Entire legal regulation for Organ Transplantation Act, version of 07.03.2021

Long title
Federal Act on the Transplantation of Human Organs
StF: Federal Law Gazette I No. 108/2012 (NR: GP XXIV RV 1935 AB 1980 p. 179. BR: 8814 AB 8819 p. 815.) [CELEX No.: 32010L0053].
Amendment
Federal Law Gazette I No. 37/2018 (NR: GP XXVI RV 108 AB 139 p. 23. BR: 9967 AB 9970 p. 880.) [CELEX No.: 32017L2399, 32017L1572]

Preamble/Promulgation Clause
The National Council has decided:
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Text

Section 1
Subject matter, scope and definitions

Subject matter
§ 1. This Federal Act lays down the conditions under which human organs may be removed and used for transplantation purposes.
Scope of application
§ 2. (1) This Federal Act applies to the donation, screening, characterization, provision, preservation, transport and transplantation of organs intended for transplantation into the human body.
(2) This Federal Act shall not apply to the use of organs for research purposes unless they are intended for transplantation into the human body.
Definitions
§ 3. For the purposes of this Federal Act, the term:
1. “Provision" means a process by which donated organs are made available;
2. “Collection unit” means a hospital or mobile team used by the hospital to perform or coordinate the provision of organs;
3. “Recipient” means the person who receives an organ transplant;
4. “Disposal” means the final location of an organ when it is not used for transplantation;
5. “Preservation” means the use of chemical substances, altered environmental conditions or other means to prevent or delay biological or physical deterioration of organs from the time of removal to the time of transplantation;
6. “Organ” means a distinct part of the human body, composed of various tissues, which maintains its structure, vascularization and capacity to perform physiological functions with marked autonomy. Parts of organs are also considered to be organs if their function is to be used in the human body for the same purpose as the whole organ, while maintaining the requirements of structure and vascularization;
7. “Organ characterization” means the collection of the relevant information on the characteristics of an organ necessary to assess its suitability for transplantation in order to carry out a proper risk assessment, minimize the risks to the recipient and optimize organ allocation;
8. “Traceability” means the ability to locate and identify the organ at any stage from donation to transplantation or disposal, including the ability to identify the donor, the collection centre and the recipients at the transplantation centers, and to locate and identify any relevant non-personal information on products and materials with which the organ comes into contact;
9. “Serious adverse event” means any adverse and unexpected event associated with any link in the chain from donation to transplantation that could result in the transmission of an infectious disease, death or conditions that are life-threatening, result in disability or loss of function, or result in or prolong hospitalization or morbidity;
10. “Serious adverse reaction” means any unintended response, including infectious disease, in the living donor or the recipient that may be associated with any link in the chain from donation to transplantation and that is life-threatening, results in disability or loss of function, or results in or prolongs hospitalization or morbidity;
11. “Donation” means any making available of organs for transplantation purposes;
12. “Donor” means any person who expresses the wish to donate organs to the personnel working at a collection centre and any deceased person from whom organs are removed for transplantation purposes;
13. “Donor characterization” means the collection of the relevant information on the donor's characteristics necessary to assess his/her suitability for organ donation in order to carry out a proper risk assessment, minimize the risks to the recipient and optimize organ allocation;
14. “Transplantation” means a procedure by which certain functions of the human body are restored through the transfer of an organ from a donor to a recipient;
15. “Transplant centre” means a hospital where the transplantation of organs is carried out and whose authorization is granted by the respective Provincial Government under the respective Provincial Hospitals Act includes this;

16. “Procedural instructions” means written instructions describing the steps of a specific procedure, including the materials and methods to be used and the expected end result.

Section 2
Principles of Organ Donation

Principles of donation
§ 4. (1) Organs may only be donated voluntarily and free of charge.
(2) It is prohibited to offer or promise donors of organs or third persons a financial gain or comparable advantage in return for a donation. Legal transactions that violate this prohibition shall be null and void.
(3) Paragraphs 1 and 2 shall not preclude the granting of adequate compensation to living donors for loss of earnings and other expenses caused by the donation and the related medical measures and the granting of compensation in the event of damage occurring as a result of the donation and the other related medical measures.
(4) Advertisements for the need of organs or their availability shall not contain any reference to financial gain or comparable advantages.
(5) Organs shall not be the subject of legal transactions aimed at profit.
(6) Information about the donor or recipient shall be exempt from the right of access pursuant to Article 15 of Regulation (EU) 2016/679 on the protection of individuals with regards to the processing of personal data, on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), OJ No L 119, 04.05.2016 p. 1.

