Law on The Quality and Safety of Human Tissues and Cells (Tissue Law)

Tissue

Date of production: 20.07.2007

Full quote:

"Tissue Act of 20 July 2007 (BGBl. I p. 1574), which was repealed by Article 17 of the Law of 9 August 2019 (BGBl. I p. 1202) has been amended'

Status: Modified by Art. 17 G v. 9.8.2019 I 1202

This law is intended to implement Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 establishing quality and safety standards for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells(OJ No. EU No L 102 p. 48). The obligations under Directive 98/34/EC of the European Parliament and of the Council of the European 22 June 1998 laying down a procedure for the provision of information in the field of standards and technical regulations and the Rules on Information Society services(OJ No. EC No L 204 p. 37), as amended by Directive 98/48/EC of the European Parliament and the Instalment of 20 July 1998 (OJNo. 18), have been observed.

Type 1 to Art 6 ----

Art 7 Publication permit

The Federal Ministry of Health may comply with the wording of the Transplant Act and the Transfusion Act as valid on 1 August 2007 in the Federal Gazette.

Article 8 Entry into force

This Law shall enter into force on the first day of the month following the proclamation.

Law regulating the transfusion system (Transfusion Act - TFG)
TFG

Date of issue: 01.07.1998

Full quote:

"Transfusion Act in the version promulgated on 28 August 2007 (Federal Law Gazette I p. 2169), as last amended by Article 11 of the Act of 19 May 2020 (Federal Law Gazette I p. 1018)."

Status: Revised by Decree of 28.8.2007 I 2169; last amended by Art. 11 G v. 19.5.2020 I 1018

Footnote

(+++ Text reference as of: 7/7/1998 +++)

Section One Purpose of the Act, Definitions

§ 1 Purpose of the law

The purpose of this Act is to ensure, in accordance with the following provisions on the collection of blood and blood components from humans and the use of blood products, the safe collection of blood and blood components and the safe and secure supply of blood products to the population, and therefore to promote self-sufficiency in blood and plasma on the basis of voluntary and unpaid blood donation.

§ 2 Definitions

For the purposes of this Act

1. donation shall mean the quantity of blood or blood components collected from human beings which contains active substance or
   medicinal product or intended for the manufacture of active substances or
   medicinal products and other products for human use,

2. donation establishment means an establishment which collects donations or whose activity is directed towards the collection of donations and, where they are intended for use, their testing, processing, storage and placing on the market,

3. blood products are blood preparations within the meaning of Section 4(2) of the German Medicines Act, sera derived from human blood within the meaning of Section 4(3) of the German Medicines Act and blood components intended for the manufacture of active substances or medicinal products.

Section Two Collection of blood and blood components

§ 3 Supply mandate

(1) Donor centers have the task of collecting blood and blood components to supply the population with blood products.

(2) In order to fulfil the task referred to in paragraph 1, the donor establishments shall cooperate with each other. They shall assist each other, in particular in the event of supply shortages. They shall lay down the details of the cooperation in an agreement.

(3) Donors provide a valuable service to the community. For reasons of health protection, they are to be cared for in a particularly trusting and responsible manner by the donating institutions.

(4) The authorities responsible under Land law and the higher federal authority responsible for health education are to promote the education of the population about voluntary and unpaid blood and plasma donation.

§ 4 Requirements for donation facilities

A donation facility may only be operated if

1. sufficient personnel, structural, spatial and technical equipment is available,

2. the donation establishment or the sponsor of donation establishments has appointed a chief medical officer who has the necessary expertise in accordance with the state of medical science, and

3. a medical person is present when the collection of the donation from a human being is carried out.

The senior medical officer pursuant to sentence 1 no. 2 may at the same time be the medical officer pursuant to sentence 1 no. 3. The protection of the personal privacy of the donor, the proper collection of the donation and the prerequisites for emergency medical care of the donor must be ensured.

5 Selection of donors

(1) Only persons who have been found fit to donate under the responsibility of a medical person in accordance with the state of medical science and technology and whose fitness has been determined by a medical person may be admitted to donate. Admission to donation collection should not take place insofar as and as long as the person willing to donate is to be excluded from donation collection or deferred according to guidelines of the German Medical Association.

(2) When collecting autologous blood, blood for stem cell separation and plasma for fractionation, the suitability of the donor must also be assessed according to the specific characteristics of these blood products.

(3) The person responsible for the management of quality control according to § 14 paragraph 1 number 1 of the German Medicines Act must ensure that the donor is examined for infection markers, at least for human immunodeficiency virus (HIV), hepatitis B and hepatitis C virus infection markers, according to the state of the art in medical science and technology before the donation is released. In the case of autologous blood collections, these tests must be carried out in accordance with the special features of these collections. Orders of the competent higher federal authority remain unaffected.

§ 6 Information, consent

(1) A donation collection may only be carried out if the donor has been informed in advance and in a form that is understandable to him or her about the nature, significance and performance of the donation collection and the

tests and has consented to the donation collection and the tests. The donor must confirm the information and consent in writing. At the same time as giving consent, the donor must declare that the donation can be used, unless he or she makes use of the confidential self-exclusion.

(2) The donor must be informed about the processing of personal data associated with the collection of the donation. The donor must confirm this information in writing or electronically.

§ 7 Requirements for the removal of the donation

(1) The identification of the donor, the laboratory tests to be carried out and the collection of the donation must be carried out in accordance with the state of the art in medical science and technology.

(2) The collection of the donation may only be carried out by a medical person or by other qualified personnel under the responsibility of a medical person.

§ 8 Donor immunisation

(1) A plasma required for the preparation of specific immunoglobulins
Donor immunisation may only be carried out if and as long as it is necessary in the interest of an adequate supply of these medicinal products to the population. It shall be carried out in accordance with the state of the art in medical science and technology.

(2) An immunisation programme may only be carried out if and as long as

1. the risks associated with it for the persons on whom it is to be performed are medically justifiable,

2. the persons to whom it is to be administered have given their written consent to it, after having been informed by a medical person of the nature, significance and risks of immunisation and of the processing of personal data involved, and have confirmed this in writing or electronically,

3. its performance is directed by a medical person who is competent according to the state of medical science,

4. an immunisation plan in accordance with the state of medical science is available,

5. medical supervision of the health status of the donors is ensured during the immunisation period,

6. the competent authority has been notified of the implementation of the immunisation programme, and

7. the affirmative vote of an independent ethics committee formed in accordance with Land law and responsible for the medical person in accordance with sentence 1 no. 3 is available.

When notifying the competent authority and obtaining the vote of the Ethics Committee in accordance with points 6 and 7, no personal data may be transmitted. Authorised medicinal products shall be used for immunisation.

(3) A record of the implementation of the immunisation programme shall be drawn up on the basis of the immunisation plan (immunisation record). Section 11 shall apply mutatis mutandis to the immunisation protocol. This must include records of all events that occur in connection with the implementation of the

immunisation programme and may affect the health of the donor or the desired success of the immunisation programme. Red cell preparations used for immunisation shall be documented and certified to the immunised person.

(4) The events referred to in the third sentence of paragraph 3 shall be reported immediately by the medical officer in charge of the immunisation programme to the ethics committee, the competent authority and the pharmaceutical entrepreneur of the medicinal product used for immunisation. The date of birth and the sex of the immunised persons concerned shall be communicated.

§ 9 Haematopoietic stem cells from peripheral blood and other blood components

The cells required for the separation of hematopoietic stem cells from peripheral blood and from other
The pre-treatment of donors required for blood components must be carried out in accordance with the state of the art in medical science. Section 8 (2) to (4) shall apply accordingly.

§ 10 Compensation for expenses

(1) The donation shall be made free of charge. The donating person may be granted an expense allowance, which shall be based on the direct expenditure depending on the type of donation.

11 Donor documentation, data protection

(1) Any donation collection and related procedures shall be carried out without prejudice to medical documentation obligations for the purposes regulated in this Act, for purposes of medical treatment of the donor and for purposes of risk assessment under the Medicines Act. The records shall be kept for at least fifteen years, in the case of sections 8 and 9 for at least twenty years, and the information required for tracing purposes for at least thirty years, and shall be destroyed or deleted when retention is no longer necessary. They shall be arranged in such a way as to permit immediate access. If the records are kept for more than thirty years after the last donation from the same donor documented at the donor center, they shall be anonymized. (1a) In the case of haematopoietic stem cell preparations from peripheral blood or umbilical cord blood, the unique donation number pursuant to Section 2 No. 21 of the Ordinance on the Manufacture of Medicinal Products and Active Substances shall additionally be recorded and retained for traceability purposes. The Federal Ministry of Health shall
be empowered to provide for exceptions to the obligation under sentence 1 by ordinance requiring the consent of the Bundesrat.

(2) The donation establishments may process personal data of the willing and donating persons insofar as this is necessary for the purposes specified in paragraph 1. They shall transmit the logged data to the competent authorities and the competent higher federal authority, insofar as this is necessary for the fulfilment of monitoring tasks pursuant to the Medicinal Products Act or for the prosecution of criminal offences or offences that are closely related to the collection of the donation. The date of birth and the sex of the donor must be stated for the purpose of risk assessment in accordance with the German Medicines Act.

§ 11a Blood depots

The provisions of Section 3(1), sentences 1, 3 and 4, Section 4(1), sentences 1 and
2, Section 7(1), sentences 1, 2 and 4 and Section 20(2) of the Ordinance on the
Production of Medicinal Products and Active Substances as well as Section 16(2) and Section 19(3) shall apply mutatis mutandis to blood depots of health care establishments which store and dispense blood products exclusively for internal purposes, including use.

§ 12 Authorisation to issue ordinances

The Federal Ministry of Health may, by ordinance subject to the consent of the Bundesrat, in accordance with

The Federal Medical Association and other experts may, in consultation with the Federal Medical Association and other experts, regulate the technical requirements under this section, insofar as this is necessary to avert risks to human health or to prevent risks. The ordinance may, in particular, specify the details of the requirements to be met by 1. donation establishments,

2. the selection and screening of donors,

3. the education and consent of donors,

4. the donation withdrawal,

5. donor immunisation and pre-treatment for blood stem cell collection, and

6. the documentation of the donation collection and the protection of the documented data

regulated. The Federal Ministry of Health may transfer the authorisation pursuant to sentence 1 to the competent higher federal authority by ordinance without the consent of the Bundesrat.

12a Guidelines on the state of the art in medical and dental science and technology for the collection of blood and blood components

(1) The German Medical Association may, in agreement with the competent higher federal authority, establish in guidelines the generally recognised state of the art in medical science and technology for the collection of blood and blood components in addition to the provisions of the statutory instrument pursuant to Section 12. The assessment of the risk leading to the exclusion or deferral of certain groups of persons from donation shall be updated in the event of new medical, scientific or epidemiological findings and reviewed to determine whether the exclusion or deferral is still necessary to ensure a high level of health protection for recipients of blood donations. In the preparation of the guidelines, the appropriate participation of experts from the professional and transport communities concerned and of the competent authorities of the Federation and the Länder must be ensured. The guidelines shall be published by the competent higher federal authority in the Federal Gazette.

(2) Compliance with the state of the art in medical science and technology is presumed if the guidelines of the German Medical Association pursuant to paragraph 1 have been observed.

(3) Paragraphs 1 and 2 shall apply mutatis mutandis to the Federal Dental Association in the field of dentistry.

Section Three Use of blood products

§ 13 Requirements for the implementation

(1) Blood products shall be used in accordance with the state of the art in medical science and technology. The requirements for identity assurance, the preparatory examinations, including the intended testing for infectious disease markers and the reserve samples, the technique of application, and the education and consent must be observed. Medical personnel who, in connection with the use of blood products perform or request laboratory tests must be particularly competent for these activities. The The use of autologous blood also depends on the special features of these blood products. The persons to be treated must be informed about the possibility of using autologous blood, insofar as this is provided for according to the state of medical science.

(2) Medical personnel who use blood products on their own responsibility must have sufficient experience in this activity.

§ 14 Documentation, data protection

(1) The attending physician must document or have documented every use of blood products and of medicinal products for the specific therapy of coagulation disorders in haemophilia for the purposes regulated in this Act, for the purposes of the medical treatment of the persons affected by the use and for the purposes of risk assessment in accordance with the Medicinal Products Act. The documentation shall include the information provided and the declarations of consent, the result of the blood grouping, insofar as the blood products are used in a blood group-specific manner, the examinations carried out and the presentation of effects and adverse events.

(2) Blood products and medicinal products used for the specific therapy of coagulation disorders in haemophilia must be documented immediately by or under the responsibility of the attending physician with the following information:

1. Patient identification number or corresponding unique information about the person to be treated, such as surname, first name, date of birth and address,

2. Batch Name,

3. Pharmaceutical central number or
   - Name of the preparation
   - Name or company name of the pharmaceutical entrepreneur
   - Quantity and strength,

4. Date and time of application.

In the case of haematopoietic stem cell preparations derived from peripheral blood or umbilical cord blood, at least the information set out in Part B of Annex VI to Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards the traceability requirements, the reporting of serious adverse events and undesirable effects reactions as well as certain technical requirements for coding, processing, preservation, Storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32), as last amended by Directive (EU) 2015/565 (OJ L 93, 9.4.2015, p. 43), as applicable. In the case of autologous blood, these provisions shall apply mutatis mutandis. The health care facility (hospital, other medical facility treating persons) shall ensure that the data of the documentation can be used in a patient- and product-related manner.

(2a) If the use of medicinal products for the specific therapy of coagulation disorders in haemophilia is carried out by the patient within the framework of home self-treatment, the patient shall carry out the documentation in accordance with paragraphs 1 and 2. The medical person who permanently treats this patient for haemostasis disorders (haemophilia-treating medical person) must check the patient's documentation at least once a year for conclusiveness and completeness and incorporate it into his/her own documentation.

(3) The records, including computerised data, shall be kept for at least fifteen years and the data referred to in paragraph 2 for at least thirty years. They shall be immediately available for tracing purposes. The records shall be destroyed or deleted when retention is no longer necessary. If the records are kept for longer than thirty years, they shall be made anonymous.

(3a) The health care facilities that treat haemophilia patients in need of treatment for a limited period of time as part of an inpatient or outpatient stay shall provide the haemophilia-treating physician with information on the reason for the treatment with blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia as well as their documentation in accordance with paragraph 2.

(4) Healthcare establishments may process personal data of the persons to be treated to the extent necessary for the purposes referred to in paragraphs 1 and 2a. They shall transmit the documented data to the competent authorities insofar as this is necessary for the prosecution of criminal offences closely related to the use of blood products. For the purposes of risk recording under the Medicinal Products Act, the date of birth and the sex of the person to be treated shall be provided.

§ 15 Quality assurance

(1) Healthcare facilities that use blood products must set up a quality assurance system for the use of blood products in accordance with the state of the art in medical science and technology. They shall appoint a medical person who is responsible for the transfusion medical tasks and is equipped with the necessary competences (person responsible for transfusion). In addition, for each treatment unit in which blood products are used, they must appoint a medical person who works in patient care and has basic knowledge and experience in transfusion medicine (transfusion officer). If the health care facility has a donation facility or an institute for transfusion medicine or if it is a health care facility with acute care, a commission for transfusion medical matters (transfusion commission) must also be formed.

(2) Within the framework of the quality assurance system, the qualifications and tasks of the persons working in close connection with the use of blood products shall be defined. In addition, the principles for patient-related quality assurance of the use of blood products, in particular the documentation, including the documentation of the indication for the use of blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia, and the interdisciplinary quality assurance system shall be defined.
information exchange, monitoring of use, use-related effects, side effects and adverse reactions and any additional therapeutic measures required.

§ 16 Obligation to provide information

(1) In the event of any adverse events associated with the use of blood products and medicinal products for the specific
If adverse events occur during the treatment of coagulation disorders in haemophilia, the attending physician must immediately take the necessary measures. He/she shall inform the person responsible for transfusion and the person responsible for transfusion or the other persons to be informed in accordance with the quality assurance system of the health care facility.

(2) In the event of a suspected adverse reaction or adverse drug reaction to a blood product, the pharmaceutical entrepreneur must be informed immediately. coagulation disorders in haemophilia, the competent higher federal authority must also be informed. The notification must contain all necessary information such as the name of the product, the name or company of the pharmaceutical entrepreneur, the batch designation and, if available, the Uniform European Code pursuant to Section 4 (30a) of the German Medicines Act. The date of birth and the sex of the person in whom the adverse reaction or adverse drug reaction is suspected must be stated.

(3) The professional duties of notification remain unaffected.

§ 17 Blood products not used

(1) Unused blood products shall be properly stored, transported, dispensed or disposed of within the health care facilities. Blood products derived from cellular blood components and fresh plasma shall be transported and dispensed only in accordance with a written or electronic procedure established within the quality system. If the procedure is established electronically, it shall be ensured that the electronic documents are readily accessible to the respective recipients at all times and that they are adequately protected against unauthorised tampering. Unused autologous blood samples shall not be used on other persons.

(2) The whereabouts of unused blood products shall be documented.

18 State of the art in medical and dental science and technology for the use of blood products

(1) The German Medical Association, in agreement with the competent higher federal authority and after hearing experts, and taking into account the guidelines and recommendations of the European Union, the Council of Europe and the World Health Organisation on blood and blood components, shall establish in guidelines the generally recognised state of the art in medical science and technology, in particular for

1. the use of blood products, including the documentation of the indication for the use of blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia, the testing for infection markers of the persons to be treated on the occasion of the use of blood products and the requirements for the reserve samples,

2. quality assurance of the use of blood products in health care facilities and their monitoring by the medical profession,

3. the qualifications and duties of persons closely associated with the use of blood products,

4. the handling of unused blood products in health care facilities

shall be established. During the drafting process, the appropriate participation of experts from the professional and trade circles concerned, in particular the sponsors of the donor institutions, the umbrella organisations of the health insurance funds, the German Hospital Federation, the National Association of Statutory Health Insurance Physicians and the competent authorities of the Federation and the Länder shall be ensured. The guidelines are published by the competent higher federal authority in the Federal Gazette.

(2) It shall be presumed that the generally recognised state of the art in medical science and technology has been observed with regard to the requirements under this section if and to the extent that the guidelines of the German Medical Association pursuant to paragraph 1 have been observed.

(3) Paragraphs 1 and 2 shall apply mutatis mutandis to the Federal Dental Association in the field of dentistry.

Fourth section Tracing

§ 19 Procedure

(1) If a donor center determines or has a reasonable suspicion that a donor is infected with HIV, hepatitis viruses or other pathogens that can lead to serious courses of disease, the removed donation must be discarded and the whereabouts of previous donations must be traced. The procedure for verifying the suspicion and for tracing is based on the state of scientific knowledge. In particular, the following duties of care must be observed:

1. the traceability period for previous donations to protect against the respective transmission risks must be adequate,

2. a donation suspected to be infectious must be blocked until a decision on further action has been made by repeat or confirmatory test results,

3. clarity must be obtained without delay on the donor's infectious status and on his donations suspected of being infected,

4. a confirmed infectious donation must be safely discarded,

5. the necessary information procedures must be complied with, with Section 16 (2) sentence 3 applying mutatis mutandis, and

6. the initiation of the traceability procedure shall be notified to the competent authority without delay if the confirmatory test results confirm infectivity, are questionable or if retesting is not possible; Section 16(2), third sentence, shall apply mutatis mutandis.

The responsible medical person at the donor centre must inform the donor without delay of the infection status confirmed at the time of donation. He/she must provide the donor with detailed information and advice. If blood products which are suspected of transmitting infectious agents have been used, the health care facilities are obliged to inform the persons treated immediately and to recommend testing. Written consent of the treated person shall be obtained prior to testing. The treated person shall be advised in detail.

(2) If it is established or if there are reasonable grounds for suspecting that a person to be treated or who is being treated has been infected by a blood product pursuant to sub-section 1, first sentence, in a health care facility, the health care facility must immediately investigate the cause of the infection. It shall identify the blood product that may be responsible for the infection or the suspicion and provide the information in accordance with Section 16 (2). The pharmaceutical entrepreneur shall arrange for the donor to be identified and a follow-up examination to be recommended. Paragraph 1, sentence 8 shall apply accordingly. If the infectiousness of the donor is confirmed or not excluded during the follow-up examination or if a follow-up examination is not feasible, the procedure according to paragraph 1 shall apply accordingly.

(3) The health care facilities, the donation facilities and the pharmaceutical entrepreneurs shall cooperate with the competent authorities of the Federation and of the Länder in order to determine the cause of the infection in accordance with paragraph 2. In particular, they shall be obliged to provide the information required for this purpose. Section 16 (2) sentence 3 shall apply accordingly.

(4) The measures carried out in accordance with paragraphs 1 to 3 shall be documented for the purposes of further traceability procedures and risk assessment in accordance with the Medicinal Products Act.

§ 20 Authorisation to issue ordinances

The Federal Ministry of Health is hereby empowered, after hearing experts, to adopt a Ordinance, with the consent of the Bundesrat, regulating the details of the procedure of the traceability, provided that this is necessary to prevent risks to the health of humans or for the risk provisioning is required. In particular, the regulation can be used to lay down rules on a secure

The Commission shall adopt measures on the identification of the infection status of donors and persons to be treated, on the documentation and transmission of data for tracing purposes, on the period of tracing and on the blocking and storage of blood products.

