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)

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

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

Article 3

1. It is not allowed to demand or accept payments or other financial benefit for cells, tissues and organs taken from donors.

2. The repayment of costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs taken from donors is not a payment or financial benefit within the meaning of paragraph 1.

3. The costs of recovery, storage, processing, sterilization, distribution and transplantation of cells, tissues or organs include the costs of: a recovery of cells, tissues or organs from a donor; a hospitalization of a potentially living donor; an issuance of medical opinions; a recovery procedure; laboratory tests performed before and after the recovery; a cell culture for transplantation; a transport from or to the medical care institution where the transplantation has to be done; a storage, processing and sterilization.

4 . The repayment of costs referred to in paragraph 3 shall be done by the medical care institution, which has been supplied with cells, tissues or organs for transplantation.

5. The minister competent to do with health matters shall by means of a decree state the manner of setting the costs of doings related to recovery, storage, processing, sterilization and distribution of cells, tissues and organs and also the manner of repaying these costs, including costs referred to in paragraph 3 and procedures of carrying out these doings.

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 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 Donors of Bone Marrow and Cord Blood, hereinafter named “Register of Bone Marrow and Cord Blood” shall be established in order to render bone marrow, peripheral blood hematopoietic cells and cord blood transplantations from not related donors possible.

2. The Register of Bone Marrow and Cord Blood is made up of two sections:
1) the register of bone marrow and peripheral blood hematopoietic cell donors;
2) the register of cord blood.

3. In the register referred to in paragraph 2, item 1, shall be entered the following data about a donor of bone marrow and peripheral blood hematopoietic cell:
1) name and surname;
2) date and place of birth;
3) permanent residence;
4) PESEL (state identification number) number, if relevant;
5) information about histocompatibility antigens (HLA);
6) entity, which performed a HLA tests;
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 tissue and cell bank shall without delay transfer the data referred to in paragraph 3 and 4 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 17

1. Persons who wait for bone marrow, cell or organ transplantations shall be entered on the National List of Persons Waiting for Transplantations, hereinafter named “the list”.

2. A physician qualifying for transplantations shall make the entry.

3. The entry shall contain the following data:

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

4. An entry on the list is a condition of transplant obtainment by a recipient.

5. A selection of a recipient shall be made on the basis of medical criteria stated in the regulations enacted in virtue of paragraph 8.

6. The data referred to in paragraph 3 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 list.

8. The minister competent to do with health matters shall by way of a decree state:

1) the manner and procedure of setting up the National List of Persons Waiting for Transplantations;
2) the medical criteria and manner of recipient selection;
3) the manner of informing people about their entry position on the list of persons waiting for transplantations;

- taking the up-to-date medical knowledge, the maintaining of an equal access to transplantation procedures and the possibility of keeping the list in electronic form into consideration.

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. The personal data about a donor and recipient of a transplant shall be confidential and submitted to the protection stated in the regulations on the

professional and business secrecy and in the regulations on medical documentation kept by health care institutions.

2. If an organ has to be recovered from a living donor, then the regulation in paragraph 1 does not apply to a disclosure of personal data about a donor and a 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 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 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 above-mentioned documents may be kept in electronic form too.

Article 35

1. The minister competent to do with health matters shall conduct inspections in:

1) tissue and cell banks to determine compliance with:
   a) the requirements of permission obtainment referred to in article 26, paragraph 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 to do with health matters shall by means of a decree state the procedure of inspection that entities authorized on the basis of the regulations of the Act have to perform:

1) in tissue and cell banks;
2) in the entities referred to in article 26, paragraph 6, item 7, article 36, paragraph 1 and article 37, paragraph 1, within the scope of activities stated in the permissions given in virtue of the regulations stated in the Act;

- taking especially the manner of carrying out individual inspection procedures, theirs scope and the inspection procedure documentation into account and having regard to the need of ensuring an efficient inspection completion.

Chapter 7

Handling of cells, tissues and organs in health care institutions and laboratories

Article 36

1. A handling of cells, tissues and organs that consists in:

1) recovery – shall be allowed to perform exclusively health care institutions, forensic medicine departments and anatomical pathology departments of medical academies and universities that have a medical faculty and medical R & D units;
2) organ storage - shall be allowed to perform exclusively health care institutions, which are carrying out transplantations;
3) transplanting - shall be allowed to perform exclusively health care institutions, which have a relevant permission given by the minister competent to do with health matters.

2. The permission referred to in paragraph 1 shall be given separately for procurement and transplantation of cells, tissues and organs from human cadavers and for procurement and transplantation of cells, tissues and organs from living donors.

3. The regulations in article 26 and article 27, paragraph 1-5 respectively shall apply to granting the permission referred to in paragraph 1, whereas the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues shall carry out the tasks and activities assigned for the National Centre for Tissue and Cell Banking.

4. The entity referred to in paragraph 1 in its application for permission shall state the anticipated scope of transplantation procedures.

5. The doings referred to in paragraph 1 shall perform persons who have the required professional qualifications.

6. The minister competent to do with health matters before granting the permission referred to in paragraph 1 shall consult the National Transplantation Council.