Section 3
Protection of the donor and the recipient and selection and evaluation of donors

Removal of organs from deceased persons for the purpose of transplantation
§ 5. (1) It is permissible to remove individual organs from deceased persons in order to save the life or restore the health of another person through their transplantation. The evaluation and selection of the organs shall be carried out in accordance with the state of medical science. The removal is not permitted if the doctors have a declaration in which the deceased or, before his/her death, his/her legal representative has expressly rejected organ donation. A declaration is also present if it is entered in the register of objections kept by the Austrian National Public Health Institute. The removal must not lead to a disfigurement of the corpse that violates reverence.
(2) The removal may only be carried out after a doctor authorized to practice independently has established that death has occurred. This doctor may neither perform the removal nor the transplantation. He/she must not otherwise be involved in or affected by these interventions.
(3) The removal of organs may only be carried out in or by removal units which meet the requirements of § 16 par. 1 lit. (a) and from (c) to (g) of the Federal Act on Hospitals and Sanatoria (KAKuG), Federal Law Gazette No. 1/1957.
(4) The removal of organs and parts of organs from deceased persons for the purpose of transplantation shall have priority over the removal of cells and tissues for use in humans. The availability of organs and parts of organs of deceased persons for the purpose of transplantation shall not be impaired by the removal of cells and tissues for human application.

Register of objections
§ 6. (1) The register of objections kept by the Austrian National Public Health Institute (§ 5 para. 1) has the purpose of documenting the objection of persons who expressly refuse organ donation, in order to effectively prevent organ removal.
(2) The declaration of objection implies consent to the processing of personal data. The declaration shall be signed by the person expressly refusing organ donation.

(3) The following data of the person who has declared an objection or for whom an objection has been declared may be processed in the objection register: name, date of birth, gender, national insurance number, address, name of legal representative, if applicable.
(4) The Austrian National Public Health Institute shall issue a confirmation of registration. The objection to organ removal and the associated consent to the processing of data in the objection register may be revoked in writing at any time. In this case, the registration is to be deleted immediately.
(5) The Austrian National Public Health Institute shall take data security measures in accordance with the General Data Protection Regulation for the operation of the objection register. A data security program, in which all data security measures required for the operation of the objection register are to be ordered, is to be drawn up, which is binding for all employees of the Austrian National Public Health Institute.
(6) The managing director shall assign the access authorizations for the employees of the Austrian National Public Health Institute who are authorized to access the register on an individual basis. Access authorization to the objection register may only be granted if the authorized persons have been instructed on the provisions of the General Data Protection Regulation and the data security program according to para. 5.
(7) Authorized persons shall be excluded from further exercising their access authorization if they no longer need it for the further fulfillment of the tasks assigned to them or if they do not use the data in accordance with their intended purpose.
(8) When processing data pursuant to paras. 2 and 3, the use of the name and the area-specific personal identifier GH and AS (§ 10 para. 2 E-Government Act, Federal Law Gazette I No. 10/2004) for patient identification is permissible.
(9) The Austrian National Public Health Institute is entitled to request information on the time and cause of death of persons whose data is processed in the register from the Austrian Federal Institute of Statistics.
(10) The managing director shall ensure that the identity and role of the persons authorized to access the register are verified and recorded for each access in accordance with the state of the art.
(11) The managing director shall ensure that appropriate, state-of-the-art precautions, which take into account the provisions of the General Data Protection Regulation, are taken to prevent the destruction or alteration of data by program malfunctions (viruses) and to prevent the destruction, alteration or retrieval of data by unauthorized users or systems.
(12) All data use processes carried out in the area of the objection register, such as entries, changes, queries and transmissions, shall be logged.

Obligation of the Withdrawal Units

§ 7. (1) Each organ removal unit is obliged to ensure that there is no entry of an objection in the objection register before removing organs from deceased persons by making an enquiry to the Austrian National Public Health Institute.
(2) For this purpose, organ removal units are entitled to make the query online in the objection register. The Austrian National Public Health Institute must ensure that the query is designed in such a way that in the case of queries only the data required to verify the entry of an objection is visible in the register.
(3) The granting of access authorizations for queries by collection units shall be documented in a comprehensible way by the Austrian National Public Health Institute. When granting access authorizations by collection units, it must be ensured that access rights are only granted to the extent necessary for the purpose of the query. The granting of access authorization must refer to specific persons, whose clear identity and scope of authorization must be proven to the Austrian National Public Health Institute.