Section Five Reporting

§ 21 Coordinated reporting system

(1) The sponsors of the donation establishments and the pharmaceutical entrepreneurs shall submit to the competent
Federal higher authority annually in accordance with sentence 4 the figures on the extent of the collection of blood and
blood components as well as on the extent of the production, loss, expiry, placing on the market, import and export of blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia. The health care facilities shall report the figures on the consumption and expiry of blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia to the competent higher federal authority annually in accordance with sentence 4. Details of the blood products and medicinal products for the specific therapy of coagulation disorders in haemophilia to be reported in accordance with sentences 1 and 2 shall be regulated in the statutory instrument pursuant to Section 23. The reports must be submitted after the end of the calendar year, at the latest by 1 March of the following year. The competent higher federal authority shall inform the
Land authority responsible for monitoring if the reports are repeatedly not submitted or are incomplete.

(1a) The haemophilia practitioner shall report the number of patients with coagulation disorders in haemophilia, differentiated according to the severity of the disease and according to age groups, as well as the total amount of medicinal products used in these patient groups for the specific therapy of
coagulation disorders in haemophilia according to sentence 3 to the German
Haemophilia Register according to § 21a. In the case of written or electronic consent of the treated patient, instead of the report according to sentence 1

1. to the trust centre pursuant to Section 21a (2), first sentence, the personal identification data in accordance with the pseudonymisation procedure specified pursuant to Section 21a (2), fourth sentence, and

2. to the German Haemophilia Register pursuant to Section 21a (1), first sentence, the pseudonymised data in accordance with the specifications made pursuant to Section 21a (3), third sentence, and Section 2 (4), second sentence, number 3

the Transfusion Act Reporting Ordinance, in particular

a) the details of the patient's age, sex and place of residence,

b) the treatment data,

c) the details of the health insurance fund,

d) the information on the withdrawal of the patient's consent or on the death of the patient

to report. The reports must be submitted after the end of the calendar year, at the latest by 1 July of the following year. The notification pursuant to sentence 1 or sentence 2 fulfils the notification obligation pursuant to paragraph 1 sentence 2 for medicinal products for the specific therapy of coagulation disorders in haemophilia.

(2) The competent higher federal authority shall compile the data reported in accordance with paragraphs 1 and 1a in anonymised form in a report and make it public. It shall treat reporting data as strictly confidential.

(3) The donor establishments shall send the competent authority a list of the health care establishments supplied once a year and shall make this list available to the competent higher federal authority on request.

§ 21a German Haemophilia Register, authorisation to issue ordinances

(1) The Paul Ehrlich Institute, in cooperation with the Gesellschaft für Thrombose- und Hämostaseforschung e. V., the Deutsche Hämophiliegesellschaft zur Bekämpfung von Blutungskrankheiten e. V. and the Interessengemeinschaft Hämophiler e. V. a clinical register under the name "Deutsches Hämophilieregister". The German Haemophilia Register has the following tasks in particular:

1. the collection, collation, verification and evaluation of the reports pursuant to section 21(1a),

2. the determination of the details of the data set according to paragraph 3 sentence 3 and § 2 paragraph 4 sentence 2 number 3 of the Transfusion Act Reporting Ordinance in accordance with the state of medical science and technology including the updating of the data set,

3. the specification of the details of the pseudonymisation procedure pursuant to paragraph 2 sentence 4,

4. the evaluation of the collected data and the feedback of the evaluation results to the haemophilia treating physicians in order to improve the care of patients with coagulation disorders in haemophilia,

5. the provision of the necessary anonymised data to create transparency in the provision of care, for the purposes of health services research and for the further development of the scientific basis in the field of coagulation disorders in haemophilia in accordance with paragraph 5,

6. international cooperation with other haemophilia registries,

7. the promotion of interdisciplinary cooperation in haemophilia treatment.

(2) The Paul Ehrlich Institute shall, with the involvement of an independent third party, set up a trust centre that is separate from the German Haemophilia Register in terms of organisation, personnel and technology. The trust centre shall collect the personal identification data transmitted to it in accordance with Section 21 (1a) sentence 2 number 1, generate a pseudonym from this data, transmit the pseudonym to the German Haemophilia Register and delete the personal identification data temporarily stored only for the generation of the pseudonym immediately after the transmission of the pseudonym. A pseudonymisation procedure shall be used that excludes the identification of patients according to the respective state of the art. The pseudonymisation procedure shall be determined by the German Haemophilia Register in consultation with the Federal Commissioner for Data Protection and Freedom of Information and the Federal Office for Information Security and the parties involved in accordance with paragraph 1, sentence 1. The pseudonym generated by the relying party may only be transmitted to the German Haemophilia Register, may only be processed by the German Haemophilia Register for the tasks specified in paragraph 1 sentence 2 and may not be transmitted to any other body.

(3) The German Haemophilia Register shall collect the following data for the tasks specified in paragraph 1, sentence 2:

1. the data on the reporting haemophilia treating physician as well as on the time and the year or period of the report according to § 2 paragraph 4 sentence 2 number 1 and 2 of the Transfusion Act (Transfusionsgesetz-) Notification Ordinance,

2. the anonymised data submitted by the haemophilia patient in accordance with the first sentence of Section 21(1a) and

3. in the case of written or electronic consent by the patient being treated

   a) the pseudonym generated by the relying party in accordance with paragraph 2, and

   b) the data transmitted by the medical person treating haemophilia in accordance with § 21 paragraph 1a sentence 2 number 2.

The German Haemophilia Register shall merge the pseudonym transmitted by the relying party pursuant to paragraph 2 with the data transmitted to the German Haemophilia Register pursuant to sentence 1 number 3 letter b. Further details on the type and scope as well as on the transmission procedure of the data to be transmitted to the German Haemophilia Register pursuant to Section 21 (1a) sentence 2 number 2 and Section 2 (4) sentence 2 number 3 of the German Haemophilia Act shall be determined by the German Haemophilia Register.
Transfusion Act Reporting Ordinance is issued by the German Haemophilia Registry in coordination with the Federal Commissioner for Data Protection and Freedom of Information and the parties involved in accordance with paragraph 1 sentence 1. When determining the data in accordance with sentence 3, those data in particular shall be determined which are in principle also collected for the treatment documentation and which are medically or methodologically necessary in order to

1. to determine the quality of diagnostics or of the treatment of patients with coagulation disorders in haemophilia using appropriate indicators,

2. possible concomitant diseases and complications,

3. to determine mortality,

4. to create transparency with regard to the supply situation,

5. to further develop the scientific basis in the field of coagulation disorders in haemophilia; and

6. allow for appropriate validation or risk adjustment in the analysis of the data.

The German Haemophilia Register shall publish an up-to-date overview of the type and scope of the data collected and of the transmission procedure pursuant to sentence 3 in the Federal Gazette. It must be ruled out that patients can be reidentified by the processing of the data at the Trust Office and the German Haemophilia Register. In the event of revocation of the patient's consent or death, the patient's data shall be made anonymous.

(4) The medical person treating haemophilia shall inform their patients with coagulation disorders in haemophilia about the processing of their personal data and about the purpose of the German Haemophilia Register. The information shall include information about the possibility of giving written or electronic consent

1. the inclusion of pseudonymised patient and treatment data in the German Haemophilia Register, and

2. to improve the care of patients with coagulation disorders in haemophilia

   a) the transmission of these data back to the reporting haemophilia attending physician, and

   b) in the transmission of evaluation results of these reported data to the reporting haemophilia treating physician.

In the absence of consent, the information provided shall include the information that the medical person treating haemophilia is obliged to report anonymised data to the German Haemophilia Register in accordance with Section 21 (1a) sentence 1 and that the German Haemophilia Register transmits anonymised evaluation results of the data reported in accordance with Section 21 (1a) sentence 1 to the reporting medical person treating haemophilia in order to improve the care of patients with coagulation disorders in haemophilia. The patient shall be informed that in case of revocation of consent or death, his/her pseudonymized data will be anonymized. The patient shall confirm the information in writing or electronically.

(4a) The German Haemophilia Register may be used to improve the care of patients with Coagulation disorders in haemophilia which have been diagnosed by a haemophilia specialist in accordance with § 21 Para. 1a, sentence 2, number 2, and shall transmit the evaluation results of these data as well as anonymised evaluation results of the patient and treatment data contained in the register back to this medical practitioner.

(5) For research purposes, the German Haemophilia Registry may send anonymised data to the German Haemophilia Register pursuant to paragraph 1 sentence 1 and to third parties. The transmission of anonymised data shall take place upon application and after conclusion of a user agreement. The Paul Ehrlich Institute shall decide on the application on the basis of a decision proposal from the Steering Committee. The data may only be processed for the tasks specified in paragraph 1 sentence 2 and in compliance with the publication principles of the German Haemophilia Registry.

(6) The Federal Ministry of Health is hereby empowered, after hearing experts, to regulate the organisational and technical structure and the use of the German Haemophilia Registry by ordinance with the consent of the Bundesrat. The ordinance may in particular specify the
More detailed rules shall be laid down on the requirements for

1. the organisational structure and management of the Registry,

2. the representation of the Registry vis-à-vis third parties,

3. the Steering Committee,

4. the technical advisory committee,

5. the rules of procedure of the participants in the Registry pursuant to paragraph 1, first sentence,

6. the application and decision-making procedure pursuant to paragraph 5, the user agreement and the publication principles of the register, and

7. the quality control and quality assurance measures.

§ 22 Epidemiological data

(1) The sponsoring donor establishments shall provide a list of the number of donors confirmed positive for an infectious marker and the number of tests performed on a quarterly and annual basis, separately for each donor establishment, indicating the total number of persons tested. Persons from whom autologous blood has been collected are excluded. The figures shall be differentiated according to the different infectious markers tested for, the type of donation, first-time donors, repeat donors, sex and age, possible route of infection, self-exclusion, region of residence and previous donations. The list must be forwarded to the higher federal authority responsible for epidemiology by the end of the quarter following the reporting period. If the lists are repeatedly not forwarded or are incomplete, the Land authority responsible for surveillance must be informed. If there is an infectious disease epidemiological issue that requires clarification, the authority to inform the competent Land authority and the competent higher federal authority shall remain unaffected.

(2) The higher federal authority responsible for epidemiology compiles the data in anonymous form and publishes an annual overview by 30 September of the following year. Reporting data must be treated as strictly confidential.

§ 23 Authorisation to issue ordinances

The Federal Ministry of Health is hereby empowered, after hearing experts, to adopt a to issue a statutory instrument, with the consent of the Bundesrat, regulating the
type, scope and method of presentation of the information pursuant to this section.

Section Six Experts

§ 24 Blood Working Group

The Federal Ministry of Health shall establish a working group of experts on blood products and the
Blood Donation and Transfusion (Blood Working Group). The working group advises the competent authorities of the
Federal Government and the Länder. It shall hold the hearings of experts provided for under this Act when ordinances are issued. The Federal Ministry of Health shall appoint the members of the working group on the proposal of the professional and specialist societies, professional organisations of the medical profession, the professional associations of pharmaceutical entrepreneurs, including the state and municipal blood transfusion services, the Plasmapheresis Working Group and the blood transfusion services of the German Red Cross, supraregional patients' associations, in particular the haemophilia associations, the Federal Ministry of Defence and the Länder. The working group shall draw up its own rules of procedure in agreement with the Federal Ministry of Health. The Federal Ministry of Health shall appoint and nominate the chairperson of the working group. It may commission a higher federal authority with the management of the working group.

Section Seven Obligations of the authorities

Section 25 Obligations of the authorities to provide information

For the purposes regulated by this Act, the federal and Land authorities responsible for the implementation of this Act shall immediately notify each other of any suspected cases of serious adverse reactions or side effects of blood products of which they become aware. Section 16 (2) sentence 3 shall apply mutatis mutandis.

Section Eight Special provisions

§ 26 Federal Armed Forces

(1) The provisions of this Act shall apply mutatis mutandis to institutions of the Bundeswehr.

(2) In the area of responsibility of the Federal Ministry of Defence, the enforcement of this Act is the responsibility of the competent authorities and experts of the Federal Armed Forces.

(3) The Federal Ministry of Defence, in agreement with the Federal Ministry of Health, may in individual cases permit exceptions to this Act and to statutory orders issued on the basis of this Act for its own area of responsibility if this is justified for the performance of the special tasks and the protection of health is safeguarded.

Ninth Section Determination of the competent higher federal authorities and other provisions

§ 27 Competent higher federal authorities

(1) The competent higher federal authority is the Paul Ehrlich Institute.

(2) The higher federal authority responsible for epidemiology is the Robert Koch Institute.

(3) The higher federal authority responsible for health education is the Federal Centre for Health Education.

(4) (omitted)

§ 28 Exceptions to the scope of application

This Act does not apply to the collection of a minor amount of blood for diagnostic purposes, to homeopathic autologous blood products, autologous blood for the manufacture of biotechnologically processed tissue products and to the collection of a minor amount of autologous blood for the manufacture of products for dental treatment, provided that these products are manufactured and used in the dental practice on the basis of the generally recognised state of the art in dental science and technology established in accordance with Section 12a (3) in conjunction with (1) and (2) and Section 18 (3) in conjunction with (1) and (2).

§ 29 Relationship to other areas of law

The provisions of the law on medicinal products, the law on medical devices and the law on epidemics shall remain unaffected unless otherwise prescribed in this Act. Transplantation law shall not apply.

§ 30 Alignment with Community law

(1) Statutory orders under this Act may also be issued for the purpose of approximating the laws of the Member States of the European Union insofar as this is necessary to implement regulations or to transpose directives or decisions of the Council of the European Union or of the Commission of the European Communities which relate to matters covered by this Act.

(2) Statutory instruments under this Act which are intended solely to transpose directives or decisions of the Council of the European Union or the Commission of the European Communities into national law do not require the consent of the Bundesrat.

Section Ten Penalties and Fines

§ 31 Penal provisions

A custodial sentence not exceeding one year or a monetary penalty shall be imposed on anyone who, contrary to the first sentence of Section 5(3), fails to ensure that the donor is examined for the infectious markers specified therein before the donation is released.

§ 32 Rules on fines

(1) It shall be a misdemeanour for any person to commit an act referred to in section 31 by negligence.

(2) It is an administrative offence for anyone who intentionally or negligently

1. operates a donation facility contrary to § 4 sentence 1 no. 2,

2. carries out an immunisation programme or pre-treatment in contravention of section 8(2), first sentence, nos. 4 or 6, in each case also in conjunction with section 9(1), second sentence, or

3. (omitted)

4. contrary to section 21(1), first or second sentence, or (1a), first sentence, also in conjunction with the second sentence, in each case also in conjunction with a statutory instrument under section 23, fails to make a report or to make a report correctly, completely or in good time.

(3) The administrative offence may, in the case referred to in paragraph 1, be punished by a fine of up to twenty-five thousand euros, in the cases referred to in paragraph 2, points 1 and 2, by a fine of up to ten thousand euros and in the other cases by a fine of up to five thousand euros.

(4) The administrative authority within the meaning of Section 36(1)(1) of the Administrative Offences Act shall be the Paul Ehrlich Institute in the cases referred to in paragraph 2(4).

Section Eleven Transitional Provisions

§ 33

Any person who, at the time of the coming into force of this Act, is engaged in the activity of using blood products and who has the
The person who fulfils the requirements of the regulations in force at that time may continue to carry out this activity.

Section Twelve Final provisions

34 Transitional provision on the occasion of the Act on the Update of the Regulations for Blood and Tissue Preparations and on the Amendment of Other Regulations

Section 21(1a) and 21a(1) to (5) shall apply from 1 August 2019.

§ 35 Transitional provision on the occasion of the Appointment Service and Supply Act

Until the generally recognised state of the art in science and technology in the field of dentistry established by the Federal Dental Association pursuant to Section 12a, paragraph 3, and Section 18, paragraph 3, has been published by the competent higher federal authority, but at the latest until 1 June 2022, Section 28 shall continue to apply in the version applicable until 10 May 2019. **§§ 36 and 37**
(omitted)

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§ 38 Return to uniform ordinance status

The parts of the statutory instruments based on sections 35 to 37 as amended therein may be amended by statutory instrument on the basis of the relevant authorisation. **Section 39 (Entry into force)**

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Law on the Donation, Removal and Transfer of Organs and Tissues (Transplantation Act - TPG)

TPG

Date of production: 05.11.1997

Full quote:

'Transplantation Act as amended by the notice of 4 September 2007 (BGBl. I p. 2206), which was last amended by Article 15 (3) of the Law of 4 May 2021 (BGBl. I p. 882)'

Status: Recast by Bek. v. 4.9.2007 I 2206;

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footnote

(+++ Proof of text from: 1.12.1997 +++)

Heading: IdF d. Art. 1 No. 1 G v. 20.7.2007 I 1574 mWv 1.8.2007

Input formula

With the approval of the Federal Council, the Bundestag has decided on the following law:

outline

Section 1 General Rules

Section 1 Objective and scope of the law

(1) The aim of the law is to promote the willingness to donate organs in Germany. To this end, every citizen should be able to deal seriously with the issue of his or her own willingness to send and to document the respective declaration. In order to enable an informed and independent decision of each individual, this law provides for a broad education of the population onthe possibilities of organ and tissuedonation.

(2) This Act shall apply to the donation and removal of human organs or tissues for the purpose of transmission and to the transfer of organs or tissues, including the preparation of such measures. It also applies to the prohibition of trade in human organs or tissues. (3) This Act does not apply to:

1. tissues taken from a person within the same surgical procedure in order to be transferred back to them without altering their official nature,

2. blood and blood components.

Section 1a Definitions

Within the meaning of this Act,

1. organs, with the exception of the skin, are all differentiated, differentiated from different tissues parts of the human body which, in terms of structure, blood vessel supply and ability to perform physiological functions, have a functional unit, including the organ parts and individual tissues of an organ, which can be used for the same purpose as the whole organ in the human body, while maintaining the requirements for structure and blood vessel supply, with the exception of such tissues intended for the manufacture of advanced therapy medicinal products within the meaning of Paragraph 4(9) of the German Medicines Act;

2. organs subject to procurement are the organs of the heart, lungs, liver, kidney, pancreas and intestines referred to in point 1, which have been taken in accordance with Paragraphs 3 or 4;

3. organs that are not capable of regeneration are all organs which cannot reform in the donor after removal;

4. are all cells consisting of cells which are not organs referred to in point 1, including individual human cells;

5. are close family members in the ranking
   a) the spouse or registered civil partner,
   b) adult children,
   c) the parents or, if the organ or tissue donor was a minor at the time of death and the care of the person at that time was only due to a parent, guardian or carer, that caretaker,
   d) the adult siblings,
   e) grandparents;

6. is the extraction of organs or tissues;

7. is transmission of organs or tissues in or on a human recipient and use in humans outside the body;

8. is a tissue device which removes, examines, processes, works or processes, preserves, marks, packs, stores or transfers tissues to others for the purpose of transmission;

9. is a medical facility with direct patient care, professionally and medically under constant medical supervision and providing medical services;

10. are procedural instructions describing the steps of a specific procedure, including the materials and methods to be used and the expected result;

11. Traceability is the ability to follow and identify the organ at every stage from donation to transmission or dislocation; this includes the ability to identify the donor, the removal hospital and the recipient in the transplant centre, as well as to all relevant, non-personal data on products and materials in contact with the organ.

Section 2 Public Education, Declaration on Organ and Tissue Donation, Organ and Tissue Donation Registers, Organ and Tissue Donation Cards

(1) On the basis of this Act, the competent bodies under state law, the federal authorities within the scope of their competence, in particular the Federal Government for Health Education, as well as the health insurance funds, shall inform the population about:

1. the possibilities of organ and tissue donation,

2. the conditions for organ and tissue collection in dead donors, including the importance of a declaration on organ and tissue donation made during their lifetime, including in relation to a patient's order, and the legal consequence of a failure to make a declaration with regard to the right of the next of kin to make decisions in accordance with Paragraph 4, and

3. the importance of organ and tissue donation with regard to the potential benefit of medical use of organs and tissues, including medicinal products derived from tissues, for sick people, and the importance of the collection of transplantation medical data in the transplantation register referred to in section 5a.

The clarification must cover the full scope of the decision and must be open to results.
The bodies designated in the first sentence should also provide identity cards for the declaration of organ and tissue donation (organ donation card) together
with appropriate information documents and make them available to the population. The Federal Government and the Länder shall ensure that the federal and state authorities responsible for issuing official documents have access to organ donation certificates together with appropriate information documents and that they provide an organ donation certificate to those entitled to receive an identity document together with appropriate information documents when issuing the identity documents.

(1a) Without prejudice to their obligations under paragraph 1, health insurance funds shall make the documents referred to in the third sentence of paragraph 1 available to their insured persons who have reached the age of 16 if they are issued with the electronic health card in accordance with Paragraph 291 (1) of the Fifth Book of the

Social Code. Private health insurance funds shall provide the documents referred to in the third sentence of paragraph 1 to their insured persons who have reached they age of 16 and make them available every five years together with the contribution notice in accordance with Section 10 paragraph 2a sentence 9 of the Income Tax Act. If health insurance funds and private health insurance companies are not able to fulfil the obligations under sentences 1 and 2 within 12 months of the entry into force of this Act, they shall:
Provide the documents referred to in the third sentence of paragraph 1 to their policy holders
within the aforementioned period in another appropriate
way. If unable to receive the declarations of the
insured regarding
organ and tissue donation in accordance with Section 291 paragraph 2 number 2 in conjunction with section 334 paragraph 1 sentence 2 number
2 of the Fifth Book of the Social Code, , the health insurance funds and the private
health insurance companies must provide the documents referred to in paragraph 1 sentence 3 to
their insured persons every two
years. By making the documents available, the health insurance companies and the public health insurance companies are asking the insured to document their declaration on organ and tissue donation and have been provided details of professionally qualified contact persons for questions on organ and tissue donation and on the significance of a lifetime declaration on organ and tissue donation, also in relation to a patient's order.

