to in this Act, in the extent not governed by it.

Article 2

1. Definitions. For the purpose of this Act:

1) 'tissue and cell bank' means organizational unit that is handling gathering, processing, sterilization, storage and distribution of tissues and cells. Units of that type may also recover and test tissues and cells;

2) 'donor' means living donor or human cadaver from which are being recovered cells, tissues or organs;

3) 'donation' means donating human cells, tissues or organs intended for use in human beings;

4) 'distribution' means transportation and delivery of tissues, cells or organs intended for use in human beings;

5) 'serious undesirable event' means unforeseen event associated with a recovery, processing, testing, storage, distribution and transplantation of cells, tissues or organs, which leads to a transmission of communicable disease, a threat to life or death, causes a body injury, deteriorates health state or may bring about a need for hospital treatment or a prolongation of such treatment;

6) 'serious undesirable reaction' means unforeseen reaction of an organism of an donor or recipient associated with a recovery or use of cells, tissues or organs in human beings, which causes a threat to life or death, a body injury, a deterioration of health state in human beings or may result in hospital treatment

or prolongation of such treatment or brings about a transmission of communicable disease;

7) 'cell' means smallest morphological and functional structure of an organism that is able to carry on basic vital activities, occurs individually or in groups and is not connected with itself through connective tissue;

8) 'preservation' means use of chemical agents, alteration of environmental factors or other factors during processing in order to prevent or delay biological or physical degradation of cells, tissues or organs;

8a) recovery and transplantation coordination – arrangements on the time, place, recovery method, supervision over the course of this process, method of transfer, transport and acceptance of cells, tissues or organ in a health care institution or tissue and cell bank and their delivery to a recipient, by an authorized employee;

8b) cell, tissue and organ recovery and transplantation coordinator – an authorized and trained employee organizing recovery and transplantation coordination;

8c) acceptance criteria – quantitative and qualitative limits, scopes or other appropriate measurements allowing to accept test results;

8d) critical moment – a stage of the process, conditions of the process, required tests or other relevant parameters or elements likely to influence the quality and safety of materials having direct contact with cells, tissues or organ which must be controlled on a basis of determined acceptance criteria;

9) 'organ' means separate and essential part of human body, which structures different tissues, is able to maintain its structure, blood supply and a capability of carrying on independent physiological activities;

10) 'recovery' means doings resulting in recovery of cells, tissues or organs for diagnostic, therapeutic, research or didactic purposes;

11) 'storage' means keeping cells, tissues and organs under appropriately controlled conditions till their distribution and use in human beings;

12) 'processing' means all doings related to preparation, transportation, preservation and packaging of cells, tissues and organs intended for use in human beings;

12a) standard operation procedures – written instructions describing the course of specific processes together with the characteristics of used materials and methods as well as expected results of these processes;

13) 'sterilization' means use of chemical reagents, biological agents and physical agents aimed at neutralizing pathogens in cells and tissues;

13a) quality assurance system – the organizational structure, procedures, processes and resources having an indirect or direct influence of achieving and maintaining the high quality;

14) 'testing' means doings consisting in conducting investigations aimed at determining an usefulness of cells, tissues and organs for transplantation in human beings;

15) 'tissue' means group of cells with specialized functions that are interconnected through intercellular substance;

15a) process validation – a documented activity aimed at demonstrating that the process conducted within the determined scope of parameters is efficient and repeated and meets determined acceptance criteria;

16) 'use in human beings' means use of cells, tissues or organs for human recipients and use outside human organisms;

17) 'living donor' means person from whom are taken cells, tissues or an organ

2. Whenever the act refers to the European Union Member States, it is understood also as the European Free Trade Association (EFTA) Member States – parties to the European Economic Area Agreement.

Article 3

1. It is not allowed to demand or accept payment, other financial or personal benefit for cells, tissues or organs recovered from a donor.

2. The repayment of costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs recovered from a donor is not a payment and does not constitute any financial or personal benefit within the meaning of paragraph 1.

3. The costs of cell, tissue and organ recovery include the costs of:

1) recovery coordination;

2) tests and issuance of medical opinions on their basis;

3) identification of a potential donor;

4) qualification of a potential recipient;

5) collective establishing a diagnosis of permanent, irreversible cessation of brain activity in a way specified in art. 9 par. 4;

6) hospitalization of a potential donor, from establishing a diagnosis of permanent, irreversible cessation of brain activity to organ recovery, together with activities consisting in maintaining organ activities;

7) laboratory tests prior to cell, tissue or organ recovery;

8) tests qualifying organs for transplantation, after recovery from a donor;

9) procedure of cell or tissue recovery;

10) tests qualifying cells or tissues for transplantation, after recovery from a donor;

11) procedure of organ recovery, including the costs incurred by a health care institution where:

a) organ or organs were recovered,

b) recovered organ or organs were transplanted.

4. The costs of recovery of bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood, apart from the costs specified in par. 3 items 1-4, 7 and 9, include the costs of:

- 1) transport of a potential donor to a health care institution where bone marrow and haematopoietic cells of peripheral blood are to be recovered and of a potential donor or donor from this health care institution;
- 2) hospitalization of a donor at a health care institution related to recovery of bone marrow and haematopoietic cells of peripheral blood;
- 3) storage and processing of bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood;
- 4) transport of recovered and processed bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood to a health care institution where transplantation has to be done;
- 5) costs incurred by a bone marrow donor centre in relation with providing bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood.

5. The costs of cell or tissue recovery from cadavers, apart from the costs specified in par. 3 items 1-4, 7, 9 and 10, include the costs of:

- 1) transport of cells or tissues from a health care institution, forensic medicine department, anatomical pathology department of a medical academy and university that has a medical faculty, medical research and development unit and funeral parlour having a dissection room to a tissue and cell bank;
- 2) personal, material and organizational costs required for cell or tissue recovery;
- 3) testing, processing, preservation, sterilization, storage and distribution of cells and tissues.

6. The costs of recovery from a living donor of regenerating cells or tissues, other than bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood, apart from the costs specified in par. 3 items 1-4, 7 and 9, include the costs of:

- 1) transport of a potential donor to a health care institution where recovery has to be done or to a health care institution where transplantation has to be done and of a potential donor or donor from these health care institutions;
- 2) hospitalization of a potential donor at a health care institution related to recovery;
- 3) storage and processing of recovered cells or tissues;
- 4) transport of recovered cells or tissues from a health care institution to a tissue and cell bank;
- 5) culture of recovered cells or tissues;
- 6) transport of recovered cells or tissues to a health care institution where transplantation has to be done.

7. The costs of organ recovery from a living donor, apart from the costs specified in par. 3 items 1-4, 7 and 11, include the costs of:

- 1) transport of a potential living donor to a health care institution where recovery has to be done or to a health care institution where transplantation has

to be done and of a potential living donor or living donor from these health care institutions

2) preparation of a potential living donor for recovery;

3) transport of a recovered organ to a health care institution where transplantation has to be done;

4) treatment of a living donor after organ recovery.

8. The costs of transplantation of organs, bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood include the costs of:

1) transplantation coordination;

2) transport of a potential recipient to a health care institution where transplantation has to be done;

3) identification and qualification of a potential recipient for transplantation;

4) performance of a transplantation procedure;

5) post-transplantation treatment, for a period laid down in the provisions on health care services financed from public funds.

9. The repayment of the costs specified in par. 3 items 6, 7 and 11, letter a is made by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues or by the National Health Fund, pursuant to the provisions on health care services financed from public funds. The costs are repaid on a basis of an invoice issued by a health care institution which recovered an organ.

10. The repayment of the costs specified in par. 3 items 8 and 11, letter b is made by a health care institution to which an organ was delivered for transplantation purposes, on a basis of an invoice issued by a health care institution which recovered an organ.

11. The repayment of the costs specified in par. 3 item 9 and in pars. 5 and 6 is made by a tissue and cell bank, on a basis of an invoice issued by an entity, referred to in art. 36 par. 1 item 1 or 3, which recovered cells or tissues.

12. A health care institution is repaid the costs specified in:

1) par. 3 items 1-5 – by the National Health Fund,

2) pars. 4, 7 and 8 - by the National Health Fund or the minister competent for health

- according to an agreement for providing health care services concluded pursuant to the provisions on health care services financed from public funds.

13. The costs, referred to in par. 3 item 10, are the activity costs of a tissue and cell bank.

14. The minister competent for health shall determine, by way of an ordinance, a detailed method of determining the costs of activities related to recovery, storage, processing, sterilization and distribution of cells, tissues and organs, taking into consideration the procedures connected with performance of these activities.

Chapter 2

Recovery of cells, tissues or organs from human cadavers

Article 4

1. It is allowed to recover cells, tissues and organs from human cadavers for diagnostic, therapeutic, research or didactic purposes.
2. It is allowed to recover cells, tissues or organs also during postmortem examinations that are being performed on the basis of separate regulations.

Article 5

1. If a deceased person did not express objection, when alive, it is allowed to recover cells, tissues, or organs from such person human cadaver for transplantation purposes.
2. A legal representative of a living minor or other person, which don't has a full legal capacity, may state an objection for such individual.
3. Minors above 16 years old may state an objection themselves.
4. The regulations of paragraph 1-3 shall not be observed in case of recovery of cells, tissues and organs performed in order to diagnose a cause of death and assess a treatment management during postmortem examinations.

Article 6

1. These objections shall be stated in the form of:
 - 1) an registration of an objection to recover cells, tissues and organs from one's own human cadaver in the Central Objection Register;
 - 2) a written statement with affixed one's own signature;
 - 3) an oral statement made in the presence of at least two witnesses and confirmed by these witnesses in writing.
2. The regulations of paragraph 1 shall be observed too with regard to objections stated by legal representatives.
3. An objection stated by one legal representative or a person referred to in article 5, paragraph 3, shall be effective in relation to the other ones.
4. It is allowed to withdraw an objection at any time in the forms referred to in paragraph 1.