Living donation

§ 8. (1) Organ donation by persons who have not reached the age of 18 is not permitted.
(2) The evaluation and selection of donors shall be carried out in accordance with the state of medical science.

(3) The collection may only be carried out if the living donor has been informed prior to the collection in a way comprehensible to the donor by a doctor about the planned collection, its purpose, the associated risks and consequences, in particular any further examinations that may be necessary after the collection, the analytical tests to be carried out and the consequences of abnormal findings, the therapeutic purpose of the organ removed, the potential benefit for the recipient, the expected prospects of success, measures for the protection of the donor and his/her data as well as existing confidentiality obligations, and if the donor has given his/her consent to the removal and testing as well as to the further use of the organ. The information must also refer to the necessity of regular medical follow-up checks to protect the donor. The information must be provided both in writing and verbally. Any waiver of this medical information shall be legally invalid.
(4) The consent must be recorded in writing. The consent must be dated and signed by the donor. If the donor is unable to sign, the consent must be given in front of three witnesses who are neither involved in the operation itself nor have a personal interest in the organ donation and who must confirm the consent with their signature. Consent may be revoked in writing or orally at any time.
(5) Prior to the removal of organs, the living donor shall undergo the necessary examinations to assess the physical and psychological risks to his/her health. A collection may not be performed if it would pose a serious risk to the life or health of the donor. If indicated by the state of medical science in accordance with the type of donation, the donor must be offered regular medical check-ups after the donation.

Follow-up care for living donors
§ 9. The collection centre is obliged to offer follow-up to living donors at least three months after donation. Thereafter, collection units must remind living donors in writing, at intervals that reflect the state of medical science, that they should undergo a follow-up examination by a specialist in order to protect the donor. For this purpose, the collection centre must draw up an individual, risk-based follow-up plan for each living donor and hand it over to the donor.

Section 4
Quality and safety of organs

Procedural instructions
§10. The Austrian National Public Health Institute has to develop scientific recommendations for all phases from donation to transplantation or disposal as well as for the after-care of the donor and to publish them on the internet. These shall include procedural instructions, in particular with regards to:
1. The verification of the donor's identity,
2. The verification of the consent of the living donor or the absence of an objection from a deceased donor,
3. The verification of the collection of the information required under this provision for the selection and evaluation of the donor and the transmission of this information to the transplant centre,
4. The rules for the allocation of organs, which shall correspond to the state of medical science, in particular according to the prospects of success and urgency for suitable patients, taking into account the criteria of the Eurotransplant International Foundation,
5. The provision, preservation, packaging and labelling of organs,
6. Transport in accordance with § 12,
7. Ensuring the traceability of organs,
8. The reporting of serious adverse events and reactions and the measures taken as a consequence in accordance with § 14, and
9. The individual, risk-based after-care plan pursuant to § 9 shall be included.

Organ and donor characterization
§ 11. (1) In order to ensure the best possible protection of the recipient, the collection shall be preceded by a characterization of both the organ and the donor. For this purpose, collection centers are required to collect the data specified in Annex A on the organ to be removed and its donor. The data indicated in Annex B shall be collected only on the basis of the decision of the collection centre, taking into account its availability and the specific circumstances of the individual case.

(2) If, due to a serious risk to life or health, the expected benefit for the recipient is greater than the risks due to incomplete data, an organ may, by way of derogation from paragraph 1, be designated for transplantation even if not all of the minimum data specified in Annex A are available.
(3) The information collected for the assessment and selection of the donor shall be transmitted without delay by the collection centre to the transplant centre.
(4) The tests necessary for the evaluation and selection of the donor shall be carried out by laboratories which have the appropriate personnel, space, operational and technical equipment according to the respective state of the art in science and technology.