(2) Anyone who makes an declaration of organ and tissue donation can consent to organ and tissue removal in accordance with Section 3, refuse it or delegate the decision of a named person of his trust (declaration on organ and tissue donation). The declaration may be limited to certain organs or tissues. Consent and transmission of the decision may be declared from the age of 16, the refusal may be declared from the age of fourteen.

(2a) No one may be required to make a statement on organ and tissue donation.

(3) The Federal Ministry of Health may, by means of a legal decree with the consent of the Federal Council, delegate to a body the task of storing the declarations on organ or tissue donation at the request of the dependant and providing information to persons entitled to do so (organ and tissue donation register). The personal data stored may only be used for the purpose of determining whether the person who made the declaration is permitted to have organ or tissue removal in accordance with Paragraph 3 or 4 and is transmitted only for that purpose in accordance with paragraph 4 or paragraph 4a. In particular, the Legal Regulation regulates:

1. the public bodies (contact points) responsible for receiving or amending a declaration of donation of organ or tissues, the use of a form, the nature of the
   data to be provided on it and the verification of the identity of the person making the declaration,

2. the transmission of the declaration by the authorities to the register and the storage of the declaration and the data contained therein at the contact points and the register,

3. the storage of the personal data of the doctors entitled to information in accordance with paragraph 4 sentence 1 at the register, as well as
   the information, storage and composition of the user identifiers and passwords for their right to provide information,

4. the deletion of the stored data and

5. the financing of the register.

(4) The information from the register may only be sent to a hospital and a doctor designated to provide information, who is not involved in the removal or transmission of the organs or tissues of the possible organ or tissue donor, nor is he/she subject to instructions from a doctor involved in the procedures. The request may only be made after the determination of death in accordance with Section 3 (1) sentence 1 no. 2. In order to verify the admissibility of the request for information to the register and the provision of the information from the register, the information and its reason and purpose shall be recorded. The information may only be transmitted to the doctor who is to take the organ or tissue removal or, under whose responsibility, tissue removal is to be carried out in accordance with section 3 (1) sentence 2, and to the person who is to be informed of the intention according to section 4 of a possible organ or tissue removal.

(4a) The information referred to in the first sentence of paragraph 4 may be transmitted in an automated retrieval procedure. The automated retrieval procedure may only be established if the bodies involved have taken the technical and organisational measures required by Articles 24, 25 and 32 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons in the processing of personal data, on the free movement of data and on the repeal of Directive95/46/ EC (General Data Protection Regulation) (OJ No. L 119 of 4.5.2016, p. 1; L 314 of 22.11.2016, p. 72; 2) as amended. The responsibility for the permissibility of the individual retrieval shall be borne by the declarant or the physician designated by a hospital to the registry as authorized to to the registry. The body entrusted with the task of storing and providing information on the declarations of organ or tissue donation in accordance with the first sentence of paragraph 3 shall verify the permissibility of the retrievals by means of suitable random sampling procedures and otherwise only if there is reason to do so.

The Federal Government may, with the consent of the Federal Council, establish a model for the organ and tissue donation card by means of a general administrative regulation and make it known in the Federal Gazette.

Section 2 Removal of organs and tissues from dead donors

Section 3 Withdrawal with the donor's consent

(1) The removal of organs or tissues is only permitted, unless otherwise specified in Sections 4 or 4a, if:

1. the organ or tissue donor had consented to the removal,

2. the death of the organ or tissue donor is determined in accordance with rules which correspond to the state of the knowledge of medical science, and

3. the procedure is performed by a doctor.

By way of derogation from the first sentence, the removal of tissues may also be carried out by other qualified persons under the responsibility and professional instructions of a doctor.

2. The removal of organs or tissues shall be prohibited if:

1. the person whose death has been found to have objected to organ or tissue removal,

2. the final, unrecoverable failure of the overall function of the cerebrum, cerebellum and brain stem is not established before removal of the organ or tissue donor in accordance with procedural rules corresponding to the state of the findings of medical science.

The doctor shall inform the next of kin of the organ or tissue donor of the intended organ or tissue removal. The person performing the removal shall record the course and extent of organ or tissue removal. The next of kin has the the right of inspection and call on a person of his/her trust.

Section 4 Withdrawal with the consent of other persons

If the doctor who performs the organ or tissue removal or has the responsibility for the removal
If tissues are to be taken in accordance with the second sentence of Section 3(1) of the second sentence, in absence of a written consent or a written objection of the potential organ or tissue donor, the next of kin must be questioned whether he/she is aware of a declaration of organ or tissue donation. If the next of kin is not aware of such a declaration, the removal is permitted under the conditions of Section 3 (1) sentence 1 no. 2 and 3, sentence 2 and paragraph 2 no. 2 only if a doctor has informed the next of kin about a possible organ or tissue removal and the latter has consented to it. If multiple organs or tissues are considered, consent shall be collected together. The next of kin must indicate??? a presumed will to donate by the possible organ or tissue donor. The doctor must inform the next of kin he/she can withdraw the declaration within an agreed period; the agreement must be in writing.

(1) The next of kin is only authorized to make a decision in accordance with paragraph 1 if he/she has had personal contact with the potential organ or tissue donor in the two years preceding his/her death.

The
Doctor has to determine this by questioning the next of kin. In the case of several close family members/next of kin, it is sufficient that one person be involved in accordance with paragraph 1 to make a decision; however the refusal of other family members must be taken into consideration. If a senior next of kin is not reachable within a reasonable time, the participation and decision of the next member of the family who is first available is sufficient. The next of kin is equal to an adult person who has been obviously close to the possible organ or tissue donor until his death in a special personal connection; he/she shall be next to the next of kin.

(2) If the potential organ or tissue donor has delegated the decision on an organ or tissue removal to a specific person, the latter replaces the next member of the family.

(3) The doctor shall record the procedure, content and result of the participation of the next of kin and persons referred to in paragraph 2 sentence 5 and paragraph 3. The next of kin and the persons referred to in the second sentence 5 and 3 paragraph of paragraph shall have the right of access.

Section 4a Removal of dead embryos and fetuses

1. The removal of organs or tissues from a dead embryo or fetus shall be permitted only if:

1. the death of the embryo or fetus is determined in accordance with rules which correspond to the state of the knowledge of medical science,

2. the woman who was pregnant with the embryo or fetus has been informed by a doctor of an eligible organ or tissue removal and has given written consent to the removal of the organs or tissues, and

3. the procedure is performed by a doctor.

In the cases of sentence 1 No. 3, section 3 (1) sentence 2 shall apply accordingly. The clarification and obtaining consent may only take place after the discovery of death.

(2) The doctor shall record the procedure, content and result of the information and consent of paragraph 1 sentence 1 No.2. The person performing the procedure shall record the course and extent of organ or tissue removal. The woman who was pregnant with the embryo or fetus has the right to inspect the records. It can involve a person of their trust. Consent can be revoked in writing, electronically or orally.

(3) In the cases referred to in paragraph 1, the woman who was pregnant with the embryo or fetus shall be considered as a donor only for the purpose of documentation, tracing and data transfer.

Section 5 Verification procedure

(1) The findings pursuant to Section 3 (1) sentence 1 No. 2 and paragraph 2 no. 2 shall each be made by two qualified doctors who have examined the organ or tissue donor independently of each other. By way of derogation from the first sentence of paragraph 3(1) sentence, it is sufficient to examine and establish by a doctor if the final, unrecoverable standstill of the heart and circulation has occurred and more than three hours have elapsed since then.

(2) Doctors involved in the examinations referred to in paragraph 1 shall not be involved in the removal or transmission of the donor's organs or tissues. Nor may they be subject to instructions from a doctor involved in these measures.
The determination of the results of the examination and its timing shall be recorded and signed by the doctors without delay, indicating the findings of the examination. The next of kin as well as thepe-soons the persons? according to Section 4 (2) sentence 5 and paragraph 3 must be given the opportunity to inspect. They may call in a person of their person of their confidence.

Section 6 Respect for the dignity of the organ and tissue donor

(1) Organ or tissue removal in deceased persons and all measures related to it shall be carried out in a manner conforming with medical due diligence, respecting the dignity of the organ or tissue donor.

(2) The donor’s body must be handed over for burial in a dignified condition. Prior to burial the next of kin is given the opportunity to see the body.

(3) Paragraphs 1 and 2 apply accordingly to dead embryos and fetuses.

Section 7 Data processing, obligation to provide information

(1) During the processing of personal data of a possible organ or tissue donor, the involvement of otherRelatives or a person in accordance with Section 4 paragraph 2 sentence 5 or paragraph 3 is permitted if this is necessary

1. in order to determine whether organ or tissue removal is permissible in accordance with Sections 3 paragraphs 1 and 2, Paragraph 4 paragraph 1 to 3 and Section 9 paragraph 3 sentence 2 or whether it is precluded by medical reasons,

2. for the information of the next of kin in accordance with section 3 paragraph 3 sentence 1,

3. on organ and donor characterization in accordance with Section 10a,

4. for tracing in accordance with Section 13 paragraph 1 or

5. on the reporting of serious incidents and serious adverse reactions on the basis of the legal regulation referred to in Section 13(4).

The transfer of this data is only permitted to persons entitled to provide information in accordance with the first sentence of paragraph 3.

2. In order to provide immediate information on the data required by paragraph 1, the following:

1. Doctors who had treated the possible organ or tissue donor for a disease that preceded death,

2. Doctors who have received information about the possible organ or tissue donor from the organ and tissue donation register in accordance with Section 2 (4) or paragraph 4a,

3. the establishment of medical care in which the death of the possible organ or tissue donor has been established in accordance with the first sentence of Paragraph 3 (1),

4. Doctors who have carried out the mortuary examination on the possible organ or tissue donor,

5. the authorities in whose custody or co-custody the body of the possible organ or tissue donor is or has been found,

6. the transplant officer of the removal hospital,

7. the responsible doctor of the transplant centre in which the organ is to be transferred or has been transferred, and

8. the person commissioned by the coordinating body (Section 11) or a tissue removing establishment, in so far as he/she has received information on the data required by paragraph 1.

The obligation to provide immediate information shall only be established after the death of the possible organ or tissue donor has been established in accordance with Section 3 (1) sentence 1 no. 2.

3. Have the right to information on the data required by paragraph 1

1. Doctors who intend to remove organs in accordance with Paragraphs 3 or 4 and who work in a hospital authorised under Section 108 of the Fifth Book of the Social Code or under other legal provisions for the transfer of such organs or cooperates with such a hospital for the purpose of removing such organs, as well as the transplant officer of the removal hospital and the responsible doctor of the transplantation centre to which the organ is to be transferred or has been transferred,

2. Physicians intending to remove tissues in accordance with Sections 3 or 4 or under whose responsibility tissues in accordance with Section 3 (1) sentence 2 and are to be taken in a medical facility which removes such tissues or cooperates with such a facility for the purpose of removing such tissues, and

3. the person appointed by the coordinating body.

The information shall be obtained together for all organs or tissues intended to be removed. They are only obtained after the death of the possible organ or tissue donor has been established in accordance with Section 3 (1) sentence 1 no. 2.

Section 3 Removal of organs and tissues from living donors

Section 8 Removal of organs and tissues

1. The removal of organs or tissues for the purpose of transfer to others shall be permitted in the case of a living person, unless otherwise specified in Paragraph 8a, if:

1. the person
   a) is of legal age and capable of consent,
   b) has been informed in accordance with paragraph 2 sentences 1 and 2 and has consented to the donation,
   c) is suitable as a donor after a medical assessment and is not likely to be endangered beyond the risk of surgery or whose health will not be seriously affected beyond after discharge,
2. the transfer of the organ or tissue to the intended recipient, after a medical assessment, is capable of preserving the life of that recipient or of curing a serious disease in the recipient, preventing its aggravation or alleviating its burden,
3. in the case of organ removal, a suitable organ of a donor according to Section 3 or Section 4 is not available at the time of organ removal, and
4. the procedure is performed by a doctor.

In addition, the removal of a kidney other organs which are non-regenerative organs is only permitted for the purpose of transfer to first or second-degree relatives, spouses, registered partners, fiancées or other persons who are manifestly close to the donor in a particular personal connection.

(2) The donor shall be informed by a doctor in an understandable form about

1. the purpose and nature of the intervention,
2. investigations and the right to be informed of the results of the investigations,
3. the measures designed to protect the donor and the scope and possible, including indirect, and late consequences of the intended organ or tissue collection for his or her health,
4. the medical confidentiality,
5. the expected likelihood of success of organ or tissue transmission and the consequences for the recipient and other circumstances related to the donation, as well as on:
6. the processing of personal data.

The donor must be informed that his consent is a prerequisite for organ or tissue removal. The declaration must be provided in the presence of another physician, to whom § 5 Para. 2 Sentences 1 and 2 apply accordingly, and, if necessary, other expert persons. The content of the and the donor's declaration of consent must be recorded in a transcript, which must be signed by the informing people, the other doctor and the donor. The minutes must also contain details on the health risks minimisation measures in accordance with the first sentence of the law. Consent can be revoked in writing, electronically or orally. Sentence 3 does not apply in the case of the intended removal of bone marrow.
3. In the case of a living person, the removal of organs may be carried out only after the donor and the recipient have agreed to take tissues only after the donor has agreed to participate in a medically recommended follow-up. A further condition for the removal of organs from a living person is that the Commission, which is responsible under national law, has given an advisory opinion on whether or not there is reasonable and factual evidence that consent to organ donation is not free or whether the organ is or is not the subject of prohibited trade under Paragraph 17. The Commission must be subject to instructions from a doctor who is involved in such measures, a person with the qualifications to be a judge and a person experienced in psychological matters. The details, in particular on the composition of the Commission, the procedure and the financing, are determined by national law.

Section 8a Removal of bone marrow in minors

By way of derogation from Section 8 (1) sentence 1 (a) and (b) and no 2, the removal of bone marrow from a minor for the purpose of transmission is permitted with the following conditions:

1. The use of the bone marrow is intended for first-degree relatives or siblings of the minor.

2. The transfer of the bone marrow to the intended recipient is, after a medical assessment, suitable to cure a life-threatening disease in the recipient.

3. A suitable donor according to Section 8 (1) sentence 1 no. 1 is not available at the time of removal of the bone marrow.

The legal representative has been informed in accordance with Section 8 (2) and has consented to the removal and use of the bone marrow. Section 1627 of the Civil Code is applicable. The minor must be informed by a doctor in accordance with Section 8 (2), insofar as this is possible with regard to his age and mental maturity. If the minor refuses the intended removal or use of the specimen or use or expresses this in any other way, this must be taken into account.

4. If the minor is able to identify the nature, meaning and scope of the donation and give consent, his or her consent is also required.

If the bone marrow of the minor is to be used for first degree relatives , the legal representative must notify the family court immediately in order to reach a decision pursuant to Section 1629 (2) sentence 3 in conjunction with Section 1796 of the Civil Code.

Section 8b Removal of organs and tissues in special cases

(1) Where organs or tissues have been taken from a living person in the course of medical treatment of that person, their transferred to another person shall be permitted only if the person has been informed of the consent and has consented to such transmission of organs or tissues in accordance with The Second Sentence

s. 8(2) and The Persons in a Living Person. For the provision of information and the informed consent, Section 8 (2) sentence 4 applies accordingly.

(2) Paragraph 1 shall apply accordingly to the production of human sperm intended for medically assisted fertilization.

(3) For a revocation of consent, section 8 paragraph 2 sentence 6 applies accordingly.

Section 8c Removal of organs and tissues for retransmission

1. The removal of organs or tissues for the purpose of transfer shall be permitted in a living person only if:

1. the person

a) is capable of consent,

b) has been informed in accordance with the second sentences of paragraph 8 (2) and has consented to the removal and transfer of the organ or tissue,

2. the removal and transfer of the organ or tissue is carried out in the context of medical treatment and is necessary for such treatment in accordance with the generally accepted state of medical science;

3. removal by a doctor.

(2) By way of derogation from paragraph 1(1), the removal of organs or tissues for the purpose of retransmission from a person who is not in a position to identify the nature, significance and scope of the intended removal and to align his will accordingly shall be permitted only if the legal representative or an authorised representative has been informed in accordance with The First and Second sentences of Paragraph 8(2) and has consented to the removal and transfer of the organ or tissue. Sections 1627, 1901 (2) and 3 and Section 1904 of the Civil Code are to be applied.

(3) The removal of organs or tissues for the purpose of transfer from a living embryo or foetus shall be permitted under the conditions laid down in paragraph 1 no 2 and 3 only if the woman who is pregnant with the embryo or foetus has been informed in accordance with the first and second sentences of Paragraph 8(2) and has consented to the removal and transfer of the organ or tissue. If this woman is not able to identify the nature, meaning and scope of the intended withdrawal and to align her will accordingly, paragraph 2 shall apply accordingly.

(4) For the purpose of documenting the provision of information and the consent given, Section 8 (2) sentence 4 applies accordingly.

(5) For a revocation of consent, section 8 paragraph 2 sentence 6 applies accordingly.

Section 3a Tissue facilities, examination laboratories, registers

Section 8d Special obligations of tissue facilities

1. Without prejudice to the provisions of the law on medicinal products, a tissue establishment which removes or examines tissues may be operated only if it has appointed a doctor with the necessary expertise in the medical science. The tissue establishment is obliged to:

1. comply with the requirements for the collection of tissues according to the state of medical science and technology, in particular for donor identification, collection procedure and donor documentation,

2. ensure that only tissues are taken from donors for whom a medical assessment according to the state of medical science and technology has shown that the donor is medically suitable for this purpose;

3. ensure that the laboratory tests required for tissue donors in accordance with the state of medical science and technology are carried out in an examination laboratory in accordance with Section 8e;

4. ensure that the tissues are used for the preparation, processing, preservation or only be released if the medical service in accordance with point 2 and the laboratory tests referred to in point 3 have shown that the tissues are suitable for these purposes,

5. ensure, before and after tissue removal in living donors, measures for the necessary medical care of the donors, and

6. ensure quality assurance of the measures set out in points 2 to 5.

The details are regulated by a legal regulation in accordance with Section 16a.

(2) Without prejudice to medical documentation requirements, a tissue establishment shall document, for the purposes specified in this Act, , for the purposes of traceability, for the purpose of medical care of the donor and for the purposes of risk assessment and monitoring in accordance with the provisions of the Medicines Act or other legal provisions in accordance with article 16a.

(3) Each tissue establishment shall keep a documentation of its activities, including information on the type and quantity of tissues removed, examined, prepared, processed, preserved, stored, used, imported, and exported, and the origin and destination of the tissues, and shall make a representation of their activities publicly available. It shall, within the time limits referred to in the fifth sentence of the competent Federal Authority, submit an annual report containing the type and quantity of the samples, processed, , stored, delivered or otherwise used, as well as the imported and tissues, including the state of origin and destination of the tissues. The report is based on a form issued by the Federal Supreme Authority and published in the Federal Gazette. The form can also be made available and used electronically. The report shall be submitted after the end of the calendar year and no later than 1 March of the following year. The competent Federal Authority shall incorporate the information transmitted by the tissue establishments anonymously into a general report and make it public. If the report of a tissue establishment is incomplete or is not available by the expiry of the period set out in the 5th sentence, the competent Federal Authority shall inform the competent authority responsible for monitoring. Tissue establishments shall send the competent authority at least every two years or, on request, a list of the health care establishments they have supplied.

Section 8e examination laboratories

The laboratory tests prescribed for tissue donors in accordance with Section 8d (1) Satz 2 No. 3 may only be carried out by an examination laboratory for which a permit has been granted in accordance with the provisions of the German Medicines Act. The examination laboratory is obliged to ensure a quality assessment for the laboratory tests prescribed in accordance with Section 8d (1) sentence 2 no. 3. **8f (discarded)**

Section 4 Removal, procurement and transfer of organs, cooperation in the collection of organs and tissues

Section 9 Admissibility of organ collection and transfer, priority for organ donation

(1) The collection of organs from deceased donors may only be carried out in collection hospitals in accordance with Section 9a.

(2) The transfer of organs of deceased donors and the collection and transfer of organ fromliving donors may only be carried out in transplant centres in accordance with Section 10. Where organs within the scope of this Act have been removed, their transfer is only permitted if the
organ removal in accordance with Section 11 (4) sentence 5 has been organised by the Coordination Office and carried out in compliance with the other regulations in accordance with Section 11. In addition, the transfer of bodies subject to procurement is only permitted if the institutions have been mediated by the intermediary in compliance with the provisions of The First sentence of Paragraph 12(3).

(3) The possible removal and transmission of an organ takes precedence over the removal of tissues; it must not be affected by tissue removal. The removal of tissues from a possible donor of organs in accordance with Paragraph 9a (2) (1) is only permitted if a person appointed by the coordinating body has documented that the removal or transfer of organs is not possible or that tissue removal is not permitted.