Article 7

1. With the purpose of registering, storing and rendering accessible an entry referred to in article 6, paragraph 1, item 1, and applications for cancelling an objection registration shall be established a central register of objections to recover cells, tissues and organs from one's own human cadavers, hereinafter named "Central Register of Objections".
2. A person concerned in an objection or a legal representative of such a person shall be immediately notified by registered mail about a made

registration or registration cancellation in the Central Register of Objections.

3. In the Central Register of Objections shall be entered the following data about a person concerned in a objection:

- 1) name and surname;
- 2) date of birth and place of birth;
- 3) PESEL (state identification number) number, if relevant;
- 4) address and permanent residence;
- 5) date of drawing up an objection or its withdrawal and the place where this has been done;
- 6) date of objection reception or date of reception of an application for objection cancellation.

4. In the circumstances referred to in article 5, paragraph 2, shall be entered also data stated in paragraph 3, item 1-3, about the legal representative in the Central Register of Objections.

5. The data referred to in paragraph 3 and 4 shall be stored for a period of 5 years from the date of death of a person concerned in a objection and after this period shall be destroyed in a manner, which makes an identification of that person impossible.

6. The information about an objection registration in the Central Register of Objections shall be imparted immediately after receipt of an inquiry from a doctor who intends to perform a recovery or a person authorized by the doctor.

7. The Central Register of Objections shall be managed by the “Poltransplant” - Organization and Co-ordination Center for Transplantation Issues.

8. The minister competent to do with health matters in consultation with the Minister of Justice shall by means of a decree state the manner of running the Central Register of Objections and the manner of confirming a registration entry in this register, taking a possibility of running this register in electronic form into account.

Article 8

1. In case of reasonable suspicion of a death resulting from of an illicit act that is a crime, it is allowed to recover cells, tissues and organs after receiving an information that a competent public prosecutor has no objection to an intention of recovering cells, tissues and organs, and in case of legal proceedings against a minor – after receiving an opinion of a Family Court.

2. The Minister of Justice in consultation with the minister competent to do with health matters shall by means of a decree state the manner and course of obtaining the information or opinion referred to in paragraph 1, particularly taking the evidential proceedings requirements and the proceedings course in cases of great urgency into consideration.

Article 9

1. A recovery of cells, tissues or organs for transplantation is admissible

after establishing a diagnosis of permanent, irreversible cessation of brain activity (brain death).

2. The criteria and procedure of establishing a diagnosis of permanent, irreversible cessation of brain activity shall state regarding the up-to-date medical knowledge specialists in relevant fields of medicine, appointed by the minister competent to do with health matters.

3. The minister competent to do with health matters shall by way of an announcement in the Official Journal "Monitor Polski" of the Republic of Poland publish the criteria and procedure of establishing a diagnosis of permanent, irreversible cessation of brain activity.

4. A board consisting of three doctors who have a specialization, and consisting at least of one specialist in anaesthesiology and intensive therapy and one specialist in neurology or neurosurgery, is establishing unanimously a diagnosis of permanent, irreversible cessation of brain activity on the grounds of the criteria referred to in paragraph 3.

5. A manager of a health care institution or a person authorized by the manager shall set up the board referred to in paragraph 4 and institute its chairman.

6. Physicians who are members of the board referred to in paragraph 4 shall not be allowed to participate in a procedure of recovery and transplantation of cells, tissues or organs from a deceased person for whom the board established a diagnosis of permanent, irreversible cessation of brain activity.

Article 9a

1. Recovery of cells, tissues or organs for transplantation is admissible after establishing a diagnosis of death due to irreversible cessation of blood circulation.

2. A physician establishing a diagnosis of death due to irreversible cessation of blood circulation may not participate in a procedure covering recovery and transplantation of cells, tissues or organs from a dead person whom he/she diagnosed dead due to irreversible cessation of blood circulation.

3. The minister competent for health shall publish, by way of an announcement, in the Official Journal "Monitor Polski" of the Republic of Poland the criteria and procedure of establishing a diagnosis of irreversible cessation of blood circulation.

Article 10

Before performing a recovery of cells, tissues or organs from a deceased person, a physician or a person authorized by the physician shall:

1) inquire, whether an objection has been submitted in the form stated in article 6, paragraph 1, item 1;

2) on the basis of accessible information or documents confirm, whether an objection has been submitted in the forms referred to in article 6, paragraph 1, item 2 and 3.

Article 11

A physician recovering cells, tissues or organs from a deceased person is under an obligation to ensure an appropriate appearance of the cadaver.

Chapter 3

Recovery of cells, tissues or organs from living donors

Article 12

1. It is allowed to recover cells, tissues or organs from a living donor with the aim of transplanting them to another person on condition that the following requirements are met:

- 1) the recovery shall take place for the benefit of a linear relative, brothers and sisters, an adopted person, a wife or husband, and with the reservation of article 13, for the benefit of another person in the event of special personal reasons giving grounds for such conduct;
- 2) it is allowed to recover bone marrow or other regenerating cells or tissues also for the benefit of a person who is different from those persons mentioned in item 1;
- 3) the justification and usefulness of a recovery of cells, tissues or organs from a donor on the basis of up-to-date medical knowledge shall determine physicians who transplant these to a specified recipient;
- 4) a recovery shall precede necessary medical examinations, which determine, whether the risk involved in the procedure does not exceed the expected range that is admissible for such kind of procedures and does not impair substantially the health state of a donor;
- 5) a person who has to become a donor, before consenting, should be informed in writing about the type of procedure, the risk associated with this procedure and the predictable consequences to one's own health state in the future by the physician who carries out the procedure and by another physician who is not directly involved in the recovery of cells, tissues or an organ;
- 6) for a pregnant woman it is allowed to become only a donor of cells and tissues; in this circumstances shall be determined the risk referred to in item 4 and 5 also with regard to the child due to be born, with a participation of a specialist in gynaecology and obstetrics and a neonatologist;
- 7) a person who has to become a donor should have a full legal capacity and voluntarily before a physician consent in writing to a recovery of cells, tissues or an organ with the aim of transplanting them to a specified recipient; the requirement for specifying the recipient of a transplant is not pertinent to a recovery of bone marrow or other regenerating cells or tissues;
- 8) a person who has to become a donor, before consenting, should be informed about the consequences of withdrawing the consent to a recovery of cells, tissues or an organ for the recipient, which are connected with the last phase of

recipient preparation for transplantation of these;

9) a person who has to become a recipient should be informed about the risk involved in procedures of recovery of cells, tissues or an organ and the possible consequences of a recovery to the donor's health state and should also consent to an implantation of cells, tissues or an organ to one's own body from a specified donor; the requirement for consenting to a transplantation to one's own body from a specified donor does not apply to bone marrow or other regenerating cells and tissues.

2. In case of immediate danger of dying, which is unavoidable unless a transplantation of bone marrow or peripheral blood hematopoietic cells will be performed, it is allowed for a minor to become a donor to one's own siblings unless it shall not result in predictable impairments of the donor's organism efficiency.

3. It is allowed to recover bone marrow or peripheral blood hematopoietic cells from a minor who does not have a full legal capacity with a consent of a legal representative of the minor after receiving an approval of the guardianship court appropriate for the permanent residence of the minor who has to become a donor. If a minor above 13 years old has to become a donor of bone marrow, then a consent given by the minor is required too.

4. The Court rules upon an application submitted by the legal representatives of a minor who has to become a donor after examining the minor and asking a competent psychologist for an opinion, and in case of minors above 16 years old – also upon an application from the minor. An expert medical opinion stating that a recovery of bone marrow shall not result in predictable impairments of the donor's organism should be annexed to the application.

5. An examination of the application referred to in paragraph 4 shall be made in seven days.

6. The minister competent to do with health matters shall by way of a decree state the health requirements, which a person who has to become a donor should meet; the list of the medical examinations and auxiliary diagnostic tests, which a person who has to become a donor of cells, tissues or an organ should undergo; and the contraindications to cell, tissue or organ donation, taking the health state of a living donor into account.

Article 13

1. In proceedings without lawsuit after examining the applicant and taking cognizance of an opinion of the Committee of Ethics of the National Transplantation Council the district court appropriate for the donor's permanent residence or temporary stay shall give an approval, required to perform a recovery of cells, tissues or an organ from living donors for the benefit of a person who is not a linear relative, a sibling, an adopted person or a spouse.

2. The regulation in paragraph 1 does not apply to bone marrow and other regenerating cells and tissues.

3. The court shall institute proceedings upon an application submitted by a person who has to become a donor. To the application should be annexed:
- 1) a written recipient's consent to recover cells, tissues or an organ from a specified donor;
 - 2) an opinion of the Committee of Ethics of the National Transplantation Council;
 - 3) an opinion on the justification and usefulness of the procedure given by the head of the team of physicians, which has to perform the transplantation;
 4. An examination of the application referred to in paragraph 3 shall be made in seven days.

Article 14

The proceedings in causes referred to in article 12, paragraph 3 and article 13, are free of law-cost.