Transport of organs
§ 12. (1) Those carrying out the transport of organs shall ensure the integrity of the organs during transport and an appropriate duration of transport, taking into account the procedural instructions according to § 10 line 6.
(2) The transport containers used for the transport of organs shall be labelled with the following information:
1. The name of the hospital in which the organs were provided and the name of the collection unit through which the organs were provided, including its address, telephone number and e-mail address;
2. The name of the transplant centre, including its address, telephone number and e-mail address;
3. The indication that the container holds an organ, stating the type of organ and, if applicable, its left or right side, and the inscriptions "HANDLE WITH CARE" and "HANDLE WITH CAUTION";
4. The recommended transport conditions, including instructions for the appropriate ambient temperature and position of the container.

(3) Each organ transported shall be accompanied by an organ and donor characterization report.
(4) Every person involved in the transport of an organ shall be bound to secrecy with regard to all facts entrusted to him or which become known to him in the course of his duties and in which there is a legitimate interest in secrecy, unless such a duty of secrecy is already imposed on him under other statutory or service regulations.

Section 5
Traceability, Organ Vigilance, Reporting

Traceability
§ 13. All parties involved in the transplantation chain shall ensure that each provision and each transplantation of an organ is fully traceable.

Organ vigilance
§ 14. (1) Serious adverse events affecting the quality and safety of organs that can be attributed to the provision, characterization, preservation or transportation of organs and serious adverse reactions observed during or after transplantation that can be attributed to the provision, characterization, preservation or transportation of organs shall be reported immediately to the Eurotransplant International Foundation and, if known, to the respective transplant centre. In addition, the aforementioned serious adverse events and serious adverse reactions must be reported to the Austrian National Public Health Institute within three working days.
(2) The measures taken in the event of a serious adverse event or a serious adverse reaction must be reported to the Austrian National Public Health Institute within three working days.
(3) In the case of a serious adverse event or a serious adverse reaction, the Austrian National Public Health Institute shall, if necessary, notify the respective provincial governor, who shall arrange for appropriate measures to be taken within the framework of sanitary supervision pursuant to §§ 60 ff of the Federal Act on Hospitals and Sanatoria, Federal Law Gazette No. 1/1957.
(4) The Federal Minister for Health may, by decree, issue more detailed provisions on the procedure to be followed in reporting serious adverse events and serious adverse reactions, as well as the type and scope of such reports.

(5) The Austrian National Public Health Institute and the Federal Office for Safety in Health Care shall ensure an exchange of the information pursuant to paras 1 to 4 and the information from the tissue vigilance reports pursuant to the Tissue Safety Act, Federal Law Gazette I No. 49/2008.

Records and reports

§ 15. (1) Collection units and transplant centers shall submit quarterly reports in anonymized form to the Austrian National Public Health Institute on the number of potential and diagnosed deceased donors, the number of donors and the type and quantity of organs provided and transplanted or disposed of in the preceding months. Upon request, these data shall be immediately transmitted to the Federal Minister of Health and the respective governor of the province.
(2) The Austrian National Public Health Institute shall publish an annual report on the activities of all collection units and transplant centers by 31 May of the following year at the latest, which shall contain in particular the number of presumptive and diagnosed living donors and dead donors as well as the type and quantity of organs provided and transplanted or disposed of.
(3) The Austrian National Public Health Institute shall, through the Federal Ministry of Health, submit a report to the European Commission by August 27, 2013, and, every three years thereafter, a report on the activities of the collection units and transplant centers under this Federal Act.

Automated data traffic

§ 16. The Austrian National Public Health Institute is authorised to collect data pursuant to § 14 using automated data traffic and to transmit such data to:

1. The Federal Ministry of Health,
2. The European Commission,
3. Competent authorities of other contracting parties to the Agreement on the European Economic Area and
4. The Eurotransplant International Foundation.

Section 6
International Organ Exchange

§ 17. (1) Transplantation centers may only import organs from third countries for the purpose of transplantation if the organ can be traced back to the donor and it is ensured that quality and safety standards are met which are at least equivalent to those of this Federal Act.
(2) The Federal Minister for Health may, by ordinance, issue more detailed provisions on the characterization of organs and donors as well as the information required to ensure traceability with regards to the international exchange of organs, if this is necessary in the interest of the quality and safety of organs.