Section 9a Removal Hospitals

(1) Extraction hospitals are hospitals approved in accordance with Section 108 of the Fifth Book of the Social Code or under other statutory provisions, which, according to their facility and human resources, can enable organ removals from potential donors in accordance with Section 3 or 4 in accordance with Section 11 (4) sentence 5. The competent authority shall designate the coordinating body to
the collection hospitals which meet the conditions set out in the first sentence and shall inform the collection hospitals in writing of this designation.

(2) The collection hospitals are obliged to:

1. The collection hospitals are obliged to report the final, irreversible loss of the overall function of the cerebrum, the cerebellum and the brainstem of patients who, according to medical assessment, could be considered as organ donors, in accordance with section 5 and to notify the coordinating body in accordance with § 11 without delay; if these patients are also considered If these patients are also considered as tissue donors, this must be notified at the same time,
2. ensure that the responsibilities and procedures for fulfilling their obligations under this Act are defined, complied with and recorded? in a statement of obligations;

3. ensure that the removal is carried out in an operating theatre in line with the state of the art of medical science and technology, in order to ensure the quality and safety of the removed organs;

4. ensure that the medical staff they deploy are qualified for their tasks;

5. comply with the regulations on organ removal made pursuant to Section 11, and

6. ensure that all deaths with primary or secondary brain damage, or the reasons for failure to identify or for failure to notify the body, are recorded as well asother reasons contrary to organ removal and that the data are transmitted anonymously to the coordinating body referred to in Paragraph 11 at least once a year.

3. The collection hospitals shall receive a flat-rate payment for the services within the framework of the organ removal and preparation. The flat-rate compensation consists of:

1. a basic flat rate for the determination referred to in paragraph 2, point 1,

2. a flat-rate payment for the benefits of intensive care, as well as

3. a flat-rate payment for benefits during organ removal.

In addition, the collection hospitals receive a compensatory supplement for the special use of the infrastructure necessary for the organ donation process.

Section 9b Transplant Officer

1. The collection hospitals shall appoint at least one medical transplant officer qualified to carry out his/her duties. If a removal hospital has more than one intensive care unit, at least one transplant officer should be appointed for each of these wards.
In the performance of the duties, the transplant officer is directly subordinated to the medical management of the removal hospital, is independent in the performance of the duties and is not subject to any instructions. The removal hospitals shall ensure that the transplant officer is able to carry out his/her duties properly and assist him/her in this. In particular, the collection hospitals shall ensure that:

1. the transplant officer is consulted when patients are considered as organ donors after a medical assessment,

2. the transplant officer is granted a right of access to the intensive care units of the removal hospital in order to carry out his/her duties,

3. all necessary information shall be made available to the transplant officer in order to fulfil the obligation under paragraph 2(5), and

4. the availability of a transplant officer is ensured through deputization arrangements.

The costs of specialist training of transplant officers are to be carried by the removal hospitals.

2. Transplant officers shall be responsible in particular:

1. that the collection hospitals fulfil their obligations under Section 9a paragraph 2(1),

2. that the relatives of donors are adequately accompanied in accordance with Section 3 or 4,

3. to prepare the procedural instructions referred to in Section 9a paragraph 2(2),

4. that the medical and nursing staff at the removal hospital are regularly informed of the importance and process of organ donation,

5. to evaluate all deaths with primary or secondary brain damage in each individual case, in particular the reasons for failure to establish or report in accordance with Section 9a (2) (1) or other reasons contrary to organ harvesting, and

6. that the management of the removal hospital is informed at least once a year of the results of the evaluation referred to in point 5 of their activities and the status of organ donation in the collection hospital.

(3) Transplant officers shall be exempted to the extent necessary for the proper performance of their tasks and for their participation in specialist training. The exemption is provided with a minimum of 0.1 places for up to ten intensive care beds each. In removal hospitals, which are transplant centres in accordance with Paragraph 10 (1), the total exemption must be a whole. The removal hospitals receive compensation for the expenses for the exemption of the transplant officers. The appropriate use of funds shall be demonstrated to the coordinating body.

(4) The details, in particular on the necessary qualifications and organisational status of the transplant officers, are determined by national law. National law may lay down the conditions under which several collection hospitals may agree in writing to appoint a joint transplant officer in order to fulfil their obligation under paragraph 1. It is necessary to ensure that the transplant
officer is able to perform his/her duties properly in each of the collection hospitals. National law may also provide for exceptions to the obligation to appoint a transplant officer, insofar as and as long as the implementation of organ removal is excluded in appropriate cases due to the special features of the removal hospital. The exemptions may be subject to authorisation by the competent authority.

9c Neurosurgical and neurological consiliar medical service, Regulatory authorisation

(1) In order to assist the removal hospitals in fulfilling their obligation under Paragraph 9a paragraph 2(1) to determine the final, unreparable failure of the overall function of the cerebrum, the cerebellum and the brain stem in patients who, after a medical assessment, are eligible as organ donors, a neurosurgical and neurological consultative on-call service shall be established. In order to organise this on-call service, the Peak Association of Health Insurance Funds, the
German Medical Association and the German Hospital Society, in agreement with the Association of Private Health Insurance, commission a suitable institution by contract. It must not be involved in the collection or transfer of organs.

(2) The body referred to in paragraph 1 shall ensure that, at all times and throughout the country, doctors qualified to determine the final, irrevocable failure of the overall function of the cerebrum, cerebellum and brain stemin a patient are available at the request of a removal hospital. Hospitals with neurosurgical or neurological departments as well as neurosurgical or neurological medical care centres and neurosurgical or neurological practices shall participate in the neurosurgical and neurological consiliar on-call service at the request of the institution designated in paragraph 1. Hospitals, medical centres and practices are entitled to a reasonable compensation for the costs they incur by making doctors available for on-call services. The participating doctors are entitled to an appropriate remuneration, subject to a flat-rate wage.

(3) In a contract, the Peak Association of Health Insurance Funds, the German
Medical Association and the German Hospital Society, in agreement with the
Association of Private Health Insurance, regulate the details of the tasks,e.g. the organisation and the financing of the neurosurgical and neurological consiliar on-call service, from the means of statutory health insurance, including the compensation referred to in paragraph 2 sentence 3 and the remuneration referred to in paragraph 2 sentence

4. The private health insurance industry can contribute to the financing of the neurosurgical and neurological consiliar medical on-call service.

(4) If a contract in accordance with paragraph 3 is not concluded by 31 December 2019 or if a contract in accordance with paragraph 1 sentence 2 is not concluded by 30 June 2021, the Federal Ministry of Health shall, by legal decree with the consent of the Federal Council, determine an appropriate body and regulate the details of the tasks, organisation and financing of the neurosurgical and neurological consiliar on-call service from statutory health insurance funds.

Section 10 Transplant centres

(1) Transplantation centres are hospitals or facilities at hospitals which, in accordance with Section 108 of the Fifth Book of the Social Code or other legal provisions for the transfer of organs of deceased donors and for the taking and transmission of organs of living donors. The authorisation under Paragraph 108 of the Fifth Book of the Social Code must be the main focus of the transfer of these bodies in order to ensure a needs-based, efficient and economical supply and to ensure the required quality of organ transfer.

(2) The transplant centres are obliged:

1. to maintain waiting lists of patients accepted for the transfer of organs subject to mediation with the information required for organ management in accordance with Paragraph 12, to decide without delay on the acceptance of a patient for organ transfer and his/her inclusion on the waiting list and to inform the attending physician thereof, as well as on the removal of a patient from the waiting list,

2. to decide on inclusion on the waiting list in accordance with rules consistent with the state of knowledge of medical science, in particular the necessity and likelihood of success of organ transmission,

3. on the basis of the rules on organ collection made pursuant to Section 11 and in the case of institutions subject to mediation to comply with the rules on organ mediation made pursuant to Paragraph 12,

4. to determine before organ transfer that organ and donor characterization has been completed and documented in accordance with Section 10a and that the conditions for preservation and transport have been complied with,

5. to immediately document any organ transfer in such a way as to allow complete traceability of organs from the recipient to the donor; in the case of the transfer of organs of deceased donors, the identification number (Section 13 (1) sentence 1) must be indicated in order to enable traceability by the coordinating body;

6. record the live organ donations carried out,

7. ensure, before and after organ transfer, measures for the necessary psychological care of patients in the hospital, and

8. In accordance with the provisions of the Fifth Book of Social Books, quality assurance measures which also allow comparison with other transplant centres to be carried out in the course of their activities in accordance with this Act, which shall apply to the follow-up of organ donors in accordance with the first sentence of Section 8(3)of the law.

Section 9a paragraph 2, point 2 and 3, shall apply accordingly.

3. The information required for organ mediation in accordance with the first sentence of paragraph 2 shall be collected, documented and sent to the mediation agency by a doctor or by a person appointed by the latter.
in accordance with the third sentence of Section 13 (3). The persons referred to in
the first sentence must not

1. err or incorrectly document a patient's state of health or document incorrectly for a notification pursuant to section 13 paragraph 3 sentence 3, or

2. report an incorrect state of health of a patient in accordance with section 13 paragraph 3 sentence 3,

favour patients in maintaining the uniform waiting list in accordance with section 12 paragraph 3 sentence 2.

Section 10a Organ and donor characterisation, transport of organs, regulatory authorisation for organ and donor characterisation and transport

(1) The person appointed by the coordinating body shall ensure, under medical advice and guidance,that the organs are released for transmission only if, after a medical assessment, organ and donor characterisation have confirmed that the organ and donor characterisation according to the state of medical science and technology has shown that the organ is suitable for transmission. The relevant information on the donor necessary to assess fitness for organ donation and the relevant information on the characteristics of the organ required for the assessment referred to in the first sentence shall be collected in accordance with a legal regulation referred to in paragraph 4 in order to carry out a proper risk assessment, to minimise the risks to the recipient of the organ and to optimise organ mediation. When collecting this information, as far as this is possible and appropriate, the next of kin shall also be interviewed in the context of the information provided in paragraph 3 (3) sentence 1 or the interview referred to in the first sentence of Paragraph 4 (1) or of other persons who may provide information on the organ donor. The first and 2 sentences shall apply accordingly to the collection of relevant information before the removal and transmission of an organ of a living donor by the responsible doctor of the transplantation centre.

(2) The Coordination Unit shall ensure that the information required for organ and donor characterisation in accordance with
laboratory tests required in paragraph 1 are carried out in laboratories which are staffed and equipped appropriately. Laboratories shall have appropriate procedural instructions to ensure that information on the organ and donor characterisation of the coordinating body is transmitted without delay.

(3) The transport of organs is successful in accordance with the procedural instructions of the coordinating body in accordance with The Second sentence of
Paragraph 11 (1). The detailed information on the identification of containers for the transport of organs is governed by a legal regulation in accordance with paragraph 4.

(4) The Federal Ministry of Healt hcan, by decree of the Federal Council, after consulting the Federal Medical Association and other experts, make regulations on organ and donor characterisation and the transport of organs. In the legislative regulation, in the special terms of the regulation, regulations may be made on the requirements for

1. the information to be collected on the current state of medical science and technology for each organ donation,

2. the procedure for the transmission of information on organ and donor characterisation, and

3. the labelling of containers for the transport of organs.

In a particular case, including a life-threatening emergency, when a risk-benefit analysis shows that the expected benefit to the organ recipient is greater than the risks arising from incomplete data, an organ or tissue may be transferred even if not all the minimum information specified in the statutory regulation referred to in point 1 of the law is available before transmission.

Section 11 Cooperation in the collection of organs and tissues, coordination body

1. The removal of organs from deceased donors, including the preparation of collection, mediation and transmission, shall be the joint task of the transplantation centres and the collection hospitals in regional cooperation. To organise this task,
The Federation of Health Insurance Funds, the German Medical Association and the German Hospital Society have a suitable
Establishment (coordination unit). It must ensure that the first-rate measures referred to in the first sentence are carried out in cooperation with the transplant centres and the collection hospitals in accordance with the provisions of this Act, on the basis of a financially and organisationally independent sponsorship, the availability of the number and qualifications of its staff, its organisation and its material equipment. The transplantation centres must be adequately represented in the coordination centre. The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Society must ensure that the coordinating body meets the requirements of sentence 3 and operates in accordance with the principles of economic efficiency. The coordinating body shall make the basic financial and financial and organizational decisions to the National Association of Health Insurance Funds, the Federal Medical Federal Medical Association and the German Hospital Federation without delay. The budgeting and financial autonomy may be changed at the instigation of the National Association of Health Insurers, the of the German National Association of Health Insurance Funds, the German Medical Association and the German Hospital by independent experts. The coordinating body shall publish an annual report. The central association Federation of Health Insurance Funds, the German Medical Association and the German Hospital Association shall ensure that the coordinating body complies with the publication requirement. (1a) The coordinating body shall organise cooperation for organ harvesting from deceased donors and the implementation of all measures necessary up to the transfer, with the exception of the mediation of organs by the intermediary in accordance with Paragraph 12, in accordance with the guidelines referred to in Paragraph 16, in order to take advantage of the existing possibilities of organ donation and to minimise the health risks to the recipients of organs by removing and providing appropriate donor organs. To this end, the Coordinating Unit shall draw up appropriate procedural instructions in compliance with the directives referred to in Paragraph 16, in particular:

1. for notification in accordance with Section 9a paragraph 2, point 1,

2. to verify donor identity,

3. to verify the details of the donor's use in accordance with Section 3 or the consent of other persons in accordance with Section 4,

4. to verify the completion of organ and donor characterization in accordance with Section 10a paragraph 1,

5. to ensure that the information on organ and donor characterisation is received by the ???? Transplantation centre, in the case of organs subject to mediation, reach the intermediary in accordance with Section 12, in good time,

6. for the removal, preservation, packaging and labelling of organs,

7. for the transport of the organs in order to ensure their integrity during transport and an adequate transport period,

8. to ensure traceability in accordance with Section 13 (1),

9. to ensure the immediate reporting of serious incidents and serious adverse reactions and the measures taken in this context on the basis of the legal regulation referred to in Paragraph 13(4).

The co-ordinating body shall ensure that the medical staff it deploys is qualified for its tasks. It advises the removal hospitals about the fulfilment of their legal obligations and the transplant officers in the evaluation of deaths with primary or secondary brain damage in accordance with Section 9b paragraph 2 (5) and in the improvement of hospital-internal procedures in the process of organ donation. The contract referred to in paragraph 2 shall provide further information on the preparation of the procedure instructions referred to in the second sentence.

(1b) The coordinating body shall evaluate the data to be transmitted by the collection hospitals to them in accordance with Paragraph 9a(2) (6) and forward the data and the results of the evaluation to the competent authorities in accordance with national law. The results of the evaluation are also forwarded by the coordination unit to the respective collection hospital on a site-by-site basis. The
requirements for the data to be transmitted by the collection hospitals to the coordination centre in accordance with section 9a (2) (6), the procedure for transmitting the data, the evaluation of the data and their forwarding shall be laid down in the contract referred to in paragraph 2.

(2) The Leading Association of Health Insurance Funds, the Federal Physicians' Association, the German hospital society and the coordinating body shall, by contract, provide details of the tasks of the coordinating body with effect for the transplantation centres and the collection hospitals. In particular, the contract regulates

1. the demands for the measures necessary in connection with organ harvesting to protect the recipients of organs and the framework arrangements for cooperation between the parties involved,

2. cooperation and exchange of experience with the mediation agency,

3. support to transplant centres in quality assurance measures,

4. the refund of reasonable expenses incurred by the Coordinating Unit for the performance of its tasks under this Act, including:

   a) the flat-rate payment of benefits in accordance with Section 9a paragraph 3 sentence 2 and the compensatory supplement pursuant to Section 9a paragraph 3 sentence 3 and

   b) replacement of the expenses incurred by the collection hospitals for the exemption from regular duties of transplant officers in accordance with Section 9b paragraph 3
   sentence 4 and

5. an arbitration procedure in the absence of agreement on the reimbursement of appropriate expenses in accordance with point 4.

The flat rates in accordance with Section 9a paragraph 3 sentence 2 must be designed on a case-by-case or day-by-case basis in such a way that the individual process steps are sufficiently differentiated. The amount of the lump sums is determined according to the actual total expenditure and personnel. The amount of the compensatory surcharge referred to in the third sentence of Paragraph 9a (3) shall be twice the sum of the flat-rate allowances which can be calculated in each case. The private health insurance industry may contribute to the financing referred to in point 4 of the second sentence. The contract in accordance with the first sentence requires agreement with the Private Health Insurance Association.

(3) The contract under paragraphs 1 and 2 and its amendment require the approval of the Federal Ministry of Health and must be made public by the Federal Government. Approval shall be granted if the contract or its amendment complies with the provisions of this Act and other law. The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Association monitor compliance with the contractual provisions. In order to fulfil their obligation under the third sentence, they shall set up a commission composed of at least one representative of the Federation of Health Insurance Funds, the German Medical Association and the German hospital society or the federal associations of hospital carriers together and two representatives of the Länder . The coordination centre, the transplantation centres and the collection hospitals are obliged to provide the Commission with the necessary documentation and the necessary information. The Commission is obliged to forward findings of infringements of this Act or of regulations adopted pursuant to this Act to the competent authorities of the Länder. The contract referred to in paragraph 2 shall provide further information on the composition of the Commission, the operation and procedure.

(4) The transplantation centres and the collection hospitals are obliged to work with each other and with the coordination centre for the removal of organs and for the removal of tissues in the event of possible organ donors in accordance with Sections 3 or 4. The coordinating body shall determine whether the conditions for organ removal are met. To this end, it shall collect the personal details of these potential organ donors and other personal data necessary for the execution of organ collection and mediation. The collection hospitals are obliged to transmit this data to the coordinating body. The organ removal is organised by the coordinating body and is carried out by the authorised doctors.

(5) The coordination unit shall keep a list of the collection hospitals in accordance with Paragraph 9a and of the transplantation centres in accordance with Paragraph 10. It documents the activities of the collection hospitals and the transplant centres and publishes an annual report on the activities of the transplant centres according to uniform requirements and containing the following de-identified data:

1. the number and type of organ harvests carried out in accordance with Paragraph 9 (1), according to organs of donors in accordance with Paragraphs 3 and 4, including the number and type of organs discarded after removal,

2. The number and nature of organ transfers carried out in accordance with Section 9(2) and their results, separated by organs of donors in accordance with Paragraphs 3 and 4 and pursuant to Paragraph 8,

3. the development of the waiting list in accordance with Section 10 (2) sentence 1 number 1, in particular patients admitted, patients who have undergone transplantation, patients who have dropped out for other reasons, and patients who have died,

4. the reasons for the inclusion or non-inclusion on the waiting list in accordance with Section 10 paragraph 2 sentence 1, point 2,

5. age group, sex, marital status and insured status of patients affected by points 2 to 4,

6. the follow-up of the donors in accordance with section 8 paragraph 3 sentence 1 and the documentation of their health risks arising from organ donation,

7. the quality assurance measures carried out in accordance with Section 10 (2) (8),

8. the results of the evaluation referred to in paragraph 1b sentence 1.

The contract referred to in paragraph 2 may agree on uniform requirements for the activity report and the information on the collection hospitals and the transplant centres.

(6) (discarded)

Section 12 Organ mediation, mediation services

(1) In order to mediate the donor and recipient bodies subject to mediation, the Peak Federation of Health Insurance Funds, the German Medical Association and the German Hospital Society shall establish or commission an appropriate
Establishment (intermediary) based on a financially and organisationally independent
sponsorship, whose number and qualifications of employees, organisation and material equipment ensure that the placement of organs is carried out in accordance with the provisions of the law.
In so far as it mediates bodies taken from countries which are not Member States of the European
Union or other States parties to the Agreement on the European Economic Area in order to entrust the institutions within the scope of the law, or taken within the scope of this Act in order to delegate the institutions in countries which are not Member States of the European Union or other States parties to the Agreement on the European Economic Area, it must also ensure that the measures necessary to protect the recipients of organs are carried out in accordance with the state of knowledge of medical science and that quality and safety requirements are met, which are equivalent to the requirements laid down in this Act and pursuant to that Law, and that full traceability of the institutions is ensured. Only organs taken in accordance with the legislation in force at the place of removal may be mediated, provided that their application does not lead to a result which is manifestly incompatible with essential principles of German law, in particular fundamental rights.

(2) A suitable institution may also be appointed as a means of contacting an organisationwhich may have its registered office outside
the scope of this Act and mediates the institutions in the context of an
international exchange of organs, applying the provisions of this Act for the mediation of organs. It is necessary to ensure that the provisions of Paragraphs 14 and 15 are applied by analogy; adequate data protection supervision must be ensured.

(3) The bodies subject to mediation are to be sent by the intermediary to ensure the prospect of success and urgency for suitable patients. The waiting lists of the transplant centers are to be treated as a single waiting list. The mediation decision shall be documented for each institution, stating the reasons, and shall be forwarded to the transplantation centre and the coordinating body, using the identification number, in order to enable the organs to be traced in full.