Article 15

1. A central register of living organ donors, hereinafter named "Register of Living Donors", shall be established in order to monitor and evaluate adequately the health state of living donors, from whom have been recovered organs for a transplantation.
2. In the Register of Living Donors shall be entered the following data:
 - 1) name and surname of a living donor;
 - 2) date and place of birth of a living donor;
 - 3) permanent residence of a living donor;
 - 4) PESEL (state identification number) number of a living donor, if relevant;
 - 5) date and place of recovery;
 - 6) recovered organ;
 - 7) name and address of the health care institution, where has been performed the recovery;
 - 8) name and surname of the physician, who performed a recovery;
 - 9) other essential medical information.
3. A health care institution, where has been performed a recovery, shall without delay transfer the data referred to in paragraph 2 to the Register of Living Donors.
4. The data referred to in paragraph 2 shall be made accessible to the minister competent to do with health matters and the National Transplantation Council.
5. The Register of Living Donors shall be managed by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues.

Article 16

1. A central register of not related potential donors of bone marrow and cord blood, hereinafter referred to as the "register of bone marrow and cord blood"

shall be established in order to enable bone marrow, peripheral blood hematopoietic cells and cord blood transplantations from not related donors.

1a. The register of bone marrow and cord blood is a database on potential donors of allogeneic bone marrow, hematopoietic cells of peripheral blood and cord blood.

2. The register of bone marrow and cord blood is made up of two sections:

1) register of potential donors of bone marrow and hematopoietic cells of peripheral blood;

2) register of cord blood.

3. In the register, referred to in par. 2, item 1, the following data on a potential donor of bone marrow and hematopoietic cells of peripheral blood shall be entered:

1) name and surname;

2) date and place of birth;

3) address of permanent residence;

4) PESEL (state identification number), if relevant;

5) information of histocompatibility antigens;

6) indication of an entity which performed a test of histocompatibility antigens;

7) other essential medical information;

4. In the register referred to in paragraph 2, item 2, shall be entered the following data:

1) designation of the collected cord blood sample;

2) date and place of collection;

3) information about the histocompatibility antigens (HLA);

4) tissue and cell bank, where the sample is being stored;

5) other essential medical information.

5. The data, referred to in pars. 3 and 4 are immediately delivered by health care institutions and foundations, referred to in art. 16a par. 1 or by tissue and cell banks to the register of bone marrow and cord blood.

6. The data referred to in paragraph 3 and 4 shall be made accessible to the minister competent to do with health matters and the National Transplantation Council.

7. The “Poltransplant” - Organization and Coordination Center for Transplantation Issues shall manage the Register of Bone Marrow and Cord Blood.

8. The minister competent to do with health matters shall by way of a decree state the manner of keeping the register referred to in paragraph 1 taking the necessity of transplantation results assessment and the possibility of keeping the register in electronic form into consideration.

Article 16a

1. The activities consisting in recruitment of donors of allogeneic bone marrow and hematopoietic cells of peripheral blood may be performed by health care

institutions or foundations, hereinafter referred to as "bone marrow donor centres", after obtaining a permission from the minister competent for health.

2. The tasks of a bone marrow donor centre include, in particular:

- 1) recruitment of potential donors of allogeneic bone marrow and hematopoietic cells of peripheral blood;
- 2) testing histocompatibility antigens or commissioning appropriate entities to perform this testing;
- 3) storage of the data, referred to in par. 8 and their update, taking into consideration a possibility of storing them in an electronic format;
- 4) organizing care of donors of allogeneic bone marrow and hematopoietic cells of peripheral blood;
- 5) immediate delivery of the data on potential donors of allogeneic bone marrow and hematopoietic cells of peripheral blood to the register of bone marrow and cord blood;
- 6) providing bone marrow and hematopoietic cells of peripheral blood to national or foreign centres dealing with transplantation of bone marrow and hematopoietic cells of peripheral blood;
- 7) cooperation with other bone marrow donor centres and centres dealing with transplantation of bone marrow and hematopoietic cells of peripheral blood

3. Substantive supervision over the activity of bone marrow donor centres is exercised by the national consultant in the field of hematology in agreement with the national consultant in the field of clinical immunology.

4. The tasks, referred to in par. 2, are performed by persons who have medical, biological or biotechnological university education and completed the training, referred to in art. 40a par.1.

5. The task, referred to in par. 2 item 2, is also financed from the funds of the "Poltransplant" - Organization and Coordination Center for Transplantation Issues, according to an agreement.

6. A bone marrow donor centre concludes with an entity whose activity influences the quality and safety of bone marrow and hematopoietic cells of peripheral blood a written agreement with regard to medical examinations and tests of histocompatibility antigens which it does not perform on its own. The provisions of art. 31 pars. 2 and 3 shall apply respectively.

7. A bone marrow donor centre concludes with a health care institution authorized to perform these activities a written agreement for recovery from potential donors of bone marrow and hematopoietic cells of peripheral blood.

8. With regard to performance of the task, referred to in par. 2 item 1, a bone marrow donor centre collects the data of potential donors of bone marrow and hematopoietic cells of peripheral blood which include:

- 1) name and surname;
- 2) date and place of birth;
- 3) address of permanent residence;
- 4) PESEL (state identification number), if relevant;

- 5) information of histocompatibility antigens;
 - 6) indication of an entity which performed a test of histocompatibility antigens;
 - 7) other essential medical information;
9. A bone marrow donor centre retains the documentation of potential donors of bone marrow and hematopoietic cells of peripheral blood for at least 30 years from the day of setting up the documentation of a potential donor of bone marrow and hematopoietic cells of peripheral blood, in a way enabling identification of a potential donor of bone marrow and hematopoietic cells of peripheral blood.
10. The minister competent for health shall determine, by way of an ordinance:
- 1) method of organization of a bone marrow donor centre,
 - 2) method of recruitment and examination of potential donors of bone marrow and hematopoietic cells of peripheral blood,
 - 3) procedure of testing histocompatibility antigens or commissioning relevant entities to perform this testing,
 - 4) method of dealing with the documentation of potential donors of bone marrow and hematopoietic cells of peripheral blood,
 - 5) procedure of making bone marrow and hematopoietic cells of peripheral blood available,
 - 6) conditions of transporting test samples from potential donors of bone marrow and hematopoietic cells of peripheral blood,
 - 7) method and conditions of organizing care of donors of bone marrow or hematopoietic cells of peripheral blood,
 - 8) procedure of delivering the data, referred to par. 8, to the register of bone marrow and cord blood,
 - 9) standard operation procedures valid in a bone marrow donor centre
- considering, in particular, proper performance of the tasks, referred to in par. 2 and assurance of the donors and recipients safety.

Article 16b

1. A bone marrow donor centre obtains the permission, referred to in 16a par. 1, if it collectively meets the following conditions:
- 1) is located in rooms protected against the loss of personal data of potential donors of bone marrow and hematopoietic cells of peripheral blood;
 - 2) head of a bone marrow donor centre is a physician who is a specialist in clinical transplantology, clinical transfusiology, hematology or oncology and paediatric hematology;
 - 3) has and applies standard operation procedures, referred to in art. 16a par. 10 item 9;
 - 4) employs persons having qualifications referred to in art. 16a par. 4.
2. The permission, referred to in art. 16a par. 1, is granted by the minister competent for health upon request of the National Centre for Tissue and Cell Banking, after giving an opinion by the National Transplantation Council.

3. To granting the permission, referred to in art. 16a par. 1, the provisions of art. 26 pars. 2, 4, 6 item 1 and 3-7, pars. 7 and 8 and art. 27 pars. 1-5 shall apply respectively.

Article 16c

1. In health care institutions performing transplantations of organs or bone marrow, hematopoietic cells of peripheral blood and umbilical cord blood, centres qualifying for transplantation may operate, hereinafter referred to as "qualifying centres".

2. The tasks of a qualifying centre include, in particular:

- 1) registration of potential recipients reported by health care institutions other than health care institutions referred to in par. 1 or by dialysis centres;
- 2) confirmation of reporting a potential recipient;
- 3) collection of the data, referred to art. 17 par. 3.

3. In a qualifying centre, the head of a health care institution, referred to in par. 1, appoints a team composed of physicians responsible for qualifying of potential recipients for transplantation, hereinafter referred to as the "team".

4. The team is composed of, at least:

- 1) one physician who is a specialist in clinical transplantology;
- 2) one physician who is a specialist in surgery or paediatric surgery, hematology, vascular surgery, cardiosurgery or clinical oncology or oncology and paediatric hematology or urology.

5. In addition, other specialists as well as representatives of other scientific fields may be appointed to the team.

6. The works of the team are managed by a physician who is a specialist in clinical transplantology, appointed by the head of a health care institution, referred to in par. 1.

7. The tasks of the team include:

- 1) evaluation of potential recipients preliminarily qualified by health care institutions other than health care institutions referred to in par. 1 or by dialysis centres;
- 2) qualifying a potential recipient for transplantation;
- 3) conduction of specialist consultations in potential recipients in cases requiring additional tests or their verification;
- 4) commissioning specialist qualification tests to be performed, in particular:
 - a) tissue typing,
 - b) level of antibodies,
 - c) specialist consultations and instrumental tests.

8. The tasks, referred to in par. 2, par. 7 items 1-3 and item 4 letter c, are financed by the National Health Fund under an agreement for providing health care services and the tasks, referred to in par. 7 item 4 letter a and b – by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues, according to an agreement.

9. Substantive supervision over the activity of centres qualifying potential recipients of organs is exercised by the national consultant in the field of clinical transplantology and of centres qualifying potential recipients of bone marrow or hematopoietic cells of peripheral blood and umbilical cord blood – by the national consultant in the field of hematology.

10. The minister competent for health shall determine, by way of an ordinance, the method of operation of qualifying centres and the method of qualifying a potential recipient, taking into consideration the health safety of potential recipients and proper performance of the tasks referred to in par. 2.

Article 17

1. A potential recipient qualified for transplantation of bone marrow, cells or organs is entered in the national list of persons waiting for transplantation, hereinafter referred to as the "list".