Section 7
Administrative Penalty Provisions

§ 18. (1) Whoever:

1. In violation of section 11 subsection 1, fails to characterize the organ or the donor or does not collect the data specified in Annex A on the organ to be removed and its donor,
2. Contrary to section 11 sub-section 3, fails to transmit the information collected to the transplant centre without delay,
3. Violates the obligation under § 11 sub-section 4,
4. Fails to comply with the requirements of § 12 during transport,
5. Violates the obligation of confidentiality according to § 12 par. 4
6. Fails to comply with the reporting obligations under § 14 subsections (1) and (2), or
7. As a collection unit or transplant centre, violates the reporting obligation under section 15 sub-section 1,

commits an administrative offense, unless the offense is a criminal offense within the jurisdiction of the courts, and shall be liable to a fine of up to EUR 7,270.

(2) Whoever:

1. Gives or promises a financial gain or comparable advantage to donors of organs or third persons contrary to § 4 par. 2,
2. Advertises the need for organs or their availability in contravention of section 4 subsection 4,
3. In contravention of § 4 sub-section 5, enters into legal transactions which have organs as their object and are aimed towards profit,
4. Contrary to § 5 sub-section 1, makes a collection even though the deceased person or, prior to his/her death, his/her legal representative have expressly rejected organ donation,
5. Contrary to section 5 sub-section 1, causes a disfigurement of a corpse which is contrary to reverence,
6. Violates § 5 sub-section 3,
7. As a collection unit, contrary to § 7, does not make an enquiry to the Austrian National Public Health Institute prior to the removal of organs from deceased persons,
8. Carries out a collection from a person who has not yet reached the age of 18, contrary to § 8 Para. 1,
9. Carries out a collection without the consent of the living donor or without the medical information provided for in § 8 sub-section 3,
10. Carries out a collection in contravention of § 8, paragraph 5, even though there is a serious risk to the life or health of the donor,
11. Violates § 13, or
12. Imports organs from third countries for the purpose of transplantation in contravention of section 17 sub-section 1, without the organ being able to be traced back to the donor or without ensuring compliance with quality and safety standards at least equivalent to those of this Federal Act,,

commits an administrative offense, provided that the act does not constitute a criminal offense falling within the jurisdiction of the courts, and shall be punished by a fine of up to EUR 36,340. The same shall apply if a serious danger to life and health has arisen from an act pursuant to subsection 1 or if the offender has already been punished twice pursuant to subsection 1.

(3) In the cases of subsection 2, the attempt shall also be punishable.

Section 8

Final Provisions

§ 19. Where reference is made in this Act to other federal laws, these shall apply in their currently applicable version.

§19a. Section 4(6), Section 6(2), (5), (6) and (11) as well as Section 7 as amended by the 2nd Data Protection Amendment Act, Federal Law Gazette I No. 37/2018, shall enter into force on 25 May 2018.

§ 20. The Federal Minister of Health shall be entrusted with the enforcement of this Federal Act.

§ 21. This Federal Act implements Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation, OJ No. L207 of 06.08.2010 p. 14, as amended by Corrigendum OJ No. L243 of 16.09.2010 p. 68.

Annex A

The following data must be collected as part of the organ and donor characterization:

1. Donor type,
2. Blood group,
3. Sex,
4. Cause of death,
5. Time of death,
6. Date of birth or estimated age,
7. Weight or estimated weight,
8. Height or estimated height,
9. Currently existing or past intravenous drug use,
10. Currently existing or past malignant neoplasms,
11. Other currently existing communicable diseases,
12. HIV, hepatitis C and hepatitis B infection (status); and
13. Basic information to assess the function of the donated organ.

Annex B

In addition to the data referred to in Annex A, based on the decision of the medical team, taking into account their availability and the specific circumstances of each case, the following are required:

1. Contact details of the collection unit needed for coordination, allocation and tracing of organs from donors to recipients and vice versa,
2. Demographic and anthropometric information needed to ensure an appropriate match between donor or organ and recipient,
3. The donor's medical history, in particular circumstances that may affect the suitability of the organs for transplantation and may pose a risk of disease transmission,
4. Data from clinical examinations needed to assess the physiological condition of the potential donor, as well as examination results indicating circumstances not noticed during the examination of the donor's medical history which may affect the suitability of the organs for transplantation or may pose a risk of transmission of diseases,
5. Data needed to assess the functional characterization of the organs and to identify potentially transmissible diseases and possible contraindications to organ donation,
6. Data on imaging studies needed to assess the anatomical status of organs intended for transplantation; and
7. Data on treatments performed on the donor that are relevant to the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of anti-infectives, medicinal or mechanical circulatory support procedures or transfusions,

to be collected.