(4) The Leading Association of Health Insurance Funds, the German Medical Association, the German hospital society and the intermediary regulate by contract the tasks of the intermediary in relation to the transplant centres. In particular, the contract regulates

1. the nature of the information on patients to be reported by the transplant centres pursuant to the third sentence of Paragraph 13(3) and the use of such information by the intermediary in uniform waiting lists for the respective types of organ transfers to be carried out,

2. the recording of the organs notified by the coordinating institution in accordance with the 4rd sentence of Section 13(1),

3. mediation of the institutions in accordance with the provisions of paragraph 3 and procedures for compliance with the provisions of paragraph 1, sentences 3
and 4,

3a. for organs removed in another Member State of the European Union or other State party to the Agreement on the European Economic Area in order to transfer the organs within the scope of this Act, or removed within the scope of this Act in order to transfer these organs in these States, the requirements for the placement of these organs in compliance with the regulations of this Act and the legal ordinances issued on the basis of this Act,

3b. the transmission of data to the transplant register in accordance with Paragraph 15e of organs which have been mediated within the scope of an international exchange within the scope of or from the scope of this Act,

4. reviewing mediation decisions at regular intervals,

5. cooperation and exchange of experience with the university and transplant centres,

6. regular reporting by the intermediary to the other contracting parties,

7. The reimbursement of reasonable expenses incurred by the intermediary agency in the performance of its duties under this Act.,

8. a contractual possibility of termination in the event of breaches of contract by the intermediary.

The contract in accordance with the first sentence requires agreement with the Private Health Insurance Association.

(5) The contract under paragraphs 1 and 4 and its amendment require the approval of the Federal Ministry of Health and must be published in the Federal Gazette. Approval shall be granted if the contract or its amendment complies with the provisions of the law and other law. The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Society monitor compliance with the contractual provisions. In order to fulfil their obligation under the third sentence, they shall set up a commission composed of at least one representative of the Federation of Health Insurance Funds, the

German Medical Association and the German hospital society and two representatives of the countries. The conciliation agency and the transplant centres are obliged to provide the Commission with the necessary documentation and the necessary information. The Commission is obliged to forward findings of infringements of this Act and regulations adopted on the basis of this Act to the competent authorities of the Länder. The contract referred to in paragraph 4 shall provide further information on the composition of the Commission, the operation and procedure.

(6) (dropped)

Section 12a Family care

1. The coordinating body shall be authorised to provide care for relatives following organ donation. In the case of care for relatives, the coordinating body may carry out the following tasks: 1. to organise family meetings,

2. inform the next of kin or persons referred to in Section 4 (2) sentence 5 or paragraph 3, the data of which they have collected in accordance with Section 7 paragraph 1 (1) (1) in conjunction with section 11 paragraph 4 sentence 3, of the meetings of relatives,

3. inform the next of kin or the persons referred to in Section 4 (2) sentence 5 or paragraph 3, the data of which they have collected in accordance with Section 7 paragraph 1 (1) (1) in conjunction with paragraph 11 paragraph 4 sentence 3, of the result of the organ transplantation in an anonymised form,

4. anonymised letters from the institution sent to the next of kin or persons in accordance with Paragraph 4 (2) sentence 5 or paragraph 3, the data of which they have collected in accordance with Section 7 paragraph 1 (1) (1) in conjunction with section 11 paragraph 4 sentence 3, are addressed to them, forwarded to them and

5. anonymous letter of the next of kin or persons referred to in Paragraph 4 (2) sentence 5 or paragraph 3, the data of which they have collected in accordance with Paragraph 7 (1) (1) (1) in conjunction with paragraph 11 paragraph 4 sentence 3, to the organ recipient via the transplant centre in which the organ was transferred to the recipient.

2. The coordinating body may process the personal data of the next of kin or persons referred to in The 4 paragraph 2 sentence 5 or paragraph 3 collected by it in accordance with Section 7 (1) (1) (1) in conjunction with the third sentence of Section 11 (4) to the extent necessary to clarify whether the next of kin or persons referred to in Section 4 (2) sentence 5 or paragraph 3

1. want to be informed about family meetings,

2. want to be informed about the result of the organ transplant, or

3. consent to the forwarding of anonymised letters from the recipient of the organ and own reply to the recipient of the organ.

3. The coordinating body may:

1. perform the tasks referred to in paragraph 1 sentence 2 number 2 only if there is an explicit confirmation of the respective next of kin or the respective person in accordance with Section 4 paragraph 2 sentence 5 or paragraph 3, and

2. perform the tasks referred to in paragraph 1 sentence 2, point 3 to 5 only if:

   a) there is an express consent of the respective next of kin or the respective person in accordance with Section 4 paragraph 2 sentence 5 or paragraph 3 and

   b) express consent of the recipient of the organ.

(4) The coordinating body may use the identification number referred to in
Paragraph 13 (1) separately from the accompanying documents for the institutions with the personal data of the next of kin or persons referred to in The 5 rd 5 or paragraph 3 of paragraph 4 (2), which have been collected by the Court in accordance with Section 7 paragraph 1 point 1 in conjunction with section 11 paragraph 4 sentence 3, and which have been processed for the performance of the tasks referred to in paragraph 1 sentence 2 point 3 to 5, provided that there is an express consent of the next of kin or persons in accordance with Section 4 paragraph 2 sentence 5 or paragraph 3 with regard to their own personal data.

(5) The transplantation centre in which the organ was transferred to the recipient may, with the express consent of the organ recipient, be entitled to indicate the identification number referred to in Section 13 (1)

1. communicate the result of the organ transplantation in an anonymised form to the coordinating body,

2. anonymous letters from the beneficiary of the institution to the coordinating body and

3. forward anonymised letters sent by the coordinating body to the recipient of the institution in accordance with the sentence of Paragraph 4(2) sentence 5 or paragraph 3 of the next of kin or persons sent by the coordinating body.

(6) About the meaning and scope

1. of the consent pursuant to paragraphs 3 and 4, the next of kin or the persons pursuant to Section 4 Paragraph 2 Sentence 5 or Paragraph 3 shall be informed by the coordinating body before consent is given,

2. the consent according to paragraph 3 number 2 letter b and paragraph 5, the organ recipient must be informed by the transplant center before the consent is given. consent by the transplant center in which the organ was transferred to the recipient, the organ the organ was transferred to the recipient.

The Transplantation Centre has informed the coordinating body of the express consent of
the recipient of the organ, indicating the identification number referred to in Section 13 (1) in an anonymised form.

7. The coordination body and the transplantation centres shall ensure that conclusions are not drawn as to the identity of the recipient of the organ and the donor and the identity of the next of kin or persons referred to in the fifth sentence of paragraph 4 (2) or paragraph 3.

Section 5 Notifications, documentation, tracing, data protection, deadlines

Section 13 Documentation, tracing, authorisation to report serious incidents and serious adverse reactions

(1) In a procedure coordinated with the transplant centres, the coordinating body shall encrypt the personal data of the organ donor and create an identification number which is exclusively intended for the coordination centre and allows a conclusion to be made as to the identity of the organ donor in order to ensure a complete traceability by the institutions. The identification number shall be included in the accompanying documents for the removed organ. The accompanying documents also contain all medical information necessary for organ transfer, including information on organ and donor characterisation in accordance with Paragraph 10a. The coordinating body shall provide details of the institution, the identification number and the medical information necessary for organ mediation to the intermediary and, after the decision of the intermediary, transmit the accompanying documents to the transplant centre where the organ is to be transferred to the recipient. The details are regulated in the contract in accordance with Section 11 (2).

(2) The coordinating body may only process information from the accompanying documents containing the personal data of the organ donor for further information on the organ donor, to the transplant centres where organs of the donor have been transferred, in so far as this is necessary to prevent a fear of health risk to the recipients of the organ.

(3) The treating physician shall immediately inform patients for whom the transfer of organ subject to mediation is appropriate with their written or electronic consent to the transplant centre where the organ transfer is to be carried out. The diagnosis must also take place if a replacement therapy is performed. The transplantation centres shall report to the intermediary the information required for organ placement on the patients admitted to the waiting lists after their written or electronic consent. If the notification referred to in sentence s. 1 or 3 does not allow a postponement because of the risk of death or serious damage to the patient's health, it may also be made without his prior consent; consent must be obtained immediately afterwards.

(4) The Federal Ministry of Health may regulate the procedure by means of a legal regulation with the consent of the Federal Council

1. for the transmission of the information necessary to ensure the traceability of the institutions referred to in paragraph 1,

2. for the reporting, documentation, investigation and evaluation of serious incidents and serious adverse reactions and, where tissue has been taken from the organ donor at the same time, for the notification to the tissue establishment receiving the tissue, and

3. to ensure the reporting of incidents of live organ donation which may be related to the quality and safety of the donated organ and serious adverse reactions to the living donor.

Section 13a Documentation of transmitted tissues by medical care facilities

Medical care institutions shall ensure that, for the purpose of tracing or for the purpose of risk assessment, in accordance with the provisions of the Medicines Act or other legislation, documentation of each transferred tissue is documented by the attending physician or under the doctor's opinion in accordance with a legal regulation in accordance with Paragraph 16a.

13b Reporting of serious incidents and serious adverse reactions in tissues

The medical facilities have the obligation to report

1. any serious case within the meaning of Section 63i paragraph 6 of the German Medicines Act and

2. any serious adverse reaction within the meaning of Section 63i(7) of the German Medicines Act that was observed during or after the transfer of the tissues and may be related to the quality and safety of the tissues. may be related,,

immediately after their detection and to report to the tissue establishment from which they received the tissue . In doing so, they shall provide all the information necessary for the traceability and for the quality and safety control in accordance with a legal regulation in accordance with Paragraph 16a.

Section 13c Traceability procedure for tissues

(1) Each tissue establishment shall lay down a procedure by which it may immediately remove and exclude from the supply any tissue which may be affected by a serious incident within the meaning of Paragraph 63i(6) of the German Medicines Act or a serious adverse reaction within the meaning of Paragraph 63i(7) of the Medicinal Products Act.

(2) Where a tissue establishment or medical care establishment has reasonable grounds to suspect that tissue may cause a serious disease, it shall investigate the cause immediately and trace the tissue from the donor to the recipient or vice versa. It shall also identify, investigate and block tissue donations from the donor if the suspicion is confirmed.

Section 14 Data Protection

If the coordinating body, the intermediary body or the tissue establishment is a non-public body within the scope of this Act, the supervisory authorities of the Länder shall monitor the application of the provisions on data protection pursuant to Section 40 (1) of the Federal Data Protection Act also in cases that do not fall within the scope of Regulation (EU) 2016/679 pursuant to Article 2 (1) of Regulation (EU) 2016/679. This shall also apply to the processing of personal data by persons other than the declarant to whom information from the organ and tissue donor register is provided pursuant to Section 2 (4) sentence 1 or (4a) sentence 1 or to whom the information has been transmitted pursuant to Section 2 (4) sentence 4.The persons involved in the provision or transmission of the information pursuant to Section 2 (4) or (4a) with the exception of the person making the declaration, those involved in the statement pursuant to Section 8, Paragraph 3, Sentence 2, those involved in the notification, information or transmission pursuant to Section 9a (2) No. 1 and Section 11 (4), as well as those involved in organ or tissue removal, organ procurement or transfer or tissue donation or transfer, as well as the persons involved in the as well as the persons who are registered with the transplant registry pursuant to Section 15b Para. 2 and at the trust center pursuant to Section 15c, Paragraph 1, Sentence 2, may not process not disclose personal data of donors and recipients. This shall also apply to personal data of persons who, pursuant to Section 3 (3), first sentence, are informed of the intended or, pursuant to Section 4 or Section 4a, of an or in accordance with Section 4 or Section 4a about a possible organ or tissue removal. The personal data collected under this Act personal data collected under this Act may not be processed for purposes other than those specified in this Act. be processed. They may be processed for judicial proceedings, the subject matter of which is the violation of the prohibition of disclosure pursuant to sentence 1 or 2..

(2a) doctors and other scientific staff of the removal hospital, the transplantation centre, the coordination centre pursuant to Section 11 and the mediation body pursuant to Section 12 may collect or transmit personal data to the organ or tissue recipient of the respective collection hospital, the respective transplant centre or the respective body in accordance with Section 11 or 12 in the context of organ and donor characterisation of the organ or tissue

donor or in the context of organ or tissue transfer to the organ or tissue recipient, by way of derogation from paragraph 2 sentence 3 for scientific research. For a particular research project, such data may be transmitted to and processed by third parties and persons other than those referred to in the first sentence, provided that:

1. the data of the data subject can no longer be assigned to the subject,

2. in the event that the purpose of the research requires the possibility of assignment, the data subject has consented, or

3. in the event that neither the possibility of attribution nor consent can be obtained with a proportionate effort, the public interest in carrying out the research project outweighs the interests of the data subject worthy of protection and the purpose of the research cannot be achieved in any other way.

The personal data shall be anonymized as far as this is possible according to the research purpose and does not require a disproportionate disproportionate effort in relation to the intended protective purpose, or, as long as anonymization is not possible anonymization is not yet possible, the data shall be pseudonymized..

(3) In the case of sperm donation, the right of the child to know his or her own ancestry shall remain unaffected by these provisions. In the case of bone marrow donation, by way of derogation from paragraph 2, the identity of the tissue donor and the recipient of the tissue may be disclosed to the other party or to the relatives concerned, provided that the tissue donor and the tissue recipient or their legal representatives have expressly consented therein.

Section 15 Retention and deletion periods

(1) The records of participation in accordance with Section 4(4), of the clarification pursuant to Section 4a(2), on the
Determination of the results of the investigation in accordance with Section 5
(2) sentence 3 and paragraph 3, for clarification in accordance with Section 8
(2) sentence 4, also in conjunction with Section 8a sentence 1 no. 4, Paragraph 8b (1) and 2, Section 8c (1) No. 1 No. 1 letter b and paragraph 2 and 3 and for the appropriate removal pursuant to Section 8 (3) sentence 2 as well as the documentation of organ collection, mediation and transmission and the information on organ and donor characterisation collected in accordance with Section 10a, unless Paragraph 15h provides otherwise, to keep 30 years in order to enable a complete traceability of the organs.

(2) The information to be documented in accordance with Paragraph 8d paragraph 2 must be kept for 30 years after the expiry date of the tissue and the data to be documented in accordance with Section 13a for 30 years after the transfer of the tissue and must be immediately available.

(3) After expiry of the retention period in accordance with paragraphs 1 and 2, the information shall be deleted or anonymised.

Section 5a Transplant Register

Section 15a Purpose of the Transplantation Register

In order to improve the data base for transplantation care and research, as well as to increase transparency in organ donation and transplantation, a transplant register will be established, in particular

1. for the further development of the rules for inclusion on the waiting list in accordance with Section 10 paragraph 2 sentence 1 number 2,

2. for the further development of organ and donor characterization and their evaluation in accordance with Section 10a paragraph 1 sentences 1 and 4,

3. for the further development of the preservation, preparation, transport of the organs in accordance with The First sentence 1 letter 4 letter b,

4. to assess serious incidents and serious adverse reactions,

5. for the further development of the rules for organ mediation in accordance with Section 12 paragraph 3 sentence 1,

6. to improve the quality of transplantation care and aftercare, as well as

7. to support the monitoring of organ donation and transplantation.

Section 15b Transplant Registry

(1) The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Society commission a suitable facility to set up and operate a transplant registry. The transplantation register must ensure that it is able to carry out the tasks assigned to it under this Section on the basis of a financially and organisationally independent sponsorship, the qualifications of its staff and its material and technical equipment.

(2) The transplantation registry maintains the transplant register. In particular, it has

1. to collect, store and check for plausibility, completeness in accordance with paragraph 15e (1)and, where necessary, to ask the transmitting bodies, through the trust body, to correct or supplement the data transmitted,

2. to create, maintain and update records from the transmitted data of an organ donation and transplantation,

3. transmit the data in accordance with Sections 15f and 15g, as well as

4. publish an annual activity report on their work, including information on the fullness of the data transmitted.

The data transmitted by the trust center pursuant to Section 15c (2), first sentence, shall be Transplantation Registry Office, in derogation of sentence 2

1. separate from the data collected in accordance with point 1 of the second sentence, and

2. in accordance with Section 15f (1) and Section 15g (1).

(3) The Transplantation Registry maintains an office in order to carry out its tasks and to support the specialist advisory board in accordance with Section 15d.

The National Association of Health Insurers, the German Medical Association and the German Hospital Federation and the Transplant Registry shall, in agreement with the Association of Private Health Insurers, regulate by contract the details of the tasks, the operation and the financing of the Transplant Registry with effect for the parties obligated to transmit the transplant medical data pursuant to Section 15e, Paragraph 1, Sentence 1, in particular.

2. the requirements for the processing of the data referred to in paragraph 2 sentence 2, point 1 to 3,

3. the requirements for checking plausibility, and completeness of the data referred to in paragraph 2 sentence 2, point 1,

4. cooperation with the trust body in accordance with Section 15c,

5. support for the transplant centres and the post-care facilities and doctors in outpatient care,

6. Measures to comply with data protection requirements under Articles 24, 25 and 32 of Regulation (EU) 2016/679,

7. For further information on the exchange of anonymised data with other scientific registers in accordance with Section 15g
Paragraph 3,

8. The adequate funding of the transplant registry from funds of the statutory health insurance health insurance,,

9. details of the transfer of data in accordance with Sections 15g paragraphs 1 and 2, as well as

10. uniform requirements for the activity report referred to in paragraph 2 sentence 2 point 4 and the report in accordance with Section 15g paragraph 4.

The private health insurance industry may participate in the financing of the transplant registry participate. The contract may also provide for a gradual start of operation of the transplant registry. be provided for. For regulations pursuant to sentence 1, numbers 2, 4, 6, 7 and 9, agreement must be reached with the Federal Commissioner for Data Protection and Freedom of Information..

(5) The contract and its amendment require the approval of the Federal Ministry of Health and must be published in the Federal Gazette. Approval shall be granted if the contract or its amendment complies with the provisions of this Act andonly law.

(6) The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Society monitor compliance with the contractual provisions.

(7) The transplant register is subject to the supervision of the Commissioner for the

data protection and freedom of information. Section 16 paragraph 1 sentence 2 to 4 of the Federal Data Protection Act is not applicable.

Section 15c Confidentiality

(1) The Federation of Health Insurance Funds, the German Medical Association and the German Hospital Association commission an independent trust, which is spatially, technically, organisationally and personnel-separated. The
Trust pseudonymizes the personal organ donor and donor data. The trust is entitled to restore the personal data, insofar as this is absolutely necessary

1. for the performance of the tasks of the transplant register body in accordance with Section 15b paragraph 2 sentence 2, point 1,

2. for the purpose of performing the tasks of the Commissions in accordance with the sentence 4 and 12 (5) of Paragraph 11 (3) or

3. exercise of the data subject's right of access with regard to the processing of his/her personal data by the transplantation register.

The relying party must prevent the reestablishment of the personal reference of the data vis-à-vis the transplant registry and the transmission of the identifier used for pseudonymization to third parties. third parties..

(2) The trust must merge the transplant medical data transmitted to it in accordance with Paragraph 15e(8), ensure that the data are no longer related to the individual, and then transmit that data to the transplant register. After the data has been transmitted to the transplant register, the data must be deleted at the trust office.

(3) The National Association of Health Insurance Funds, the German Medical Association, the German Hospital Federation, and the Confidentiality Body shall, in agreement with the Association of Private Health Insurers, regulate by contract the details of the tasks of the Confidentiality Body pursuant to paragraph 1 sentences 2 4 and paragraph 2, the procedure for data pseudonymization in accordance with paragraph 1, sentence 2, and the procedure for the of the data in accordance with paragraph 2, sentence 1, as well as on the financing of the trust center from funds of the statutory health insurance. The regulations on the tasks of the trust center and on the data pseudonymization pseudonymization procedure pursuant to paragraph 1, sentence 2, and the consolidation of data pursuant to paragraph 2, sentence 1. (2), first sentence, shall be agreed upon with the Federal Commissioner for Data Protection and Freedom of Freedom of Information. The private health insurance industry may participate in the financing of the trust center. of the trust center. In determining the procedure for data pseudonymization pursuant to para. 1, sentence 2, and the consolidation of data pursuant to paragraph 2, sentence 1, the Federal Office for Information Information Technology shall be involved.The contract and its amendment require the approval of the Federal Ministry of Health and must be made known in the Federal Republic of Germany. Approval shall be granted if the contract or its amendment complies with the provisions of this Act and other law.

(4) The Leading Association of Health Insurance Funds, the German Medical Association and the German Hospital Society monitor compliance with the contractual provisions.

(5) The trust is subject to the supervision of the Federal Commissioner for Data Protection and Freedom of Information. Section 16 paragraph 1 sentence 2 to 4 of the Federal Data Protection Act is not applicable.

Section 15d Advisory Board

1. A specialist advisory board shall be set up at the transplantation register centre. The Advisory Board consists of two representatives each

1. the coordinating body in accordance with the second sentence of Section 11 (1),

2. the intermediary in accordance with Section 12 paragraph 1 sentence 1,

3. the Joint Federal Committee pursuant to Section 91 of the Fifth Book of the Social Code,

4. the Commission in accordance with the 4st sentence of Section 11(3),:

5. the Commission in accordance with the 4nd sentence of Section 12(5),

6. the German Transplantation Society and

7. patient organisations mentioned or recognised in the Patient Participation Ordinance.

Further experts can be consulted on a case-by-case basis. The Expert Advisory Board shall consult the scientific medical societies in the preparation and updating of the nationwide uniform data set in accordance with Section 15e paragraph 5.