2. The entry of the data, referred to in par. 3, in the list is made by a physician managing the team referred to in art. 16c par. 3.

3. The entry contains the following data:

- 1) name and surname of a potential recipient;
- 2) date and place of birth of a potential recipient;
- 3) permanent residence or address for correspondence of a potential recipient;
- 4) PESEL (state identification number) number of a potential recipient, if relevant;
- 5) medical diagnosis;
- 6) blood group and Rh factor of a potential recipient;
- 7) type of planned transplantation;
- 8) urgency of transplantation according to medical criteria valid for a given type of transplantation;
- 9) name, surname and place of practice of a physician who made the entry;
- 10) other essential medical information.

4. Entering in the list is a condition of transplant obtainment by a recipient.

5. Selection of a potential recipient is made on the basis of medical criteria specified in the provisions issued pursuant to par. 8.

6. The data, referred to in par. 3, are made available to the minister competent for health and to the National Transplantation Council.

7. The list is managed by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues.

8. The minister competent for health shall determine, by way of an ordinance:

- 1) the method and procedure of creating and keeping the list,
 - 2) medical criteria and method of selection of a potential recipient,
 - 3) method of informing potential recipients of their entry position in the list
- taking into consideration the up-to-date medical knowledge and maintenance of equal access to transplantation procedures as well as a possibility of keeping the list in an electronic form.

Article 18

1. A National Register of Transplantations, hereinafter named “Register of Transplantations” shall be established in order to monitor adequately transplantations of cells, tissues and organs.
2. In the Register of Transplantations shall be entered the following data:
 - 1) name and surname and permanent residence of a transplant recipient;
 - 2) date and place of birth of a transplant recipient;
 - 3) PESEL (state identification number) number of a transplant recipient, if relevant;
 - 4) date of transplantation;
 - 5) type of transplanted cells, tissues or organs;
 - 6) name and address of the health care institution, where has been performed the transplantation;
 - 7) information about the survival of the recipient and transplant in the period of 3 and 12 months after the transplantation and then every 12 months till the transplant failure or the death of the transplant recipient.
3. The health care institution, which currently is taking care of the transplant recipient shall transfer the data referred to in paragraph 2.
4. The data referred to in paragraph 2 shall be made accessible to the minister competent to do with health matters and the National Transplantation Council.
5. The “Poltransplant” - Organization and Coordination Center for Transplantation Issues shall manage the Register of Transplantations.
6. The minister competent to do with health matters shall by way of a decree state the manner of managing the register referred to in paragraph 1, taking the necessity of transplantation results assessment and the possibility of keeping the register in electronic form into account.

Article 19

1. Personal data of a potential donor, donor, potential recipient and recipient are confidential and subject to protection provided for in the provisions on professional and business secrecy and in the provisions on the medical documentation kept by health care institutions.
2. If an organ is to be recovered from a living donor, the provision of par. 1 does not apply to disclosure of personal data on a donor and recipient to these persons respectively.

Chapter 4

Special methods of recovery and transplantation of cells, tissues and organs

Article 20

1. It is allowed to transplant for therapeutic purposes cells, tissues or organs recovered from animals to humans beings.

2. In case of the transplantations referred to in paragraph 1 shall be required a positive opinion given by the National Transplantation Council.
3. To transplantations referred to in paragraph 1 shall apply the regulations on medical experiments.

Article 21

It is allowed to recover cells, tissues or organs with the aim of transplanting them from organs or parts of organs, which were removed for reasons that differ from a recovery of cells, tissues or organs, after obtaining a consent to their use from the donor or a legal representative of the donor.

Chapter 5

Donation of cells, tissues and organs or their parts

Article 22

1. A donor of bone marrow or other regenerating cells and tissues is entitled to use the title of "Transplant Donor".
2. The health care institution, where have been recovered bone marrow or other regenerating cells or tissues, shall issue a badge and identity card, which confirm an entitlement to use the title of "Transplant Donor".
3. A transplant donor who donated bone marrow or other regenerating cells and tissues more than once and an organ donor are entitled to use the title of "Transplant Donor Worthy".
4. The minister competent to do with health matters upon an application from the "Poltransplant" - Organization and Coordination Center for Transplantation Issues shall issue a badge and identity card, which confirm an entitlement to use the title of "Transplant Donor Worthy".
5. The expenditures of issuance of the badges and identity cards referred to in paragraph 2 and 4 shall be covered from the part of the state budget, which is at the disposal of the minister competent to do with health matters.
6. The minister competent to do with health matters shall by way of a decree state the identity card and badge model, the course and procedure of conferring a "Transplant Donor" and "Transplant Donor Worthy" badge and also the manner of documenting the number of recoveries with the purpose of conferring this badge, taking the data collected by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues and the propagation of donation of cells, tissues and organs into consideration.

Article 23

1. A "Transplant Donor" and "Transplant Donor Worthy" is entitled to use outpatient health care services without appointment.
2. A donor of bone marrow or peripheral blood hematopoietic cells and an organ donor who in consequence of the recovery procedure suffered a body injury or health breakdown, have the right to claim for compensation on the

basis of the regulations of the Civil Code.

Article 24

Entities, which undertake activities within the scope of propagation of cell, tissue or organ donation, shall be under an obligation to inform about the range of these activities the minister competent to do with health matters.

Chapter 6 Cell and Tissue Banks

Article 25

Cell and tissue banks shall be established with the aim of gathering, processing, sterilizing, storing and distributing tissues and cells appropriated for transplantation.

Article 26

1. The doings referred to in article 25 shall be performed by a cell and tissue bank after obtainment of a permission given by the minister competent to do with health matters to perform these doings.

2. A cell and tissue bank shall submit an application for the permission referred to in paragraph 1 to the National Centre for Tissue and Cell Banking.

3. The minister competent to do with health matters upon an application from the National Centre for Tissue and Cell Banking and after the National Transplantation Council pronounces its opinion shall give the permission referred to in paragraph 1.

4. The permission referred to in paragraph 1 shall be given for five years.

5. A cell and tissue bank shall obtain the permission referred to in paragraph 1 on condition that it meets the following requirements:

1) employment of persons who have appropriate qualifications, including a person responsible for this bank observance of the regulations of the Act and the rules stated in the quality assurance system referred to in article 29;

2) possession of rooms and equipment that correspond with the professional and sanitary requirements stated in the regulations enacted in virtue of article 27, paragraph 7;

3) presentation of a project of the quality assurance system referred to in article 29.

6. To the application referred to in paragraph 2 should be annexed:

1) an information about the number of employees and their qualifications;

2) an opinion given by a competent state sanitary inspector on the fulfilment of the

requirements that are stated in the regulations enacted in virtue of article 27, paragraph 7;

3) a list of rooms and equipment;

4) a description of the organizational structure of the cell and tissue bank;

- 5) a description of the range of activities performed by the employees of the cell and tissue bank;
- 6) a description of the anticipated range of activities of the cell and tissue bank;
- 7) a list of entities, which the cell and tissue bank shall commission to perform doings referred to in article 31 and a detailed definition of commissioned doings together with copies of contracts concluded with these entities.
7. To the application referred to in paragraph 2 should be annexed also in writing the name and surname of the responsible person referred to in paragraph 5, item 1, hereinafter named “responsible person”.
8. If the responsible person is temporarily replaced by another person, the cell and tissue bank shall immediately transfer the name and surname of the substitute person to the National Centre for Tissue and Cell Banking and inform about the date of duties commencement by the substitute person.

Article 27

1. The cell and tissue banks shall immediately inform the National Centre for Tissue and Cell Banking about all the data changes referred to in article 26, paragraph 5-8.
2. The minister competent to do with health matters shall evaluate, whether:
 - 1) a cell and tissue bank, which is applying for the permission referred to in article 26, paragraph 1, meets the requirements for permission obtainment;
 - 2) the entities referred to in article 26, paragraph 6, item 7, meet the requirements stated in the regulations enacted in virtue of paragraph 6 and 7 within the range of activities stated in a contract concluded with a cell and tissue bank.
3. The evaluation referred to in paragraph 2 shall be made on the grounds of a postcontrol report drawn up after control completion in order to ascertain, whether a tissue and cell bank, which is applying for the permission referred to in article 26, paragraph 1, meets the requirements for permission obtainment.
4. The minister competent to do with health matters shall withdraw the permission in the event that:
 - 1) a tissue and cell bank discontinues meeting the requirements for permission obtainment referred to in article 26, paragraph 1;
 - 2) a tissue and cell bank renders a control completion, which is necessary to ascertain, whether it meets the requirements for realization of the tasks stated in the Act, impossible;
 - 3) the entities referred to in article 26, paragraph 6, item 7, don't meet the requirements stated for tissue and cell banks in the regulations enacted in virtue of article 27, paragraph 7, within the scope of activities defined in a contract concluded with a tissue and cell bank, or
 - 4) persons employed by the entities referred to in article 26, paragraph 6, item 7, don't meet the requirements stated in the regulations enacted in virtue of article

27, paragraph 6.

5. The permission granting, the permission granting refusal and the permission withdrawal referred to in article 26, paragraph 1, shall be effected by means of an administrative decision. A decision on a permission withdrawal is immediately put into effect. The decision defines the procedure of transferring stored tissues and cells to another tissue and cell bank or tissue and cell banks that have a permission.

6. The minister competent to do with health matters by means of a decree shall state the required qualifications of persons employed in tissue and cell banks who perform activities connected with processing, storage, distribution or testing of human tissues and cells, having regard to the safety of donors and recipients.

7. The minister competent to do with health matters by means of a decree shall state the professional and sanitary requirements for tissue and cell banks, taking the scope of procedures that are being carried out into account and having regard to the health safety of donors and recipients.