7 The minister competent to do with health matters by means of a decree shall state:

1) the professional qualifications of persons who are procuring cells, tissues and organs and persons who are transplanting them, having regard in particular to physicians who are specialists in clinical transplantology, surgery, paediatric surgery, cardiosurgery, vascular surgery, urology and physicians who are specialists in other fields of medicine;
2) the requirements, which should meet entities, referred to in paragraph 1, where shall be performed procedures that consist in recovery, storage or transplantation of cells, tissues and organs;
3) the detailed rules of co-operation between the entities referred to in paragraph 1 that pertain to recovery, storage of cells, tissues and organs with the aim of using them for transplantations;
4) the requirements, which should meet a medical documentation on recovery of cells, tissues and organs, storage and transplantation of these - taking the necessity of ensuring health safety for recipients and donors of cells, tissues or organs into consideration.

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.

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 Co-ordination 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 "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues shall be assigned to particularly the following tasks:

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 article 36, paragraph 1.

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 National Centre for Tissue and Cell Banking shall be assigned to particularly the following tasks:

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.

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 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 Council shall be assigned to particularly the following tasks:

1) pronouncement of opinions on programmes of recovery, storage and transplantation of cells, tissues and organs;
2) pronouncement of opinions on the activities:
   a) of the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues;
   b) of the National Centre for Tissue and Cell Banking;
3) performance of informative activities within the scope of recovery of cells, tissues and organs with the aim of saving life and health;
4) pronouncement of opinions on draft normative acts within the scope of recovery, storage and transplantation of cells, tissues and organs;
5) co-operation with domestic and foreign organizations and associations, which aim at developing transplantology, and with the physician’s self-government;
6) pronouncement of opinions on the applications referred to in article 26, paragraph 2 and article 36, paragraph 3;
7) pronouncement of opinions on applications for performing transplantations of cells, tissues and organs recovered from animals;
8) pronouncement of opinions on:
   a) the applying for permissions tissue and cell banks and entities referred to in article 36, paragraph 1, the medical diagnostic laboratories or entities, which have such permissions till now, compliance with the requirements stated in the regulations in the Act;
   b) the compliance with set procedures of recovery, storage and transplantation of cells, tissues and organs and compliance with requirements of the set quality assurance system - on the grounds of serious adverse reactions and serious adverse events reported by entities, which are recovering, storing and transplanting cells, tissues and organs;
   c) the quality of medical services provision within the scope of recovery, storage, transplantation and distribution of cells, tissues and organs;
9) elaboration of annual reports on the results of cell, tissue and organ transplantations - on the basis of materials that have been rendered accessible to the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues, the National Centre for Tissue and Cell Banking and other institutions involved in procedures of recovery and transplantation of cells, tissues and organs - for the minister competent to do with health matters.

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. Within the scope of the supervision referred to in paragraph 1 the minister competent to do with health matters shall in particular:

1) obtain or require information in the form of reports on the activities, which the Council, the National Centre for Tissue and Cell Banking, the "Poltransplant" - Organization and Co-ordination Centre for Transplantation Issues performed;
2) control the keeping of the registers and lists referred to in the Act;
3) grant or refuse granting permissions the tissue and cell banks, the units referred to in article 36, paragraph 1, and the laboratories and withdraw such permissions after consulting the Council;
4) perform inspections referred to in the Act, or instruct completion of such inspections;
5) impart upon an application from the European Commission or an appropriate body of an other EU member state written information about the results of the inspection referred to in article 35 within the scope of consistency with the regulations of the directive 2004/23/EC of the European Parliament and Council of Europe of March 31st, 2004.

3. The minister competent to do with health matters shall:

1) represent reports to the European Commission once in a three years on:
   a) the proceedings undertaken on the territory of the Republic of Poland within the scope of propagation of cell, tissue and organ donation;
   b) the manner of observing the regulations of the above-mentioned directive on the territory of the Republic of Poland;
2) perform the inspection referred to in article 35 upon a motivated written application from an appropriate body of an other EU member state in case of serious adverse reaction or serious adverse event occurrence after transplantation;
3) impart upon an application from the European Commission or an appropriate body of an other EU member state written information on the results of the

inspection, referred to in article 35, performed upon the application 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. All those who with the purpose of acquiring financial benefits buy or sell other people's cells, tissues or organs, run an agency for the purchase and sale of cells, tissues or organs or take part in transplantations of recovered in defiance of the regulations of the present act cells, tissues or organs that originate from living donors or human dead bodies, shall be liable to a penalty of imprisonment of up to three years.
2. All offenders who have a fixed income source through perpetration of the crime stated in paragraph 1 shall be liable to a penalty of imprisonment of up to five years.

Article 45

All those who perform activities, which the regulations in the Act provide for tissue and cell banks, without having the required permission shall be liable to a fine, a penalty of imprisonment or a penalty of imprisonment of 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.

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 amendments[3)]) 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 amendments[4)]) 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 theirs 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.

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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.

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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).