2. The Advisory Board shall advise and assist the Transplantation Register and the Trust Body. In particular, it shall be involved

1. in the determination of the rules of procedure for data transmission to the Transplantation Registry pursuant to Section 15e, Paragraph 4, Sentence 2, and
2. when establishing the Rules of Procedure for the Transfer of Data by the Transplantation Registry in accordance with Section 15f (2) Satz 2.

The Advisory Board proposes the nationwide uniform data set and its updating in accordance with section 15e paragraph 5 sentence 2. In the case of applications for the transmission of data for research purposes in accordance with the third sentence of Section 15g (2) of the second sentence, the Advisory Board shall be consulted.

(3) The Association of Health Insurance Funds, the German Medical Association and the German Hospital society in agreement with the Association of Private Health Insurance shall provide the Advisory Board with its rules of procedure. The Rules of Procedure provide, in particular, for details on the composition, working methods and procedures.

Section 15e Data relations to the transplant register office and to the trust office

(1) The following are obligated to transmit transplant medical data to the transplant registry:

1. the coordinating body pursuant to Section 11, Paragraph 1, Sentence 2,

2. the intermediary agency pursuant to Section 12, Paragraph 1, Sentence 1,

2. the transplant centres,

3. the Joint Federal Committee pursuant to Section 91 of the Fifth Book of the Social Code and

4. the facilities and doctors in the outpatient care that are entrusted with the care.

By way of derogation from the first sentence, the institutions and doctors in the outpatient care responsible for the follow-up may report the data to be transmitted to the transplant centre where the organ transfer was carried out. The transplant centre transfers this data to the transplant registry. The obligation to provide medical transplant data applies to data collected after 1 January 2017.

1. 2. The transplant medical data to be transmitted to the transplant registry pursuant to paragraph 1 are the transplant medical data are the transplant medical data ofthe data required for inclusion on the waiting list in accordance with Section 10 paragraph 2 sentence 1 Nummer 2 in conjunction with section 16 paragraph 1 sentence 1 number 2, the data of the patients admitted to the waiting list,

2. the transplant-medically relevant data of patients on the waiting list collected after inclusion on the waiting list by the transplant centres,

3. the data required for organ placement in accordance with section 12 paragraph 3
sentence 1 in conjunction with paragraph 16 sentence 1 sentence 1 point 5 of the patients and deceased organ donors included on the waiting list,

4. the data of the living organ donor collected in the course of the medical assessment referred to in the first sentence of Paragraph 8 (1) (1) (c),

5. the data required for organ and donor characterisation in accordance with Section 10a (1) sentence 1 and 4 of deceased and living organ donors,

6. the data on collection, preservation, packaging, labelling and transport, which are documented on the basis of the procedure instructions referred to in Paragraph 11 (1) sentence 2, point 6 and 7, in conjunction with Paragraph 16 (1) sentence 1 point 4 letter b,

7. the data of organ transfer of organs of deceased and living organ donors,

8. the data collected in the context of inpatient and outpatient follow-up of organ recipients and living organ donors, and

9. the quality assurance data specified in the guidelines of the Joint Federal Committee pursuant to Section 136 (1) sentence 1, point 1, of the Fifth Book of the Social Code,

to the extent that such data are necessary for the purposes of the transplantation register referred to in Paragraph 15a.

(3) The personal data must be forwarded to the trust office for pseudonymisation prior to transmission to the transplantation register in accordance with Section 15c.

(4) The Peak Association of Health Insurance Funds, the German Medical Association and the German Hospital society, in agreement with the Association of Private Health Insurance and the Federal Commissioner for Data Protection and Freedom of Information, shall determine the procedure for the transmission of the data, including the initial and ongoing transmission, in a Rules of Procedure. The expert advisory board in accordance with Section 15d is to be involved.

(5) The transmission of transplantation medical data to the transplant register centre shall be carried out on the
basis of the nationwide uniform data set. The nationwide uniform data set as well as
its
The update is agreed on by the top association of the health insurance funds, the
German Medical Association and the German Hospital Society in agreement with the
Association of Private Health Insurance and the Federal Commissioner for Data Protection and Freedom of Information on a proposal of the FederalAdvisory Council pursuant to Section15d. In doing so, the guidelines of the Federal Medical
Association in accordance with section 16 paragraph 1 sentence 1 and the guidelines and decisions of the Joint Federal Committee in accordance with Sections 136 to 136c of the Fifth Book of the Social Code must be observed. The nationwide uniform data set must be published by the Federal Ministry of Health in the Federal Gazette.

(6) The transmission of personal data of a patient included in the waiting list or of a organ recipient is only permissible if the patient or organ recipient on the waiting list has given their the patient or the organ recipient. The transfer of personal data from a organ donor is permissible only with the express consent of the living organ donor. has been given. The transmission of personal data in accordance with sentence 1 or sentence 2 shall not be permitted after the death of the the waiting list, the organ recipient or the organ donor is only permissible if the respective express consent the respective express consent also extends to the transfer of data after death. The patient the waiting list, the organ recipient and the living organ donor must be informed by a physician at the transplant center of the transplant center about the significance and scope of the consent. In particular, they must be informed that in the event of revocation of their consent under data protection law in accordance with paragraph 7, the data transmitted up to that point may continue to be processed. If a transplant center transmits the data transplantation medical data of a patient on the waiting list, of an organ recipient or of a living organ recipient or a living organ donor to the intermediary body pursuant to Section 13, Paragraph 3, Sentence 3 or to the to the Federal Joint Committee on the basis of guidelines pursuant to Section 136 (1) sentence 1 no. 1 of the Fifth Book of the German Social Code (Sozialgesetzbuch), the respective body must also be informed of the information provided and the consent consent of the patient included in the waiting list, the organ recipient or the living organ donor. organ donor. If a patient included in the waiting list, an organ recipient or a living organ donor is treated by a facility entrusted with follow-up care or by a physician in outpatient outpatient care, the transplant center shall inform the institution or physician of the facility or physician of the informed consent given and of the declared consent of the waiting-listed patient, organ the waiting list, the organ recipient or the living organ donor.(7) In the event of a revocation of the consent referred to in paragraph 6, the data transmitted to the transplant register may be further processed, provided that this is necessary for the purposes of the transplantation register in accordance with Section 15a.

(8) The coordinating agency pursuant to Section 11, Paragraph 1, Sentence 2, the intermediary agency pursuant to Section 12, Paragraph 1, Sentence 1, and the Federal Joint Committee pursuant to Section 91 of the Fifth Book of the Social Code are obligated to transmit the transplant medical data pursuant to Paragraph 2, which were collected from January 1, 2006, up to and including December 31, 2016, to the trust agency, notwithstanding Paragraph 6, on the basis of the nationally uniform data set pursuant to Paragraph 5. The transmission of transplant medical data pursuant to sentence 1 is only permissible if the personal data of the

patients who have been included in the waiting list and the personal data of the patients who have been included in the waiting list have been transmitted to the trust agency. the waiting list and the personal data of organ donors and organ recipients before they are have been altered in a procedure prior to transmission to the trust center in such a way that the respective no longer be able to establish a reference to a person, but it is possible to combine the data in the the trust center is possible. The German National Association of Health Insurance Funds, the German Medical Association and the German Hospital Association and the trust center shall, in agreement with the Association of Private Health Insurers and the Federal Commissioner for Data Protection and Freedom of Information. and the Federal Commissioner for Data Protection and Freedom of Information. in rules of procedure. The Federal Office for Information Security shall be involved in determining the procedure. Information Technology shall be involved..

Section 15f Data transfer by the transplant registry

(1) The transplant register

1. the coordinating body to carry out its tasks, in particular the further development of organ and donor characterisation and its evaluation in accordance with the first sentence of Paragraph 10a (1) and the evaluation of serious incidents and serious adverse reactions, the data required,

2. the data required for the further development of organ mediation in accordance with section 12 paragraph 3 sentence 1,

3. the data required to update the guidelines in accordance with section 16 paragraph 1 sentence 1,

4. to the commissions in accordance with the 4rd sentence of Paragraph 11 (3) and the 4th sentence of Paragraph 12 (5) of the Commission, the data necessary for the performance of their monitoring activities,

5. the transplant centres have the data necessary to fulfil their respective obligations in accordance with Section 135a(1) of the Fifth Book of the Social Code to ensure and further develop the quality of the medical transplantation services they provide,

6. the Joint Federal Committee pursuant to Section 91 of the Fifth Book of the Social Code, which
further develops of guidelines and decisions on quality assurance for medical transplantation services in accordance with Sections 136 to 136c of the Fifth Book of the Social Code, as well as

7. the competent authorities of the Länder to carry out their duties in the authorisation of transplant centres in accordance with Paragraph 10 (1) and in the context of the monitoring of the provisions of this Act and in the context of the legal regulations adopted pursuant to this Act.

The data can be transmitted in an automated retrieval procedure. The automated retrieval procedure may only be set up insofar as the bodies involved have taken the technical and organizational measures required in accordance with Articles 24, 25 and 32 of Regulation (EU) 2016/679 have taken the necessary technical and organizational measures. have been taken. The responsibility for the permissibility of the individual retrieval lies with the retrieving body. The transplant registry shall document the reason for and purpose of the individual retrieval. It verifies the It shall verify the permissibility of the retrievals by means of suitable sampling procedures and otherwise only if there is reason to do so. The agencies pursuant to sentence 1 may process the data exclusively for their respective purposes specified in sentence 1..

(2) The Federation of Health Insurance Funds, the German Medical Association and the German Hospital society shall determine the procedure for the transmission of data in a guidelines in agreement with the Association of Private Health Insurance and the Federal Commissioner for Data Protection and Freedom of Information. The technical advisory board pursuant 15d is to be involved.

Section 15g data transfer by the transplantation registry for research purposes, data exchange

(1) The Transplantation Registry may transmit anonymised data to third parties for research purposes after concluding a user agreement.

(2) The Transplantation Registry may provide third parties with data in pseudonymised form for a particular research project, provided that the purpose of the research requires the processing of pseudonymised data and the data subject has expressly consented. Consent is not required if 1. It can only be obtained with a disproportionate effort,

2. the public interest in the implementation of the research project outweighs the interests of the data subjects which are worthy of protection, and

3. the purpose of the research cannot be achieved in any other way.

The data will be transmitted on request. The application will be decided by the Federation of Health Insurance Funds, the German Medical Association and the German Hospital Society in agreement with the Association of Private Health Insurance, after consulting the Advisory Board in accordance with Section 15d. The data shall be anonymised as soon as this is possible in accordance with the purpose of the research. They may only be processed for scientific research purposes. Unless the data are anonymised, publication is only permitted with the express consent of the data subjects.

(3) The Transplantation Registry may, in order to promote the purposes of the Transplantation Register, process anonymised data from scientific registers in accordance with Section 15a and provide anonymised data to these registers.

(4) The Transplantation Registry shall publish an annual report on the data submitted in accordance with paragraphs 1 to 3.

Section 15h Retention and Deletion Periods

(1) The transplant register body shall:

1. the data of the patient or organ recipient on the waiting list, together with the data of the organ donor, and

2. the data of the living organ donor

and to inform the trust authority of the deletion as soon as such data are no longer necessary for the purposes of the transfer of data in accordance with the first sentence of Paragraph 15f of paragraph 1, at the latest 80 years after the patient has been admitted to the waiting list or after the organ has been taken from the living organ donor. Insofar as the data in the transplant register is to be deleted, the trust must also delete the personal data of the patient or the organ recipient who has been added to the waiting list together with the personal data of the organ donor and the personal data of the living organ donor.

(2) Third parties to whom data have been transmitted in accordance with Section 15g paragraph 2 shall be deleted as soon as their

processing is no longer necessary for the purpose of research, no later than 20 years after the transmission.

Section 15i Appropriations for regulations

(1) If the contract with the transplant registry in accordance with Section 15b (4) does not come to an end by 1 November
In 2019, the Federal Ministry of Health, with the consent of the Federal Council, shall designate the transplantation register body by decree and regulate the details of its tasks, its operation and its financing in accordance with Section 15b paragraph 4.

(2) If the contract with the trust body in accordance with Section 15c paragraph 3 does not come to be concluded by 1. The Federal Ministry of Health, with the consent of the Federal Council, shall determine the trust body and regulate the details of its tasks in accordance with Section 15c paragraph 1 sentence 2 to 4 and paragraph 2, the procedure for data pseudonymisation in accordance with Section 15c paragraph 1 sentence 2 and the procedure for merging the data in accordance with paragraph 2
sentence 1 and the financing of the trust body in accordance with Section 15c paragraph 3.

Section 5b Guidelines on the State of Knowledge of Medical Science, Regulatory Authorisation

Section 16 Guidelines on the State of Medical Science on Organs

(1) The Federal Medical Association shall determine the state of the art of medical science in guidelines for

1. the rules for the determination of death in accordance with Section 3 (1) sentence 1 no. 2 and the procedural guidelilnes on the
   Determination of the final, non-reversible failure of the overall function of the cerebrum, cerebellum and brain stem in accordance with Section 3 (2) (2), including the medical qualifications required for this purpose,

1a. the rules for determining death in accordance with Section 4a (1) sentence 1 no.

2. the rules for inclusion on the waiting list referred to in Paragraph 10(2) (2), including documentation of the reasons for inclusion or refusal of inclusion,

3. the medical assessment in accordance with Section 9a paragraph 2, point 1,

4. the requirements for the measures necessary in connection with organ harvesting to protect the recipients of organs, including their documentation, in addition to the organ and
   donor characterization in accordance with Section 10a, in particular at

   a) the examination of the organ donor, the organs and the recipients of organs in order to minimise the health risks to the recipients of organs, in particular the risk of transmission of diseases;

   b) the preservation, preparation, storage and transport of the organs in order to maintain them in a condition suitable for transplantation or further processing and storage prior to transplantation;

   c) the detection and treatment of incidents of live organ donation which may be related to the quality and safety of the donated organ or serious adverse reactions in the living donor detected in the course of his follow-up care,

5. the rules for organ mediation in accordance with Section 12 (3) sentence 1,

6. the requirements for the quality assurance measures necessary in connection with organ removal and transfer, and

7. the requirements for the recording of live organ donations in accordance with Section 10 (2) (6).

Compliance with the state of knowledge of medical science is presumed if the guidelines of the German Medical Association have been observed.

(2) The German Medical Association shall determine the procedure for the development of guidelines pursuant to Paragraph 1 and for the adoption of resolutions. The guidelines according to paragraph 1 must be justified; in particular, the determination of the state of the art of medical science must be presented in a comprehensible manner. In the development of the guidelines, the appropriate participation of experts from the affected professional and public circles, including the National Association of Health Insurers, the German Hospital Federation, the German Transplantation Society, the Coordination Unit pursuant to Section 11, the Mediation Unit pursuant to Section 12 and the competent authorities of the Länder shall be provided for. Furthermore, in the preparation of the guidelines pursuant to paragraph 1, sentence 1, nos. 1, 1a and 5, physicians who are not involved in the removal or involved in the removal or transfer of organs, or are subject to the instructions of a physician who is involved in such (1) sentence 1, nos. 2 and 5, persons qualified to hold judicial office and persons qualified to perform and persons from the circle of patients, in the preparation of guidelines pursuant to subsection 1 [...] shall be appropriately represented..
(3) The guidelines referred to in paragraph 1 and their amendments shall be submitted to the Federal Ministry of Health for approval. The Federal Ministry of Health may request additional information and additional comments from the Federal Medical Association as part of the approval procedure.

Section 16a Ordinance

The Federal Ministry of Health may, by ordinance with the consent of the Bundesrat and after the Federal Medical Association and other experts, regulate the requirements for quality and safety in the the removal of tissues and their transfer, insofar as this is necessary to prevent risks to human health or for risk prevention. health of humans or for risk prevention. The ordinance may in particular regulate the details of the requirements for

1. the removal and transfer of tissues including their documentation and to the protection of the documented data,;

2. the medical assessment of medical suitability as a tissue donor,

3. the examination of tissue donors,

4. the reporting of quality and safety deficiencies and serious undesirable actions by medical care institutions and

5. education and obtaining the consent of tissue donors or consent to tissue removal

The Federal Ministry of Health may transfer the authorisation under sentence 1 to the competent federal authority by decree without the consent of the Federal Council.

Section 16b Guidelines on the state of knowledge of medical knowledge on the collection and transmission of tissues

(1) In addition to the provisions of the Ordinance pursuant to Section 16a of The German Medical Association, the Federal Medical Association may determine in accordance with the generally accepted state of the art of medical science in consultation with the competent Federal Authority for the collection and transmission of tissues, in particular the requirements for the

1. the medical assessment of medical suitability as a tissue donor,

2. the examination of tissue donors and

3. the collection, transmission and use of human tissues.

In drawing up the guidelines, the appropriate participation of experts from the relevant professional and public circles, including the competent authorities of the federal and state governments, must be ensured. The guidelines are published by the competent federal authority in the Federal Gazette.

(2) Compliance with the state of the art of medical science is presumed if the guidelines of the Federal Medical Association referred to in paragraph 1 have been complied with.

Section 6 Prohibition rules

Section 17 Prohibition of organ and tissue trafficking

(1) It is prohibited to trade in organs or tissues intended to be used for the treatment of another. Sentence 1 does not apply to

1. the granting or acceptance of an appropriate remuneration for the measures necessary to achieve the objective of medical treatment, in particular for the removal, preservation, further preparation, including measures for the protection of infection, the storage and transport of organs or tissues, and

2. medicinal products manufactured from or using organs or tissues and subject to the authorisation requirements under Section 21 of the German Medicines Act, are also subject to registration in connection with Section 37 of the German Medicines Act, or registration pursuant to Section 38 or Section 39a of the German Medicines Act, or are exempted from registration by legal decree pursuant to Section 36 of the German Medicines Act or active substances within the meaning of Section 4 (19) of the German Medicines Act, or active substances manufactured from or using cells.

2. It shall also be prohibited to remove organs or tissues which are the subject of prohibited trafficking under the first sentence of paragraph 1, to transfer them to another person or to have them transferred to another person.

Section 7 Penalty and Fine Rules

Section 18 Organ and tissue trade

(1) Anyone who trades with an organ or tissue in accordance with Section 17 (1) sentence 1 or, contrary to Section 17(2), removes, transmits or allows himself to be transferred, shall be punished with a custodial sentence of up to five years or a fine.

(2) If the offender acts commercially in the cases referred to in paragraph 1, the penalty is a custodial sentence of one year to five years.

(3) The attempt is a criminal offence.

(4) The court may refrain from punishment under paragraph 1 in the case of organ or tissue donors whose organs or tissues have been the subject of prohibited trafficking and in the case of organ or tissue recipients, or to reduce the penalty under its terms(Section 49(2) of the Criminal Code). **Section 19 Other criminal rules**

(1) Who

1. contrary to Paragraph 8(1) sentence 1 no. 1 letter a or letter b or no 4 or section 8c (1) no. 1 or no 3, paragraph 2 sentence 1, also in conjunction with paragraph 3 sentence 2, or section 8c .3 sentence 1, removes an organ or tissue,

2. contrary to Section 8 (1) sentence 2, an organ is taken from or

3. contrary to Paragraph 8b(1) sentence 1, also in conjunction with paragraph 2, an organ or tissue used for transfer to another person or gains human sperm,

is punishable by a custodial sentence of up to five years or a fine.

(2) Anyone who, contrary to Section 3 (1) sentence 1 or paragraph 2, section 4 (1) sentence 2 or section 4a (1) sentence 1, takes an organ or tissue is punishable by a custodial sentence of up to three years or a fine.

(2a) A custodial sentence of up to two years or a fine shall be imposed on anyone who intentionally raises, documents or transmits the state of health of a patient contrary to paragraph 10(3) sentence 2.

(3) who

1. in accordance with Section 2 (4) sentence 1 or sentence 4, provides or transmits information,

2. contrary to Section 13 (2) of an indication processed or

3. contrary to Section 14 (2) sentence 1, also in conjunction with sentence 2, or sentence 3, personal data disclosed or processed,

is punishable by a custodial sentence of up to one year or a fine.

(4) In the cases of paragraphs 1, 2 and 2a, the attempt is a criminal offence.

(5) If the offender acts negligently in the cases referred to in paragraph 2, the penalty is imprisonment of up to one year orfine.