Article 28

1. The head of an tissue and cell bank shall appoint the responsible person.

2. The person referred to in paragraph 1 should have at least:

- 1) university education in the field of medical or biological science;
- 2) a two years' professional experience gathered in tissue and cell banks or in entities, which perform procedures connected with processing, preservation, storage, distribution, recovery or testing of human tissues and cells.

3. The responsible person is assigned to the following scope of tasks:

1) assurance of compliance with:

- a) the requirements of human tissue and cell recovery;
- b) the matching criteria for donor's tissues and cells;
- c) the requirement of performing specified laboratory tests in donors;
- d) the procedures of tissue and cell recovery and the procedures of taking tissues and cells in a tissue and cell bank;
- e) the requirements of tissue and cell preparation;
- f) the procedures of processing, testing, sterilization, storage and distribution of tissues and cells;
- g) the requirements of direct distribution of specific tissues and cells to receivers;

2) impartment of information to the National Centre for Tissue and Cell Banking about each case of serious adverse events or serious adverse reaction;

3) management of permanent monitoring of the employees of a tissue and cell bank compliance with the quality assurance system;

4) transfer of necessary data to the register of tissue and cell banks;

5) promotion of volunteer donation of tissues and cells.

Article 28a

A tissue and cell bank is obliged to provide employees, whose activities influence the quality of cells and tissues and safety of donors and recipients, including a responsible person, with the trainings referred to art. 40a par. 1.

Article 29

1. A tissue and cell bank shall work out and implement a quality assurance system, which particularly defines the manner of monitoring tissue and cell state on the way between a donor and recipient and all sorts of medical products and materials, which get into direct contact with transplanted tissues and cells.

2. The following documents in particular are included in the quality assurance system:

- 1) standard operation procedures;
- 2) guidelines;
- 3) procedure instructions;
- 4) report forms;
- 5) donor cards;
- 6) information about a tissue or cell destination place.

3. The minister competent to do with health matters by means of a decree shall state: the requirements, which the quality assurance system referred to in paragraph 1 has to meet, particularly the requirements of tissue and cell storage, registration of donors data; and also the necessity to establish standard operation procedures, taking the documents referred to in paragraph 2 into account.

Article 30

1. A tissue and cell bank shall mark cells and tissues with unique signs in a manner that renders an identification of a donor of these possible.

2. The identification referred to in paragraph 1 shall ensure a possibility of determining data on:

- 1) a cell or tissue recovery;
- 2) a reception in a tissue or cell bank;
- 3) a testing, processing, sterilization, storage and distribution of tissues or cells.

3. The minister competent to do with health matters by means of a decree shall state the manner of unique marking that renders an identification of tissue or cell donors possible and also the method of marking tissues or cells by means of that unique marking, taking the necessity to ensure recipients safety into consideration.

Article 31

1. A tissue and cell bank shall conclude a written contract of co-operation within a specified scope with an entity, which through its activities has an effect on the quality and safety of tissues and cells processed in co-operation with that entity.

2. A tissue and cell bank before concluding the contract referred to in

paragraph 1 shall be under an obligation to verify, whether the entity meets with the requirements stated in the regulations enacted in virtue of article 27, paragraph 6 and 7 and in the quality assurance system referred to in article 29.

3. A tissue and cell bank shall keep the contracts mentioned in paragraph 1 for the control purposes referred to in article 35.

Article 32

A tissue and cell bank shall be under an obligation to:

- 1) mark, package tissues and cells and also document those procedures;
- 2) ensure the best quality of the tissues and cells during distribution;
- 3) ensure performance of all procedures related to tissue and cell storage under controlled conditions appropriate to each procedure.

Article 32a

1. A tissue and cell bank concludes an agreement for storage of cells or tissues with a person who deposited these cells or tissues there.

2. An agreement, referred to in par. 1, determines, in particular:

- 1) day on which elapses the period for which the permission, referred to in art. 26 par. 1, was granted;
- 2) tissue and cell bank or banks having the permission, referred to in art. 26 par. 1, to which stored cells or tissues shall be delivered in case of cessation of the activity by a tissue and cell bank, including also a case of withdrawal of the permission by the minister competent for health.
- 3) a tissue and cell bank informs persons, who deposited cells or tissues in this tissue and cell bank, of withdrawal of the permission by the minister competent for health.

Article 33

The minister competent to do with health matters by means of a decree shall state the detailed conditions of handling tissues and cells in tissue and cell banks, taking the present regulations provided by the EC law pertinent to this scope and the well-being of donors into account.

Article 34

A tissue and cell bank shall be under an obligation to gather and keep documents relevant to stored and dispensed tissues and cells for at least 30 years from the day of dispensing these for transplantation in a manner rendering an identification of donors and recipients of tissues and cells possible. The abovementioned documents may be kept in electronic form too.

Article 35

1. The minister competent for health executes an inspection in:

- 1) tissue and cell banks to determine compliance with:
 - a) the requirements to obtain the permission, referred to in art. 26 par. 1, or

- b) the requirements provided by the Act;
- 2) the entities referred to in article 26, paragraph 6, item 7, to determine compliance with:
 - a) the requirements defined for tissue and cell banks in the regulations enacted in virtue of article 27, paragraph 7, within the scope of procedures stated in a contract concluded with a tissue and cell bank, or
 - b) the requirements defined in the regulations enacted in virtue of article 27, paragraph 6, by employees of these entities.
- 2. The minister competent to do with health matters may assign the tasks referred to in paragraph 1 to the National Centre for Tissue and Cell Banking.
- 3. In each case of suspected serious adverse event or serious adverse event shall be performed an inspection, but not less frequently than once in a two years.
- 4. Authorized employees of an office that attends to the minister competent to do with health matters needs or in the case referred to in paragraph 2 employees of the National Centre for Tissue and Cell Banking Inspection shall perform procedures on the basis of a personal authorization that contains:
 - 1) the legal basis;
 - 2) the inspection body designation;
 - 3) the date and place of issuance;
 - 4) the full name of an authorized employee;
 - 5) the inspected unit designation;
 - 6) the date of inspection commencement and the anticipated inspection completion time;
 - 7) the scope of inspection;
 - 8) the signature of the person who has given the authorization with the post or function filled by this person;
 - 9) an instruction on the rights and duties pertaining to the inspected unit.
- 5. The authorized employees referred to in paragraph 4, hereinafter named "controllers", shall be entitled:
 - 1) to have free entrance into buildings and rooms in an inspected unit;
 - 2) to have insight into all sorts of documents relevant to activities of an inspected unit;
 - 3) to require oral and written explanations from employees working in an inspected unit.
- 6. A controller shall represent the results of accomplished inspections in protocols.
- 7. In protocols on inspections shall be indicated irregularities in the inspected unit performance and stated postcontrol recommendations on how to eliminate the found irregularities as well as the date of elimination or an information that no irregularities were found.
- 8. An inspected unit has the right to file reservations to the minister competent to do with health matters within fourteen days from the date of

inspection protocol handing over.

9. The minister competent to do with health matters shall allow or reject such reservations within 14 days from the date of filing these, whereas the opinion of the minister competent to do with health matters is ultimate.

10. In the event that an inspected unit did not put into effect the postcontrol recommendations within the time-limit the minister competent to do with health matters may withdraw the permission referred to in article 26, paragraph 1.

11. The minister competent for health shall determine, by way of an ordinance, the method of executing, by entities authorized pursuant to the provisions of the act, inspections of:

- 1) tissue and cell banks,
- 2) entities referred to in art. 16a par. 1, art. 26 par. 6 item 7, art. 36 par. 1 and art. 37 par. 1, with regard to the activity covered by the permissions issued pursuant to the provisions of the act,
- 3) qualifying centres with regard to meeting the requirements provided by the Act and provisions issued pursuant to art. 16c par. 10
 - taking into particular consideration the method of executing individual inspection activities, their scope and documentation of the course of an inspection, bearing in mind the need to ensure efficient execution of an inspection.

Chapter 7

Handling of cells, tissues and organs

Article 36

1. Handling of cells, tissues and organs consisting in:

- 1) recovery of cells, tissues and organs from living donors – may be performed exclusively in health care institutions;
- 2) recovery of organs for transplantation from cadavers – may be performed exclusively in health care institutions;
- 3) recovery of cells and tissues from cadavers - may be performed in health care institutions, forensic medicine departments, anatomical pathology departments of medical academies and universities that have a medical faculty, medical research and development units and funeral parlours having a dissection room;
- 4) storage of organs - may be performed exclusively in health care institutions carrying out transplantations;
- 5) transplantation - may be performed exclusively in health care institutions.

1a. The activities, referred to in par. 1 items 1, 4 and 5 may be performed by entities having the permission granted by the minister competent for health.

2. (deleted).

3. To granting the permission, referred to in par. 1a, the provisions of art. 26 and art. 27 pars. 1-5 shall apply respectively, however, the tasks and activities of the National Centre for Tissue and Cell Banking are performed by the

"Poltransplant" - Organization and Coordination Center for Transplantation Issues.

4. A permission application of the entity, referred to in par. 1 items 1, 4 and 5, specifies the expected scope of transplantation procedures.

5. The activities, referred to in par. 1, are performed by persons having appropriate professional qualifications.

6. The minister competent for health, prior to issuance of the permission for the activity, referred to in par. 1 items 1, 4 and 5, consults the National Transplantation Council.