Section 20 Rules on fines

(1) Acts in an unlawful manner, any person who intentionally or negligently

1. contrary to Section 5 (2) sentence 3 or paragraph 3 sentence 3 makes a recording not, not correct, not complete or not in time,

2. contrary to Paragraph 8d(1) sentence 2 no. 3 in conjunction with a legal regulation pursuant to Section 16a sentence 2 No. 3 does not ensure that a laboratory examination is carried out,

3. contrary to Paragraph 8d(2) in conjunction with a legal regulation pursuant to Paragraph 16a sentence 2 no. 1, a tissue removal, a tissue delivery, a related measure or an indication mentioned therein is not, correctly, not fully or not in due time,

3a. contrary to section 8d paragraph 3 sentence 2, a report not sent, incorrect, not complete or not in due time,

4. contrary to Paragraph 9 (1) or paragraph 2 sentence 1 or sentence 3, an organ shall be taken or transferred,

5. transfers an organ in contravention of the second sentence of Section 9 (2) without the removal of the organ having been organized by the organized by the coordination center,,

6. contrary to Paragraph 10 (2) (4), it is not correct, not complete or not in due time that the organ and donor characterization has been completed in accordance with Section 10a (1) or that the conditions for transport in accordance with Section 10a paragraph 3 sentence 1 have been complied with,

7. contrary to Paragraph 10 (2) (5), the transfer of organs is not, not properly, not fully or not documented in good time,

8. contrary to Section 10a (1), first sentence, fails to ensure that an organ is released for transfer only under the conditions specified therein. for transfer only under the conditions specified therein,,

9. contrary to Paragraph 13a in conjunction with a legal regulation pursuant to Section 16a sentence 2 No. 1 does not ensure that a transferred tissue is documented,

10. contrary to section 13b sentence 1 in conjunction with a legal regulation pursuant to Section 16a sentence 2 no. 4, a quality or safety defect or a serious undesirable reaction is not, not properly, not properly documented or not fully documented or does not make a notification, correctly, not complete or not in time, or

11. a legal regulation pursuant to Section 10a paragraph 4 sentence 1, section 13 paragraph 4 or paragraph 16a sentence 1 or an enforceable order on the basis of such a legal regulation, insofar as the legal regulation refers to this provision of fines for a particular offence.

(2) In the cases referred to in paragraphs 1, point 1 to 3 and 4 to 11, the offence may be punishable by a fine of up to EUR 30 000 and, in the other cases, by a fine of up to EUR 5 000.

(3) For the purposes of Paragraph 36 (1) (1) of the Law on Administrative Offences, the Paul Ehrlich Institute shall be the administrative authority in the cases referred to in paragraph 1 point 3a.

Section 8 Final Rules

Section 21 Competent Federal Authority

The responsible federal authority within the meaning of this act is the PaulEhrlich Institut.

Section 22 Relationship with other areas of law

The provisions of the Embryo Protection Act and the Stem Cell Act remain unaffected.

Section 23 Bundeswehr

In the area of the Federal Ministry of Defence, the implementation of this system is the responsibility of the competent authorities and experts of the Bundeswehr for monitoring.

Section 24

(Amendment to the Criminal Code)

Section 25 Transitional arrangements

(1) When this Act enters into force, existing contracts for regulatory objects in accordance with Section 11 shall continue to apply until they are superseded by a contract pursuant to Sections 11 (1) and (2) or replaced by a legal decree pursuant to Section 11(6).

(2) When this Act enters into force, existing contracts for regulatory objects in accordance with Section 12 shall continue to apply until they are superseded by a contract pursuant to Section 12 (1)or replaced by a legal decree pursuant to Section 12(6).

Section 26 (entry into force, expiry)

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Ordinance on the Quality and Safety Requirements of Tissue Removal and Transmission under the Transplantation Act (TPG Tissue Ordinance - TPG-GewV)

TPG-GewV

Date of production: 26.03.2008

Full quote:

"TPG Tissue Ordinance of 26 March 2008 (BGBl. I p. 512), which was last adopted by
Article 2 of the Ordinance of 7 March 2008.
July 2017 (BGBl. I p. 2842) has been amended"

Status: Last modified by Art. 2 V v. 7.7.2017 I 2842

*) This Regulation is intended to implement the

- Directive 2004/23/EC ens European Parliament and the Council of 31 March 2004 laying down quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ No. EU No L 102 p. 48),

- Directive 2006/17/EC of 8 February 2006 on the implementation of Directive 2004/23/ EC of the European Parliament and of the Council on technical rules for the donation, procurement and testing of human tissues and cells (OJ No. EU No L 38 p. 40),

- Directive 2006/86/EC of 24 October 2006 on the implementation of the Directive 2004/23/EC of the European Parliament and of the Council on traceability requirements, the reporting of serious incidents and adverse reactions, as well as certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ No. EU No L 294 p. 32).

footnote

(+++ Proof of text from: 5.4.2008 +++) (+++
Official reference of the standard-giver to EC law:
Implementation of EGRL 23/2004 (CELEX No: 304L0023) EGRL 17/2006 (CELEX No: 306L0017) EGRL 86/2006 (CELEX No: 306L0086) +++)

Input formula

Pursuant to Section 16a sentences 1 and 2 of the Transplantation Act as amended by the notice of 4 September 2007 (BGBl. I p. 2206), the Federal Ministry of Health, after consulting the German Medical Association and other experts, prescribes:

Section 1 Scope of application

This regulation applies to tissue establishments as defined in § 1a No. 8 of the Transplantation Act, which remove tissues as defined in § 1a No. 4 of the Transplantation Act (collection facility) or which perform the laboratory tests required for tissue donors in an examination laboratory pursuant to Section 8e of the

Transplantation Act. It also applies to medical care facilities that transfer tissues within the meaning of Section 1a No. 4 of the Transplantation Act..

Section 2 Requirements for the removal of tissues

In order to comply with the requirements for the removal of tissues in accordance with Section 8d (1) sentence 2 No.
In particular, the Transplantation Act obliges the collection facility to ensure that the method of collection is appropriate with regard to the type of tissues donated and that the biological and physical properties necessary for their use are preserved.

Section 3 Requirements for the medical assessment of the donor's medical suitability

(1) The medical assessment of the medical suitability of the dead donor in accordance with Section 8d (1) sentence 2 no. 2 of the Transplantation Act is based on the risk assessment with regard to the respective use and the type of tissue. The requirements set out in Appendix 1 No. 1 must be observed. The donor shall be excluded from the donation if one of the reasons for the exclusion referred to in Appendix 1(2)has been fulfilled, unless this is deviated from in the case of a single case for medical reasons and on the basis of a risk assessment by a doctor.

(2) F For the medical evaluation of the living donor of tissues other than germ cells, paragraph 1 shall apply mutatis mutandis, provided that the requirements specified in Appendix 2 shall be observed. .

Section 4 Requirements for laboratory tests and examination procedures

In the case of laboratory tests required for tissue donors within the meaning of Section 8d (1) Satz 2 No. 3 of the Transplantation Act, the sampling facility shall carry out or have carried out at least the laboratory tests for tissue donors referred to in Appendix 3(1) in an examination laboratory, with the exception of germ cells. Investigations, with the exception of the donation of germ cells, must comply with the requirements set out in Appendix 3(2).

Section 5 Requirements for donor file and removal report

1. Prior to collection or examination, the collection facility shall establish a donor file in which only the following information is documented:

1. donor identity, with information on the surname, first name, gender and date of birth or, where recognised, the allocation number allocated by the collection facility for the tissue donor and the identification of the donor as an organ donor, if organs have been removed from the donor for the purpose of transfer;

2. in the case of dead donors, the documentation of the donor's consent in accordance with Section 3 para. 1 No. 1 of the Transplantation Act or the consent of the next of kin in accordance with Section 4(1) of the Transplantation Act or a person referred to in Section 4 (2) sentence 5 or paragraph 3 of the Transplantation Act or the consent of the woman who was pregnant with the embryo or fetus, in accordance with Section 4a (1) sentence 1 no. 2 of the
Transplantation Act and, in the case of living donors, the consent of the donor pursuant to Section 8, Section 8b or 8c of the Transplantation Act;

3. the medical and behavioural information required for the medical assessment of donor fitness in accordance with Paragraph 3 or Paragraph 6;

4. Results of medical history and behavioural anamnesis, in particular with regard to possible exposure to infection, as well as the findings of physical examination and other examinations carried out for the medical assessment of donor fitness in accordance with Paragraph 3 or Paragraph 6;

5. in the case of dead donors, an autopsy, if one has been carried out;

6. Result of the medical assessment of the donor's medical suitability in accordance with Section 3 or Section 6;

7. Results of laboratory tests in accordance with Section 4 or Section 6;

8. provided that section 41a of the Medicinal Products and Drug Manufacturing Regulation requires that the Donation identification sequence in accordance with Section 41b paragraph 1 of the Medicinal Products and Drug Manufacturing Ordinance or the unambiguous donation number in accordance with Section 41b paragraph 2 of the Medicinal Products and Drug manufacturing regulation, otherwise the labelling code to which the removed tissue was granted by the collection device.

The entire donor file must be compiled by a doctor.

2. The collection facility shall send a sampling documentation to the tissue establishment which is working or processing the tissue taken, containing at least the following information:

1. name and address of the tissue establishment receiving the tissue;

2. donor identity with information on surname, first name, gender, date of birth and living donor address or, where recognised, by the collection facility for the tissue donor, assigned identification number and identification of the donor as an organ donor, if organs have been taken from the donor for the purpose of transfer;

3. description of the tissue taken and, if section 41a of the medicinal product and active substance production ordinance is required to comply with the donation identification The Medicinal Products and Drug Manufacturing Ordinance or the unique donation number in accordance with Section 41b (2) of the Medicinal Products and Drug Manufacturing Ordinance, otherwise the labelling code;

4. Surname, first name and address of the doctor responsible for the removal;

5. The date, time and place of removal and the manner of removal in compliance with the requirements of Section 34 of the Medicinal Products and Drug Manufacturing Ordinance.

The removal report must document that the tissues are approved for processing, , preservation or storage within the meaning of Section 8d (1) sentence 2 no. 4 of the Transplantation Act.

Section 6 Conditions for the use of germ cells in the context of medically assisted fertilization measures

(1) For the use of germ cells in the context of medically assisted fertilization measures, it is necessary, after medical assessment, that the use be medically indicated and that the health protection of the recipient and the child is ensured. For the necessary laboratory tests and examination procedures, Section 4 shall apply in accordance with the requirements laid down in Appendix 4(1) and (3). Sections 2 and 5 apply. If sperm cells are not obtained in a collection facility, the name and address of the tissue facility to receive the sperm cells, as well as information on the donor identity and the date and time of extraction, shall be documented in the collection report in accordance with Section 5(2).

(2) For the heterologous use of sperm cells in the context of

(3) measures of medically assisted fertilization, it is necessary, in addition to the requirements of paragraph 1, that the donor, according to medical assessment, is suitable for sperm donation on the basis of his age, state of health and medical history, and that health risks to others resulting from the use of the donated sperm cells are excluded. The

donor's information is to be provided by means of a questionnaire and a subsequent personal interview with the donor by the physician. For the 4 shall apply mutatis mutandis to the necessary laboratory examinations and examination procedures, subject to the requirements set out in Annex 4, Nos. 2 and 3 shall apply accordingly. Section 7 Documentation of transferred tissues by medical care facilities

In order to fulfil their obligation under Section 13a of the Transplantation Act to ensure that each tissue transferred is documatively with the following information:

1. identification of the tissue recipient by information on the surname, first name, sex, date of birth and address or, where recognised, the allocation number allocated by the institution of medical care to the tissue recipient;

2. the day and time of transmission;

3. Surname, first name and address of the doctor transferring tissue;

4. the name and labelling code of the transferred tissue, provided that the tissue is not marked with the Single European Code referred to in point 6 in accordance with Paragraph 41a of the Medicinal Products and Drug Manufacturing Regulation;

5. name of the tissue device from which they received the tissue;

6. the Single European Code in accordance with Section 4(30)a of the Medicines Act, if any.

Section 8 Notification of serious incidents by medical care institutions

(1) The medical facilities shall establish and maintain a procedure for the fulfilment of their obligation under Section 13b of the Transplantation Act, which ensures that any serious incident which may be attributed to the collection, examination, processing, , preservation, storage or delivery, including the transport of the tissue used, shall be documented immediately after its detection and reported without delay to the tissue establishment from which they received the tissue.

(2) In order to prevent serious incidents, the requirements laid down by the tissue establishment from which the establishment of medical care received the tissue must be observed. In doing so, the medical facilities shall communicate all the information necessary for traceability and for quality and safety control. At least:

1. description of the tissue concerned and, if available, the Single European Code in accordance with Section 4(30a) of the German Medicines Act, otherwise the labelling code and

2. The nature and extent of the quality or safety defect identified which may be related to a serious incident during the collection, examination, treatment,processing, preservation, , storage or delivery of the tissue concerned.

Section 9 Reporting of serious adverse reactions by medical care institutions

Health care facilities shall establish and maintain a process to fulfill their obligation under section 13b of the Transplantation Act, which ensures that any serious adverse reaction observed during or after the transfer of the tissue and which may be related to the quality and safety of the tissue, is documented immediately after its detection and reported to the tissue Is documented and reported immediately to the tissue establishment from which they received the tissue.

(1) In order to report serious adverse reactions, the requirements laid down by the tissue establishment from which the institution of medical care received the tissue must be observed. In doing so, the medical care facilities shall provide all the information necessary for he traceability and quality and safety checks. At least: 1. the information referred to in Sections 7, point 1 to 4 and 6,

2. The day, time and course of observation of the serious adverse reaction and

3. Type of severe adverse reaction observed.

Section 10 Entry into force

This Regulation shall enter into force the day following the announcement. **Conclusion**

The Federal Council has agreed.

Appendix 1 Requirements for the medical assessment of the medical suitability of the dead donor in accordance with Section 3 (1)

(Location: BGBl. I 2008, 515 - 516)

1. Donor evaluation

   a) The medical and behavioural information required for the assessment of donor fitness in accordance with Sections 3 and 6 shall be collected by a doctor.

   b) In order to collect the information, the necessary sources shall be used in compliance with the requirements of Paragraph 7 of the Transplantation Act, including the following sources, to the extent that they are appropriate: (aa) the donor's medical records;

bb) the assessmentof a person who knew the donor well;

cc) a questioning of the attending physician;

dd) a consultation with the family doctor;

(ee) the autopsy report.

c) In addition, a physical examination shall be carried out in order to identify signs that are sufficient as such for the exclusion of the donor or which must be verified on the basis of the donor's medical and personal history.

d) The entire donor file shall be checked and evaluated by a doctor for suitability of the donor.

2. Exclusion criteria

a) Unknown cause of death, provided that the cause of death does not emerge from the autopsy after removal and that no other exclusion criterion referred to below applies;

b) Disease of unknown etiology in prehistory;

c) Presence or prevention of malignant disease, with the exception of primary basal cell carcinoma, in situ cervical cancer and some primary tumors of the central nervous system, which are to be evaluated according to scientific findings; Donors with malignant diseases maybe eligible for corneal donations, except donors with retinoblastoma, haematological neoplasties and malignant tumors of the eye background;

d) Risk of disease transmission by prions. This risk exists in

aa) persons whohave been diagnosed withCreutzfeldt-Jakob disease or the new variant of CreutzfeldtJakob disease or who have non-iatrogenic Creutzfeldt-Jakob disease in the family history;

bb) Individuals with a history of rapidly progressive dementia or any degenerative neurological disease, including those of unknown cause;;

cc) Recipients of hormones derived from the human pituitary gland (such as growth hormones), recipients of cornea, sclera and dura mater grafts, and individuals who underwent undocumented neurological surgery (in which Dura mater may have been used).

Further precautions may be recommended for the new variant of CreutzfeldtJakob disease.

e) Systemic infection that is not under control at the time of donation, including bacterial infections, systemic viral, fungal or parasitic infections, or significant local infection in the tissues to be donated;

Donors with bacterial sepsis can be assessed and considered for eye donation, but only if the corneas are in an organ cotlure
, which enables the detection of possible bacterial contamination
of the tissue;

f) History of HIV infection, clinically or by confirmed laboratory tests;,
risk of transmission of acute or chronic hepatitis B (except for persons
with demonstrated immunity), hepatitis C and HTLV I/II or signs of risk factors for these infections;

g) History of chronic, systemic autoimmune disease that could have a deleterious effect on the tissue being effect on the tissue to be removed;transferred???;

h) Signs of invalid test results of donor blood samples due to aa) haemodilution, in accordance with the specifications in Appendix 3 no. 2, if no pretransfusion sample is available, or

bb) Treatment with immunosuppressive agents;

i) signs of other risk factors for infectious diseases on the basis of a risk assessment taking into account the travel and exposure history of the
donor and the local prevalence of infectious diseases;

j) signs on the donor's body suggesting a risk of infection within the meaning of point 1 (c);

k) intake or exposure to a substance (such as cyanide, lead, mercury, gold) which could be transmitted to the recipient in a harmful dose;

l) recently vaccinated with a live vaccine from attenuated virus, which is considered a risk of transmission;

m) Heterograft and xenograft transplants;

n) Additional reasons for deceased children

aa) All children of HIV-infected mothers and children to whom a reason for exclusion referred to in point 2 (a) to (m) applies shall be excluded as donors until the risk of transmission of infection can be definitively eliminated;

bb) Children under 18 months of age of mothers with HIV, hepatitis C or HTLV infection or at risk of such infection who have been breastfed by the mother during the previous 12 months shall be excluded as donors, irrespective of the examination law;

cc) Children of mothers with HIV, hepatitis C or HTLV infection or at risk of such infection who have not been breastfed by the mother during the previous 12 months and whose results, physical examinations and the examination of medical records do not indicate HIV, hepatitis C or HTLV infection may be authorised as donors.

Appendix 2 Requirements for the medical assessment of the medical suitability of the living donor in accordance with Section 3 (2)

(Location: BGBl. I 2008, 517;
regarding the individual amendments see footnote)

1. Donor evaluation (for tissues for transfer to others)

a) The medical and behavioural information required for the assessment of donor fitness in accordance with Sections 3 and 6 shall be collected by a doctor.

b) The donor must be interviewed to collect the information. The doctor has to ensure that the donor understood the information provided and had the opportunity to ask questions and receive satisfactory answers, and the donor confirmed that he/she had provided all the information to the best of his knowledge and belief. In addition, the following sources may provide information with the consent of the donor, to the extent
appropriate:

aa) the donor's medical records;

bb) a questioning of the attending physician;

cc) cc) a
consultation with the family doctor.

c) In addition, a physical examination may be performed to detect signs that may be sufficient as such to exclude the donor or which need to be verified on the basis of the donor's medical and personal history.

d) The entire donor file shall be checked and evaluated by a doctor for the suitability of the donor.

2. Reasons for selection and exclusion

a) Tissues for retransmission
If the tissues taken are to be stored or cultivated before retransmission, the minimum requirements for biological laboratory tests in accordance with Paragraph 4 in conjunction with Appendix 3 shall be met. Positive results of the investigation do not result in this tissue not being stored, processed and

transferred back if appropriate storage conditions are in place to avoid any risk of cross-contamination with other grafts or contamination with Adventiv agents or confusion.

b) Tissues for transfer to other (aa) donors to whom tissues are to be taken for transfer to others shall be selected on the basis of their state of health and medical history, collected by means of a questionnaire and a personal survey by a doctor, in accordance with point bb. This test shall include relevant factors that may contribute to the identification and exclusion of persons whose donation could be associated with a health risk to themselves or to others, e.g. by the risk of disease transmission.

bb) The collection facility shall be set up on the basis of the type of tissues to be donated, the physical condition of the donor, the anamnesis and the determination of the results of clinical examinations and laboratory tests to determine the donor's health status.

cc) The grounds for exclusion referred to in Annex 1(2) shall apply, with the exception of point (a). Depending on the type of tissue to be donated, additional criteria may be necessary for further specific exclusion reasons, e.B.: aa) pregnancy (except for donors of amniotic membrane); bb) Breastfeeding.

Appendix 3 Required laboratory tests and examination procedures in accordance with Section 4

(Location: BGBl. I 2008, 518 - 519)

1. Biological tests prescribed for donors

a) All donors must be tested at least as follows:

HIV 1 and 2	Anti-HIV-1, 2
hepatitis B	HBsAg Anti HBc
Hepatitis C	Anti-HCV-Ab
syphilis	See letter d

b) d) HTLV-I antibody tests shall be carried out on donors who live or come from areas with high prevalence or whose sexual partners or parents come from such areas.

c) If the anti-HBc test is positive and HBsAg is negative, further risk assessment studies are required to determine clinical usability.

d) A validated test algorithm should be used to exclude infection with Treponema pallidum. A specific or non-specific non-reactive test may allow the release of the tissues. If a non-specific test is performed, a reactive test result does not prevent removal or release, provided that a specific test confirming Treponema is not reactive. A specified sample whose sample responds to a specific Treponema test shall be subject to a thorough risk assessment to determine clinical usability.

e) Under certain circumstances, additional laboratory tests may be required, depending on the donor history and the characteristics of the donated tissues (e.B. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi).

f) For tissues to be transferred back, Annex 2 (2) (a) applies.

2. General requirements for the investigation procedure

a) The examination procedure used must be recognised in accordance with the general state of medical science and technology in terms of its intended use.

b) Biological examinations are carried out on the serum or plasma of the donorand should not be carried out on the other liquids or secretions, such as .B humor aqueus or humor vitreus, unless this is clinically justified by the use of a procedure validated for such a liquid.

c) If potential donors have lost blood and recently received donated blood, blood components, colloids or crystalticoids, the results of the blood test may be falsified due to hemodilution of the sample. An algorithm should be used to assess the degree of hemodilution in the following circumstances: aa) **Premortal blood sampling:** if within 48 hours before the blood sampling of a supply of blood, blood components or colloids or
within one hour of the blood sampling an infusion of crystalloids has taken place;

bb) **Postmortem blood sampling:** if there has been an administration of blood, blood components, or colloids within 48 hours prior to death or an Infusion of crystalloids has occurred..

Tissue establishments may accept tissues from donors with more than 50 % plasma dilution only if the methods of examination used for such plasma are valided or if a pretransfusion sample is available.

d) In the case of dead donors, blood samples must be taken as soon as possible and no later than 24 hours after death, unless a blood sample has already been taken immediately before death.

e) (a) In the case of living donors excluding donors of bone marrow stem cells, blood samples must be taken at the time of donation or, if this is not possible, within seven days before or after the donation (this is the "donation sample").

bb) If the tissues are stored for a long period of time, living donors from whom tissues are removed for the purpose of for the purpose of transfer to others, re-sampling and re-testing is required after 180 days. sampling and repeat testing is required after 180 days. In this process, the donor sample may be be collected up to 30 days before and seven days after donation.

cc) If tissues of living donors from which tissues are taken for the purpose of transfer to others can no longer be stored and therefore no re-sampling is possible, point aa applies.

f) If, in the case of a living donor (except donors of bone marrow stem cells taken for transmission to others) the"donation sample", as defined in letter e double letter aa, is additionally tested for HIV, HBV and HCV by means of nucleic acid amplification (NAT) methods, the test of a repetitive blood sample may be omitted. Also, the retry test may be omitted if the processing includes an inactivation step that has been validated for the viruses in question.

g) When bone marrow is taken, blood samples must be taken for examination within 30 days prior to donation.

h) If the donor is a newborn, the biological donor test can be carried out on the mother of the donor to avoid unnecessary interventions on the newborn.

Appendix 4 Required laboratory tests for the use of germ cells in accordance with Section 6

(Location: BGBl. I 2008, 520)

1. Laboratory tests required for the use of human germ cells

a) In the case of sperm processed and not stored for intrauterine semen transfer and provided that the tissue establishment can demonstrate that the risk of cross-contamination and exposure of staff has been met by the use of
validated procedures, the doctor responsible for the collection may refrain from carrying out the biological examinations referred to in point (b to e).

b) The following biological tests shall be carried out to determine whether there is a risk of cross-contamination:

HIV 1 and 2	Anti-HIV-1.2
hepatitis B	HBsAg AntiHBc
Hepatitis C	Anti-HCV-Ab

Where, as part of medically assisted fertilization measures, an egg is taken from a woman whose egg is to be fertilised, the second sentence of Appendix 2 (2) (a) shall apply to the medical assessment accordingly.

c) If the results of the tests for HIV 1 and 2, hepatitis B or hepatitis C are positive or if no results are available or the risk of infection of the donor is known, the donation must be stored separately.

d) HTLV-I antibody tests shall be carried out on donors who live or come from areas with high prevalence or whose sexual partners or parents come from such areas.

e) Under certain circumstances, additional tests may be required depending on the donor's history (e.B. RhD, Malaria, CMV, T. cruzi).

2. Required laboratory tests for the heterologous use of sperm

The heterologous use of sperm must meet the following criteria:

a) The donors' serum or plasma samples must be negative for HIV 1 and 2, HCV, HBV, and syphilis when tested in accordance with Appendix 3, No. 1(a); the urine samples from semen donors must also be negative when tested for chlamydia using the nucleic acid amplification technique (NAT). react negatively.).

b) HTLV-I

antibody tests shall be carried out on donors who live or come from areas with high prevalence or whose sexual partners or parents come from such areas

c) Under certain circumstances, additional tests may be required depending on the donor's history (e.B. RhD, Malaria, CMV, T. cruzi).

3. Requirements for the investigation procedures

a) The examination procedures shall be carried out in accordance with Annex 3 (2) (a) and (b).

b) For the use of germ cells in accordance with Paragraph 6 (1), blood samples must be taken within three months before the first donation. For the use of further donations within the same partnership, the further blood samples must be taken no later than 24 months and a half from the previous blood sample.

For the heterologous use of sperm cells in accordance with Section 6(2), the blood samples shall be taken at the time of each donation. The sperm donations shall be stored under quarantine conditions for at least 180 days. The donor shall subsequently be retested. If a donor's blood sample is additionally tested for HIV, HBV, and HCV by nucleic acid amplification technique (NAT), the test of a repeat blood sample

may be omitted. Also, the repeat test may be omitted if the processing includes a inactivation step that has been validated for the validated for the viruses in question..

Regulation on the requirements for organ and donor characterisation and the transport of organs and on the requirements for the reporting of serious incidents and serious adverse reactions (TPG Regulation on the Quality and Safety of Organs - TPGOrganV)

TPG-OrganV

Date of production: 11.02.2013

Full quote:

"TPG Regulation on the Quality and Safety of Organs of 11 February 2013 (BGBl. I p. 188), which were Article 1 of the Ordinance of 28 May 2014 (BGBl. I p. 601, 1582) **Status:**Modified by

Art. 1 V v. 28.5.2014 I 601, 1582 **footnote**

(+++ Proof of text from: 16.2.2013 +++)

The V was adopted as Article 1 d. V v.11.2.2013 I 188 by the Federal Ministry of Health after consulting the Federal Medical Association and other experts, in agreement with the Federal Ministry of Economics and Technology and with the approval of the Federal Council. It entered into force on 16.2.2013 in accordance with Article 4 of that V.

Section 1 Scope of application anddefinitions of concepts

1. This Regulation regulates the requirements for

1. organ and donor characterization in accordance with Section 10a paragraph 1 of the Transplantation Act,

2. the procedure for the transmission of information on organ and donor characterisation,

3. the identification of containers for the transport of organs in accordance with Section 10a paragraph 3 of the Transplantation Act,

4. the procedure for the transmission of information necessary to ensure the traceability of the institutions;

the reporting, documentation, investigation and evaluation of serious adverse events and serious adverse reactions and, if tissue was collected from the organ donor at the same time, reporting to the was collected from the organ donor, reporting to the tissue facility that received the tissue, and

5. the reporting of incidents in the live donation of organs which may be related to the quality and safety of the donated organ and the reporting of serious adverse reactions to the live donor.

(2) For the purposes of this Regulation,

1. the transplantation centre responsible is?? the transplant centre, where the organ is to be transferred within the scope of the Transplantation Act on the basis of the mediation decision of the mediation agency;

2. the Member State of origin of the Member State of the European Union or of another State Party to the Agreement on the European Economic Area, in which the institution is taken outside the scope of the Transplantation Act for the purpose of transfer;

3. Member State of destination, the Member State of the European Union or any other Member State
The State Party to the Agreement on the European Economic Area, in which the institution is placed outside the scope of the Transplantation Act for the purpose of transfer;

4. an authorised body in the Member State of origin or a member of the
Member State of destination, a body to carry out the tasks under Article 17(1) of the
2010/53/EU of the European Parliament and the Council of 7 July 2010 on Quality and
Safety standards forhuman organs intendedfor transplantation(OJ No. L 207 of
6.8.2010,
14, L 243 of 16.9.2010, p. 68), or a European organisation for the
Exchange of organs delegated to tasks in accordance with Article 21 of Directive 2010/53/EUn;

5. a serious incident of any adverse and unexpected event, from donation to transplantation, which could lead to 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 hospital treatment or morbidity;

6. a serious adverse reaction of any unintended reaction, including an infectious disease, in the live donor or the recipient, which is connected to any link in the chain from the
donation up to transplantation and which is life-threatening, results in
disability or loss of function, or results in or prolonged hospital treatment or morbidity;

7. the specification of the organ, the anatomical description of an organ, including information on the nature of the organ and the situation in the human body, and whether it is a complete organ or apart of an organ, including information on the lobe or segment of the organ.

Section 1 Organ and donor characterisation

Section 2 Necessary information on organ and donor characterisation

Without prejudice to the third sentence of Paragraph 10a(4) of the Transplantation Act, the following information shall be collected by the person appointed by the coordinating body under medical advice and guidance or by the responsible doctor of the transplantation centre for each organ donation, taking into account the state of the medical science and technology:

1. the removal hospital,

2. Donor type,

3. blood group

4. sex

5. cause of death

6. time of death

7. date of birth or estimated age,

8. weight

9. size

10. existing or past intravenous drug use,

11. currently existing or past malignant neoplasms,

12. other communicable diseases currently in existence,

12a. vaccinations with live vaccines carried out within the last 30 days,

13. Results of HIV, Hepatitis C and Hepatitis B tests,

14. basic information on the evaluation of the function of the donated organ.

Section 3 Further information on organ and donor characterisation

The following information shall be collected after a medical assessment by the person appointed by the coordinating body under medical advice and guidance or by the responsible doctor of the transplantation centre, taking into account the state of medical science and technology, the availability of the relevant information and the particular circumstances of the case concerned:

1. as general information, the contact details of the removal hospital and the coordination and mediation agency needed for the coordination, distribution and tracing of donated organs;

2. as donor data, the demographic and anthropometric data needed to ensure an appropriate match between donor, organ and recipient;

3. as a donor, the donor's medical history, in particular circumstances which could affect the suitability of the organs for transplantation and risk the transmission of disease;

4. as physical and clinical data, the data from clinical studies needed to assess the physiological condition of the potential donor, as well as the results of the investigation, which indicate circumstances which have not been noticed in the examination of the donor's medical history which may affect the suitability of the organs for transplantation or the risk of transmission of diseases;

5. as laboratory values, the data needed to assess the functional characterisation of organs and to identify potentially communicable diseases and possible contraindications to organ donation;

6. as imaging examinations, the examinations of imaging techniques required to assess the anatomical, morphological and functional status of the organs intended for transplantation;

7. as therapy, the treatments carried out on the donor and which are decisive for the assessment of the functional condition of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic-influencing measures or transfusions.

Section 4 Application of the emergency procedure of the Line2010/53/EU

In collecting the information on organ and donor characterisation referred to in Paragraphs 2 and 3, the person appointed by the coordinating body must immediately observe changes or additions to the information to be collected which, in accordance with the state of medical science and technology, are subjec tto urgent procedure under Article 24 in conjunction with Article 28 of Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on quality and safety standards for human organs intended for transplantation (OJNo. 14, L 243 of 16.9.2010, p. 68). The first sentence shall apply accordingly to the collection by the responsible doctor of the transplantation centre for the information on organ and donor characterisation in the case of a live organ donation.

Section 2 Transport

Section 5 Procedure for the transmission of information on organ and donor characterisation in deceased donors

(1) The person appointed by the coordination unit shall immediately transmit to the intermediary the information on organ and donor characterisation collected in accordance with Paragraphs 2 and 3 of deceased donors. Where individual information is available at the time of the first transmission to the intermediary, the person appointed by the coordinating body shall transmit the information to the intermediary or to the competent transplant centre in time for medical decisions to be taken. Where the information is transmitted directly to the competent transplant centre, the person appointed by the coordinating body shall inform the intermediary without delay.

(2) The person responsible for the intermediary shall immediately forward to the competent transplant centre the organ and donor characterisation notices submitted by the person appointed by the coordinating body referred to in paragraph 1.

Section 6 Procedure for the transmission of information on organ and donor characterisation in cross-border organ exchanges

(1) Where an organ of a deceased donor is transferred to a Member State of destination for the purpose of transfer, the person responsible shall, before the organ exchange, forward the information on organ and donor characterisation transmitted by the person appointed by the coordinating body in accordance with Paragraph 5 (1) to the competent authority or the authorised body in the Member State of destination.

(2) If an organ is procured from a Member State of origin, the responsible person shall the intermediary shall immediately notify the competent authority or the authorized body in the donor characterization information to the competent authority or the authorized body in the Member State of origin and forward the information without delay to the competent transplant center. without delay. If the competent

transplant center receives the organ and donor characterization information directly from the competent donor characterization directly from the competent authority, the authorized body, or the collection collection establishment in the Member State of origin, the responsible person of the transplant center shall immediately acknowledge receipt of this information and immediately inform the intermediary of this fact. of this without delay..

Section 7 Labelling of containers for the transport of organs

1. The containers used for the transport of the organs shall be provided with the following information:

1. the name of the coordinating body, including its address and telephone number;

2. the name of the transplant centre to which the organ is to be transferred, including its address and telephone number;

Indication that the container contains an organ, stating the type of organ and, if applicable, its left- or right-handedness, and the words "TO BE HANDLED WITH CARE";

3. recommended transport conditions, including instructions for the appropriate ambient temperature and position of the container.

This information may also be used in English.

2. Transport within the same facility shall not comply with the requirements referred to in paragraph 1.

Section 3 Traceability, reporting of serious incidents and serious adverse reactions

Section 8 Information on ensuring the traceability of organs in cross-border organ exchanges

1. Where an organ ??? is transferred to a Member State of destination for the purpose of transfer, the person responsible shall immediately inform the intermediary of the competent authority or body of destination in the Member State of destination:

1. the specification of the institution,

2. the identification number in accordance with Section 13 paragraph 1 of the Transplantation Act,

3. the date of removal,

4. the name of the person appointed by the coordinating body and his/her contact details.

1. 2. If an organ has been transferred from a Member State of origin for the purpose of transfer, the responsible person of the intermediary body shall without delay inform the competent authority or the authorized authority in the Member State of origin of the following information the national recipient's notification number or, if the organ has not been transplanted, on the final use of the organ,

2. where appropriate, the date of the transplant,

3. the name and contact details of the transplant centre.

Where the intermediary receives the information referred to in paragraph 1 from the competent authority or the authorised authority in the Member State of origin, the person responsible for the intermediary shall immediately confirm receipt of the information to the competent authority or authorised authority in the Member State of origin.

Section 9 Reporting of serious incidents and serious adverse reactions

(1) The person appointed by the Coordination Unit shall ensure that any serious incident, which could affect the quality and safety of the organ and which can be attributed to the collection, laboratory tests, organ and donor characterisation, preservation, transport or transplantation of the organ, and any serious adverse reaction detected during or near transfer and which can be attributed to the transplantation of the organ, , documents, examines and evaluates the cause and effects of the incident and that information is transmitted without delay to the transplant centres in which the donor's organs are to be transplanted .

(2) The corrective notification to the Coordinating Unit of any serious incident and any serious adverse reaction referred to in paragraph 1, including the reporting of all relevant and necessary alerts, shall be provided???? to:

1. the transplant officer of the removal hospital,

2. Doctors who carry out or have carried out the mortuary examination at the organ donor,

3. the authorities in whose custody or co-custody the organ donor's body is or has been found,

4. the third parties appointed by the Coordination Unit and

5. the responsible doctor of the transplant centre.

(3) The notification to the person appointed by the coordinating body in accordance with paragraph 1 shall be made without delay, when a mediation-dependent organ is taken and transferred to the intermediary in accordance with Paragraph 12 of the Transplantation Act. Where tissue has been removed from the donor at the same time, in accordance with paragraph 1 the notification shall also be made without delay to the person appointed by the coordinating body at the tissue establishments which have received the tissue for processing or processing. In the cases referred to in points 1 and 2, the coordinating body may only share the information contained in the documents containing the donor's personal data for further information on the donor, in particular, merge it and pass it on to the intermediary in accordance with Paragraph 12 of the Transplantation Act or to the tissue establishments which have received the tissue for processing , insofar as this is necessary to prevent a health hazard to the recipients of organs or tissues.

(4) (dropped)

Section 10 Reporting of serious incidents and serious adverse reactions in crossborder organ exchanges

1. In accordance with the first sentence of Section 9 (3) of the Conciliation 9 (3) sentence, the person appointed by the coordinating body shall report to the conciliation body a serious incident or a serious adverse reaction in connection with

1. an institution mediated from a Member State of origin for the purpose of the transfer, or

2. an institution which has been placed in a Member State of destination for the date of transfer, or

3. a donor whose organ has been transferred to a Member State of destination for the purpose of transfer,

the person appointed by the coordinating body shall draw up an initial report in accordance with Annex 1 and forward that report to the intermediary without delay. If further information is available after the first report, the person appointed by the coordinating body shall forward it without delay.

2. In the cases referred to in paragraph 1, the person appointed by the coordinating body shall, in the first sentence of the first sentence of the first paragraph, and 3 to prepare a final report within three months of the submission of the first report, in accordance with Annex 2 nach, to collect relevant information in consultation with the competent authorities or appointed bodies of the Member States of destination concerned and to transmit it to the intermediary without delay. In the cases referred to in the first sentence of paragraph 1, the person appointed by the coordinating body shall provide relevant information to the competent authorities or appointed bodies of the Member States of origin concerned in good time and inform the intermediary thereof.

(3) The person responsible for the intermediary shall forward the notification of the authorised person to the coordinating body referred to in the first sentence of Paragraph 9 (3) and the information received in accordance with paragraphs 1 and 2 to the competent authorities or authorised bodies of the Member States of origin or Member States of destination immediately upon receipt.

(4) If the intermediary receives the information about a serious adverse event or a serious adverse reaction from the competent authority or the authorised body in the Member State of origin or the Member State of destination, the responsible person of the intermediary shall immediately acknowledge the receipt of this information to the competent authority or the authorised body in the Member State of origin or the Member State of destination and to forward the information without delay to the competent transplant centers concerned and to the coordinating body. Where a transplant center or the coordinating body receives the information directly, the responsible person at the transplant center or coordinating center shall acknowledge receipt to the [...] Member State of origin or of the Member State of destination and inform the intermediary thereof. informed thereof.

Section 11 Reporting of incidents in the live donation of organs

The attending physician of a live donor is obliged to report immediately to the living donor any incident which is detected in the context of the medically recommended follow-up care in accordance with section 8 paragraph 3 sentence 1 of the Transplantation Act and which affects the quality and safety of the donated organ, or any serious adverse reaction in accordance with section 6 paragraph 4 sentence 2 to the living donor, which could be a result of the removal of the organ andto the transplant centre which has transferred the organ.

Section 4 Common Rules, Administrative Offences

Section 12 Common Procedural Rules

(1) The intermediary and the coordinating body shall ensure that a person is always available for emergencies and that the information provided in accordance with this Regulation is received and forwarded without delay. Where the intermediary or coordinating body receives information for which it is not competent under this Regulation, the person responsible under the first sentence shall immediately forward the information to the body responsible for this Regulation.

(2) The transmission or forwarding of information in accordance with Sections 5, 6, 8 and 10 shall be carried out in writing, electronically or by fax. It also contains

1. the date and time of transmission,

2. the contact details of the person responsible for the transmission at the intermediary or coordination body, and

3. the following note: "Contains personal data. Protect against unauthorised distribution and access by unauthorised persons.'

The information shall be documented and made available on request, to the extent permitted by the provisions of this Ordinance and the Transplantation Act.

3. The intermediary shall, in consultation with the coordinating body, ensure that the information provided in the context of the exchange of organs is provided in a common or agreed language or, in the absence of a language, made in English.

Section 13 Mediation in the Organ Exchange Association

If the intermediary has been commissioned with the procurement of organs within the scope of an international organ exchange network in accordance with § 12 paragraph 2 sentence 1 of the Transplantation Act and it is at the same time the competent authority or authorized body of the Member State of origin or the Member State of destination within the framework of the performance of its duties, the information requirements according to §§ Sections 6, 8 and 10 (3) and (4).

Section 14 Emergency regulation

In the event of an emergency, the information referred to in Sections 5, 6, 8 and 10 may be transmitted orally by way of derogation from Section 12 paragraph 2. In such cases, the written or electronic transmission must be made up without delay.

Section 15 Link between the Member States of the European Union

The intermediary and the coordinating body shall ensure that the relevant contact details for the transmission of the information provided in this Regulation are communicated to the European Commission and kept up to date. Contact details include the name of the institution, telephone number, e-mail address, fax number and postal address.

Section 16 Offences

Acts in violation of the law within the meaning of Section 20 (1) point 11 of the Transplantation Act, any person who acts intentionally or negligently

1. contrary to Paragraph 9 (1), also in conjunction with paragraph 3 sentence 1 or sentence 2, does not ensure that a serious incident or a serious adverse reaction is reported, or

2. contrary to Section 9 (2) point 1, 2, 4 or point 5 does not make a notification or does not make it in time.

Appendix 1

(Location: BGBl. 2014, 604)

The initial report on the suspicion of serious incidents or serious adverse reactions in accordance with the first sentence of Paragraph 10 (1) must contain the following information: 1. rapporteur Member State: Germany,

2. Report number: DEU/276,

3. Contact details of the coordination unit: telephone number, e-mail address and, where applicable, fax number,

4. Contact details of the person appointed by the coordinating body in accordance with Section 9 (1): telephone number, e-mail address and, where applicable, fax number,

5. The date and time of the report (YYY/MM/DD hh/mm),

6. Origin

7. Identification number in accordance with the first sentence of Paragraph 13 (1) of the Transplantation Act, or, if the organ comes from another Member State of origin, the national donor identification number,

8. all countries of destination, if known,

9. national recipient identification number(s),

10. Date and time of occurrence of the serious incident or serious adverse reaction (YYY/MM/DD hh/mm),

11. the date and time when the serious incident or adverse reaction was established (YYY/MM/DD hh/mm),

12. Description of the serious incident or serious adverse reaction,

13. actual or proposed emergency measures.

Appendix 2

(Location: BGBl. 2014, 604)

The final report on serious incidents or serious adverse reactions referred to in Paragraph 10 (2) shall contain the following information:

1. rapporteur Member State Germany,

2. Report number: DEU/276,

3. Contact details of the coordination unit: telephone number, e-mail address and, where applicable, fax number,

4. The date and time of the report (YYY/MM/DD hh/mm),

5. number(s) of the first report/reports (Annex 1),

6. Case description,

7. affected Member States or States Parties to the European Economic Area,

8. Investigation results and conclusions,

9. Preventive and corrective measures,

10. conclusion and possible follow-up.