7. The minister competent for health shall determine, by way of an ordinance:

1) professional qualifications of persons recovering cells, tissues and organs and of persons performing transplantations, considering in particular physicians who are specialists in the following fields of medicine: clinical transplantology, surgery, paediatric surgery, hematology, clinical oncology, cardiosurgery, vascular surgery, urology as well as physicians who are specialists in other fields of medicine,

1a) professional qualifications of cell, tissue and organ recovery and transplantation coordinators,

2) the requirements to be met by the entities referred to in par. 1, under which a procedure consisting in recovery, storage or transplantation of cells, tissues and organs shall be performed,

3) detailed rules of cooperation between the entities, referred to in par. 1, with respect to recovery, storage of cells, tissues and organs for their use for transplantation,

4) the requirements to be met by the medical documentation regarding recovery of cells, tissues and organs, their storage and transplantation

- taking into consideration a necessity to ensure the health safety of recipients and donors of cells, tissues or organs.

Article 36a

1. Upon request of a tissue and cell bank, the head of the entity, referred to in art. 36 par. 1 item 3, may organize a recovery team.

2. The head of the recovery team is a physician.

3. The tasks of the recovery team include, in particular:

1) organizing recovery and recovery of cells and tissues from cadavers;

2) transferring recovered cells and tissues to tissue and cell banks;

3) cooperation with physicians recovering organs for transplantation.

4. The team members other than the physician, referred to in par. 2, must have medical, biological or biotechnological university education and complete the training, referred to in art. 40a par. 1.

5. The tasks of the recovery team are financed by a tissue and cell bank, pursuant to an agreement with the entities, referred to in art. 36 par. 1 item 3.

6. Substantive supervision over the activity of recovery teams is exercised by the National Centre for Tissue and Cell Banking.

Article 37

1. Only a medical diagnostic laboratory in the sense of the regulations of the act of July 27th, 2001 on laboratory diagnostics (Official Journal of Acts of 2004 No 144, item 1529 and of 2005 No 119, item 1015), which has a permission to perform these procedures given by the minister competent to do with health matters, is allowed to perform procedures that consist in testing cells, tissues and organs.

2. The regulations of article 26 and article 27, paragraph 1-5 respectively shall apply to the permission referred to in paragraph 1.

3. The regulations of article 35, paragraph 3-10 respectively shall apply to a check, whether the laboratory referred to in paragraph 1 meets the requirements for obtainment of the permission referred to in paragraph 1.

Article 37a

1. Export of bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood from the territory of the Republic of Poland and their import to the territory of the Republic of Poland are performed by a health care institution recovering or transplanting bone marrow, haematopoietic cells of peripheral blood and umbilical cord blood, by consent of the head of the "Poltransplant" - Organization and Coordination Center for Transplantation Issues.

2. Export of cells or tissues recovered from cadavers from the territory of the Republic of Poland and import of these cells or tissues to the territory of the Republic of Poland are performed by a tissue and cell bank by consent of the head of the National Centre for Tissue and Cell Banking.

3. Export of regenerating cells or tissues other than cells and tissues referred to in par. 2, from the territory of the Republic of Poland and import of these cells or tissues to the territory of the Republic of Poland are performed by a tissue and cell bank by consent of the head of the National Centre for Tissue and Cell Banking.

4. Export of organs from cadavers from the territory of the Republic of Poland and import of these organs to the territory of the Republic of Poland are performed by a health care institution recovering or transplanting organs from cadavers, by consent of the head of the "Poltransplant" - Organization and Coordination Center for Transplantation Issues.

5. The consents, referred to in pars. 1-4, or refusals to grant them, are issued immediately for the entities specified in these provisions, each time by way of an administrative decision, upon request to which the information of meeting the requirements laid down in par. 8 is attached. These decisions are given order of immediate enforceability.

6. Against the decision of the head of the "Poltransplant" - Organization and Coordination Center for Transplantation Issues and of the head of the National Centre for Tissue and Cell Banking an appeal may be lodged to the minister competent for health.

7. The consent for export of cells, tissues or organ is refused to be granted when a potential recipient, compatible for transplantation, is included in the list.

8. The entities, granted the consents referred to in pars. 1-4, are obliged to ensure:

1) monitoring the state of exported and imported human cells, tissues and organs in transit between a donor and recipient;

2) the quality and safety of exported and imported human cells, tissues and organs designed for transplantation.

9. The data on exports and imports referred to in:

1) pars.1 and 4 – are collected and stored by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues;

2) pars. 2 and 3 - are collected and stored by the National Centre for Tissue and Cell Banking.

10. The data, referred to in par. 9, are made available to the minister competent for health and National Transplantation Council.

11. The minister competent for health shall determine, by way of an ordinance, detailed conditions of exporting human cells, tissues and organs from the territory of the Republic of Poland and importing these cells, tissues and organs to the territory of the Republic of Poland as well as the method of monitoring the state of exported and imported human cells, tissues and organs in transit between a donor and recipient, bearing in mind assurance of the quality and safety, referred to in par. 8 item 2, and taking into consideration the health safety of a recipient.

Chapter 7a

Marking, monitoring and safety and quality criteria of cells, tissues and organs

Article 37b

1. A tissue and cell bank, health care institution, referred to in art. 36 par. 1 items 1, 2 and 5 and medical diagnostic laboratory, referred to in art. 37 par. 1, mark cells, tissues or organs in a way enabling identification of their donor by way of unique symbols.

2. Identification, referred to in par. 1, provides a possibility to determine the data on recovery of cells, tissues or organs, their reception in a tissue and cell bank, health care institution, referred to in art. 36 par. 1 items 1, 2 and 5 or in a medical diagnostic laboratory, referred to in art. 37 par. 1 as well as their testing, processing, sterilization, storage and distribution.

Article 37c

1. A tissue and cell bank, health care institution, referred to in art. 36 par. 1 items 1, 2 and 5 and medical diagnostic laboratory, referred to in art. 37 par. 1, are obliged to:

1) apply measures of security and data protection against unauthorized completions, removal of information or modifications to the medical documentation of donors and against providing unauthorized persons with information;

2) apply procedures of deciding on data discrepancies;

3) ensure protection against unauthorized disclosure of the data, referred to in art. 37b par. 2, with simultaneous ensuring the ability of monitoring recovered, tested, processed, stored and distributed cells, tissues or organs.

2. The monitoring ability, referred to in par. 1 item 3, should be understood as:

1) the ability to locate and identify cells, tissues or organs at any stage from their recovery, through testing, processing and storage, to their distribution to a recipient or their disposal;

2) the ability to identify a recipient of cells, tissues or organ;

3) the possibility to locate and identify all relevant data related to medical products and materials having contact with cells, tissues or organs.

3. In addition, A tissue and cell bank, health care institution, referred to in art. 36 par. 1 items 1, 2 and 5 and medical diagnostic laboratory, referred to in art. 37 par. 1, are obliged to ensure monitoring of:

1) recovered, processed, stored or distributed cells, tissues or organs

2) medical products and materials having direct contact with cells, tissues or organs.

Article 37d

A tissue and cell bank, health care institution, referred to in art. 36 par. 1 items 1, 2 and 5 and medical diagnostic laboratory, referred to in art. 37 par. 1, are obliged to:

1) validate all processes,

2) determine critical moments of all processes which should be controlled on a basis of determined acceptance criteria,

3) evaluate equipment, technical devices and environment of the ongoing process and this evaluation is understood as a documented activity aimed at demonstration that this environment, equipment or devices are properly installed and operate properly

- in order to ensure the quality and safety required for a given type of cells, tissues or organ and to obtain expected results.

Article 37e

The minister competent for health shall determine, by way of an ordinance:

- 1) the method of creating unique symbols enabling identification of a donor of cells, tissues or organs as well as the method of marking cells, tissues or organs using these symbols,
 - 2) detailed requirements on monitoring, referred to in art. 37c par. 3
- taking into consideration a necessity to ensure the health safety of recipients.

Chapter 8

The "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, the National Centre for Tissue and Cell Banking and the National Transplantation Council

Article 38

1. There shall be established the "Poltransplant" - Organization and Coordination Centre for Transplantation Issues seated in the city of Warszawa (Poland).
2. The "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues shall be financed from the state budget and submitted to the minister competent to do with health matters.
3. The tasks of the "Poltransplant" - Organization and Coordination Centre for Transplantation Issues include, in particular:
 - 1) co-ordination of recovery and transplantation of cells, tissues and organs on the territory of the Republic of Poland;
 - 2) keeping the Central Register of Objections;
 - 3) keeping the National List of Persons Waiting for Transplantations;
 - 4) keeping the Register of Transplantations;
 - 5) keeping the Register of Living Donors;
 - 6) keeping the Register of Bone Marrow and Cord Blood;
 - 7) co-ordination of quests after non-related donors of bone marrow and cord blood with a preliminary search in the Register of Bone Marrow and Cord Blood;
 - 8) performance of educational activities aimed at disseminating the treatment with the method of cell, tissue and organ transplantation;
 - 9) co-operation with other domestic and foreign entities in the field of cell, tissue and organ exchange for transplantations;
 - 10) submission of the applications referred to in article 22, paragraph 4, to the minister;
 - 11) reception of applications from the units referred to in art. 36 par. 1 items 1, 4 and 5;

12)organizing the trainings, referred to in art. 40a par. 1, with regard to recovery, storage and transplantation of organs and bone marrow and haematopoietic cells of peripheral blood;

13)keeping the list of persons who completed the trainings, referred to in art. 40a par. 1, with regard to recovery, storage and transplantation of organs and bone marrow and haematopoietic cells of peripheral blood;

14) delivering the data, referred to in art. 16 pars. 3 and 4, to the European and global registers of bone marrow and cord blood.

4. The "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues shall be managed by a director appointed and dismissed by the minister competent to do with health matters after consulting the National Transplantation Council.

5. The minister competent to do with health matters by means of a decree shall give to the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues the statutes, which define its detailed organizational structure and detailed scope of tasks, taking the safety of recipients and the necessity of efficiently accomplishing the tasks referred to in paragraph 3 into account.

Article 39

1. There shall be established the National Centre for Tissue and Cell Banking seated in the city of Warszawa (Poland).

2. The National Centre for Tissue and Cell Banking shall be financed from the state budget and submitted to the minister competent to do with health matters.

3. The tasks of the National Centre for Tissue and Cell Banking include, in particular:

1) organization of a co-operation between tissue and cell banks;

2) performance of reference and consultative functions;

3) supervision and inspection of tissue and cell banks in respect of the merits;

4) keeping a register of tissue and cell banks;

5) organizing the trainings, referred to in art. 40a par. 1, with regard to recovery, collection, testing, processing, sterilization, storage and distribution of cells and tissues;

6) keeping the list of persons who completed the trainings, referred to in art. 40a par. 1, with regard to recovery, collection, testing, processing, sterilization, storage and distribution of cells and tissues;

7) exercising substantive supervision over the activity of recovery teams.

3a. In bone marrow donor centres, the National Centre for Tissue and Cell Banking may reimburse the cost of remuneration for the persons, referred to in art. 16a par. 4, pursuant to an agreement.

4. The National Centre for Tissue and Cell Banking shall be managed by a director appointed and dismissed by the minister competent to do with health matters after consulting the National Transplantation Council.

5. The National Centre for Tissue and Cell Banking is allowed to perform the procedures referred to in article 25 only for scientific and didactic purposes, after the National Transplantation Council pronounces its opinion and obtaining from the minister competent to do with health matters the permission referred to in article 26, paragraph 1.

6. The regulations stated in chapter 6, except article 26, paragraph 2 and 3, shall apply to the procedures referred to in article 25 that the National Centre for Tissue and Cell Banking will perform. An application for permission granting has to be submitted to the minister competent to do with health matters.

7. The minister competent to do with health matters by means of a decree shall give to the National Centre for Tissue and Cell Banking the statutes, which define its organizational structure and detailed scope of tasks, taking the safety of recipients and the necessity of efficiently accomplishing the tasks referred to in paragraph 3 into account.

Article 40

1. The National Centre for Tissue and Cell Banking shall keep a register of tissue and cell banks.

2. This register shall be a public one.

3. In this register shall be entered the following data about a tissue and cell bank:

1) the designation of a tissue and cell bank;

2) the number in the records of economic activities, in the register of entrepreneurs

or in a different relevant register;

3) the address;

4) the scope of activities.

4. The data referred to in paragraph 3 shall be made accessible through electronic channels too.

5. Data contained in the register shall be also made accessible within the network of registers of EU member states in a way specified in concert with the European Commission.

Article 40a

1. Organizing the trainings for persons whose activities directly influence the quality of cells, tissues or organs and safety of donors and recipients is carried out by:

1) "Poltransplant" - Organization and Coordination Center for Transplantation Issues for cell, tissue and organ recovery and transplantation coordinators with regard to recovery, storage and transplantation of organs and bone marrow, haematopoietic cells of peripheral blood and cord blood;

2) National Centre for Tissue and Cell Banking with regard to recovery, collection, testing, processing, sterilization, storage and distribution of cells and

tissues and recovery of bone marrow, haematopoietic cells of peripheral blood and cord blood.

2. The trainings, referred to in par. 1, are conducted in a form of a:

- 1) initial training – for newly employed persons;
- 2) continuous training, not less frequently than every 2 years – for all employees;
- 3) updating training – in case of changes in procedures or progress in scientific knowledge with regard to recovery, storage and transplantation of cells, tissues and organs.

3. The trainings, referred to in par. 1, are conducted in line with a training programme developed by the entities, referred to in par. 1, on a basis of a framework training programme laid down in the provisions issues pursuant to par. 8.

4. The trainings, referred to in par. 1, are aimed at:

- 1) gaining skills in implementing designated tasks;
- 2) gaining appropriate knowledge and understanding processes and rules of performed tasks;
- 3) understanding the organizational structure, quality assurance system and rules of protecting health and safety of the unit they are employed in;
- 4) gaining suitable information of ethical and legal aspects of performed tasks related to recovery, collection, testing, processing, sterilization, storage and distribution of cells, tissues and organs.

5. The trainings, referred to in par. 1, should be documented and after their completion, participation and results should be confirmed by a certificate.

6. The trainings, referred to in par. 1, are cost-free and are financed from the state budget funds, from the part being at the minister competent for health's disposal, allocated for financing National Centre for Tissue and Cell Banking and "Poltransplant" - Organization and Coordination Center for Transplantation Issues.

7. The units, where the trainings, referred to in par. 1, are conducted, should meet the appropriate requirements, in particular:

- 1) provide the educational facilities adapted to the number of training participants;
- 2) provide the appropriate educational staff;
- 3) ensure efficient organization of the training;
- 4) in elaborating the training programme, they should consider current knowledge, theoretical and practical achievements as well as verified results of scientific tests.

8. The minister competent for health shall determine, by way of an ordinance, framework programmes of the trainings, referred to in par. 1, the method of documenting their course, a specimen certificate of the completed training and detailed requirements towards the units where these trainings are conducted, taking into account a necessity of achieving the aims, referred to in par. 4.

Article 41

1. There shall be established the National Transplantation Council, hereinafter named "Council", as an advisory and consultative body of the minister competent to do with health matters.
2. The Council shall consist of no more than 31 members appointed for four years' tenures by the minister competent to do with health matters from among specialists in different fields of science and of one representative of the Main Chamber of Physicians. The minister competent to do with health matters shall appoint the president of the Council from among its members.
3. The members of the Council shall be entitled to obtain payment for participation in the meetings of the Council and in the meetings of the Committee of Ethics.
4. The minister competent to do with health matters shall dismiss a member of the Council before termination of tenure in case of:
 - 1) resigning one's office;
 - 2) losing one's capacity to perform assigned duties because of a chronic disease;
 - 3) unjustified non-attendance at four subsequent meetings of the Council;
 - 4) legally valid conviction for an intentional offence.
5. In case of dismissal or death of a member of the Council before termination of the member's tenure, the minister competent to do with health matters shall appoint a new member for the period till the end of this tenure in virtue of the paragraph 2, unless this tenure ends in less than 3 months.
6. The tasks of the Council include, in particular:
 - 1) giving opinions on programs regarding recovery, storage and transplantation of cells, tissues and organs;
 - 2) giving opinions on the activity of:
 - a) "Poltransplant" - Organization and Coordination Center for Transplantation Issues,
 - b) National Centre for Tissue and Cell Banking;
 - 3) conducting the information activity with regard to recovery of cells, tissues and organs for saving life and health;
 - 4) giving opinions on draft normative acts with regard to recovery, storage and transplantation of cells, tissues and organs;
 - 5) cooperation with national and foreign organizations and associations striving for development of transplantology and with the medical self-government;
 - 6) giving opinions on applications, referred to in art. 26 par. 2 and art. 36 par. 4;
 - 7) giving opinions on applications for transplanting cells, tissues and organs recovered from animals;
 - 8) giving opinions on:
 - a) meeting the requirements of the act provisions by those applying for permissions, i.e.: tissue and cell banks, entities referred to in art. 36 par. 1 items

1, 4 and 5 and medical diagnostic laboratories and entities having such permissions so far,

b) observing determined procedures with regard to recovery, storage and transplantation of cells, tissues and organs and meeting the requirements required within the determined quality assurance system – on a basis of serious adverse reactions and serious adverse events reported by the entities recovering, storing and transplanting cells, tissues and organs,

c) the quality of medical services provided with regard to recovery, storage, transplantation and distribution of cells, tissues and organs;

9) elaboration for the minister competent for health of annual reports regarding the results of cell, tissue and organ transplantations, on a basis of materials provided by the "Poltransplant" - Organization and Coordination Center for Transplantation Issues, National Centre for Tissue and Cell Banking and other institutions involved in the procedure of cell, tissue and organ recovery and transplantation.

7. Within the framework of the Council shall act a consisting of seven persons Committee of Ethics appointed by the minister competent to do with health matters from among the members of the Council, which shall be assigned to particularly the task of pronouncing opinions on the issues stated in article 13, paragraph 1.

8. The minister competent to do with health matters shall by means of a decree give to the National Transplantation Council its statutes, which specify the detailed scope, organization and procedure of activities, also for the Committee of Ethics, and the course of payments to members of the Council and the manner and procedure of opinion pronouncement, taking the necessity of the Council efficiently accomplishing tasks into account.

Chapter 9 Supervision

Article 42

1. The minister competent to do with health matters shall supervise the observance of the regulations stated in the Act.

2. As part of supervision, referred to in par. 1, the minister competent for health in particular:

1) obtains or demands information in a form of reports on the activity of the Council, National Centre for Tissue and Cell Banking and "Poltransplant" - Organization and Coordination Center for Transplantation Issues;

2) controls keeping registers and lists, referred to in the act;

3) grants or refuses to grant permissions to tissue and cell banks, the units referred to in art. 36 par. 1 items 1, 4 and 5, bone marrow donor centres and laboratories as well as withdraws these permissions, after consulting the Council;

4) executes inspections, referred to in the act or orders to execute them;
5) upon request of the European Commission or a competent body of another European Union Member State, provides written information of the results of the inspection, referred to in art. 35, with regard to compliance with the directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004.

3. The minister competent for health:

1) once in 3 years, submits to the European Commission the reports on:

a) the activities taken in the territory of the Republic of Poland with respect to propagation of cell, tissue and organ donation,

b) the manner of implementing the provisions of this directive in the territory of the Republic of Poland;

1a) every year, by 30 June, submits to the European Commission an annual report on notifying of serious adverse events and serious adverse reactions with regard to recovery, testing, processing, sterilization, storage, distribution and transplantation of cells and tissues;

2) executes the inspection, referred to in art. 35, upon motivated written request of a competent body of another European Union Member State in case of the occurrence of serious adverse reaction or serious adverse event after transplantation;

3) upon request of the European Commission or a competent body of another European Union Member State, provides written information of the results of the inspection, referred to in art. 35, executed upon request referred to in item 2.

Chapter 10

Penal regulations

Article 43

All those who disseminate notices about payable sales, purchases of cells, tissues and organs or about an agency for payable sales or purchases of cells, tissues and organs with the aim of transplanting them shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to one year.

Article 44

1. Each person who, for the purpose of obtaining a financial or personal benefit, buys or sells other person's cells, tissues or organs, acts as an agent in their purchase or sale or participates in transplanting or making cells, tissues or organs, recovered from a living donor or from cadavers against the provisions of the act available, is liable to a penalty of imprisonment from 6 months to 5 years.

2. If a perpetrator made crime, referred to in par. 1, a fixed income source, is liable to a penalty of imprisonment from 1 year to 10 years.

Article 45

Each person who, without required permission, conducts the activity provided by the provisions of the act for a tissue and cell bank, is liable to a fine, penalty of restriction of liberty or penalty of imprisonment up to one year.

Article 46

All those who without having the required permission recover cells, tissues or organs for transplantations or transplant these shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of up to three years.

Article 46a

Each person who, without required consent exports from the territory of the Republic of Poland or imports to this territory any cell, tissue or organ, is liable to a fine, penalty of restriction of liberty or penalty of imprisonment up to 3 years.

Article 46b

Each person who, against the provisions of the act, does not enter potential recipients of organs or bone marrow or haematopoietic cells of peripheral blood and cord blood in the list or performed transplantations of cells, tissues and organs to the register of transplantations or recruited potential donors of bone marrow and haematopoietic cells of peripheral blood to the register of bone marrow and cord blood, is liable to a fine or penalty of restriction of liberty.

Chapter 11

Changes in the standing regulations

Article 47

In the act of April 6th, 1990 on the Police-Force (Official Journal of Acts of 2002 No 7, item 58 with subsequent amendments³⁾) in article 19 in paragraph 1 the item 7 shall have the following wording:

"7) stated in article 43-46 of the act of July 1st, 2005 on recovery, storage and transplantation of cells, tissues and organs (Official Journal of Acts No 169, item 1411),".

Article 48

In the act of August 27th, 2004 on health care provisions financed with public means (Official Journal of Acts No 210, item 2135 with subsequent amendments⁴⁾) shall be introduced the following amendments:

1) in article 43 after paragraph 2 shall be added paragraph 3 with the following wording:

"3. The regulations in paragraph 1 and 2 shall apply respectively to the provision receivers who have the title "Transplant Donor Worthy" and produce a membership card "Transplant Donor Worthy".";

2) after article 47 shall be added article 47a with the following wording:

"Article 47a. 1. Provision receivers who are living organ donors in the sense of the regulations in the act of July 1st, 2005 on recovery, storage and transplantation of cells, tissues and organs (Official Journal of Acts No 169, item 1411) shall have the right to undergo every other twelfth month from the date of the organ recovery, but not longer than for 10 years, examinations aimed at monitoring their health state, performed by the health care institution that recovered the organ.

2. A health care institution that performed an organ recovery shall without delay transfer the examination results referred to in paragraph 1 to the Register of Living Donors kept on the basis of the regulations in the act referred to in paragraph 1.

3. The minister competent to do with health matters by means of a decree shall state the type and scope of living organ donors examinations, performed within the scope of monitoring the health state of living organ donors, having regard to controlling their health state determined by an organ donation.";

3) Article 61 shall have the following wording:

"Article 61. Ambulatory specialistic health care provisions provided an provision receiver without a referral from a sickness insurance physician shall be paid by the provision receiver, except the cases stated in article 47a, 57, paragraph 2 and article 60."

Chapter 12

Temporary, adaptation and final regulations

Article 49

The regulations standing till now shall apply to proceedings started on the basis of article 7, 9 and 10 in the act referred to in article 58, which are not yet completed till the day of implementation of the Act.

Article 50

1. The National Centre for Tissue and Cell Banking shall take over all the rights and duties pertaining to the National Centre for Tissue and Cell Banking, which has been established on the basis of the regulations standing till now.

2. The property of the National Centre for Tissue and Cell Banking, which has been established on the basis of the regulations standing till now shall in virtue of the law on the day of implementation of the Act become the property of the National Centre for Tissue and Cell Banking.

3. The passing of the rights and property of the National Centre for Tissue and Cell Banking, which has been established on the basis of the regulations standing till now, to the National Centre for Tissue and Cell Banking shall ensue gratuitously and be exempt from taxes and fees.

4. The employees of the National Centre for Tissue and Cell Banking, which has been established on the basis of the regulations standing till now, on

the day of implementation of the Act shall in virtue of the law become employees of the National Centre for Tissue and Cell Banking.

Article 51

1. The "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues shall take over all rights and duties pertaining to the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, which is operating on the basis of the regulations standing till now.
2. The property of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, which was established on the basis of the regulations standing till now, on the day of implementation of the Act shall become the property of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues.
3. The passing of rights and property of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, which was established on the basis of the regulations standing till now, to the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, shall ensue gratuitously and be exempt from taxes and fees.
4. The employees of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, which was established on the basis of the regulations standing till now, on the day of implementation of the Act shall in virtue of the law become employees of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues.

Article 52

1. The regulations standing till now that were issued on the basis of article 5, paragraph 5, article 6, paragraph 2, article 16, paragraph 4, article 17, paragraph 5 and article 18, paragraph 3 of the act mentioned in article 58, shall remain in force till an issuance of executory regulations on the grounds of the authorizations in the act, but not longer than for 12 months from the day of implementation of the Act.
2. The regulations issued on the basis of article 14, paragraph 2 of the act mentioned in article 58 shall remain in force till an issuance of executory regulations on the basis of article 27, paragraph 6 and 7, article 29, paragraph 3, article 30, paragraph 3 and article 33 of the Act, however only till April 7th, 2007.

Article 53

Health care institutions or other organizational units that are keeping national lists of persons waiting for transplantations on the basis of the regulations standing till now shall be under an obligation to transfer these lists gratuitously within 30 days from the day of implementation of the Act to the "Poltransplant" - Organization and Co-ordination Centre for Transplantation

Issues.

Article 54

The Central Register of Objections, which is being kept on the basis of the regulations standing till now, shall become the Central Register of Objections on the day of implementation of the Act.

Article 55

National and regional tissue and cell banks, which were established on the basis of the regulations standing till now, are allowed to gather, process and store cells and tissues for transplantations till December 31st, 2006.

Article 56

The health care institutions that on the day of implementation of the Act recovered and transplanted cells, tissues and organs are allowed to perform these procedures till December 31st, 2006 according to the rules standing till now.

Article 57

1. The minister competent to do with health matters shall transfer the first report referred to in article 42, paragraph 3, item 1, sub-item a, to the European Commission by April 7th, 2006 at the very latest.

2. The minister competent to do with health matters shall transfer the first report referred to in article 42, paragraph 3, item 1, sub-item b, to the European Commission, by April 7th, 2009 at the very latest.

Article 58

The act of October 26th, 1995 on recovery and transplantation of cells, tissues and organs (Official Journal of Acts No 138, item 682, of 1997 No 88, item 554 and No 104, item 661 and of 2000 No 120, item 1268) becomes invalid.

Article 59

The present act shall become effective on January 1st, 2006, whereas the regulations:

1) article 22-35, paragraph 1, 2 and 11 and article 36 and 37;

2) article 38, paragraph 3, item 11, article 39, paragraph 6, article 41, paragraph 6,

item 6 and 8, sub-item a, article 42, paragraph 2, item 3 and 5, article 45 and 48 - shall be observed till December 31st, 2006.

1) The present act shall change the act of April 6th, 1990 on the Police-Force and the act of August 27th, 2004 on health care services financed with public means.

2) The present act shall implement the regulations of the directive of the European Parliament and the Council of Europe 2004/23/EC of March 31st, 2004 on setting quality and safety standards for donation, recovery, testing,

processing, preservation, storage and distribution of human tissues and cells (EC Official Journal L 102 of April 7th, 2004).

3) The changes in the uniform wording of the mentioned act has been published in the Official Journal of Acts of 2002 No 19, item 185, No 74, item 676, No 81, item 731, No 113, item 984, No 115, item 996, No 176, item 1457 and No 200, item 1688 of 2003 No 90, item 844, No 113, item 1070, No 130, item 1188 and 1190, No 137, item 1302, No 166, item 1609, No 192, item 1873 and No 210, item 2036, of 2004 No 171, item. 1800, No 179, item 1842, No 210, item 2135, No 273, item 2703 and No 277, item 2742 and of 2005 No 10, item 70 and No 164, item 1365.

4) The changes in the mentioned act has been published in the Official Journal of Acts of 2005 No 94, item 788, No 132, item 1110, No 138, item 1154, No 157, item 1314 and No 164, item 1366.

1) This Act changes the Police [Act](#), of 6 April, 1990 and the Public Financing of Health Services [Act](#), of 27 August, 2004.

2) This Act implements the Directive 2004/23/EC of The European Parliament and The Council of The European Union of 31 March 2004 on setting standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (Official Journal of the EU L 102 of 7.4.2004).