Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act)

of 8 October 2004 (Status as of 1 May 2016)
Please note: this translation does not yet include the amendments of 01.01.2017

The Federal Assembly of the Swiss Confederation,

based on Article 119*a* paragraphs 1 and 2 of the Federal Constitution[1], and having considered the Dispatch of the Federal Council of 12 September 2001[2],

decrees:

Chapter 1 General Provisions

Art. 1 Aim

[1] This Act sets out the requirements for the use of organs, tissues or cells for transplantation purposes.

[2] It is intended to contribute to the availability of human organs, tissues and cells for transplantation purposes.

[3] It is intended to prevent the improper handling of organs, tissues or cells in the context of human transplantation medicine, in particular commercial activities involving organs, and to protect human dignity, privacy and health.

Art. 2 Scope

[1] This Act applies to the handling of organs, tissues or cells of human or animal origin and products obtained from them (transplant products) intended for transplantation into humans.

[2] It does not apply to the handling of:

a. artificial or devitalised organs, tissues or cells;

b. blood, with the exception of blood stem cells;

c. blood products;

AS **2007** 1935
1 SR **101**
2 BBl **2002** 29

d. germ cells, impregnated egg cells and embryos in the context of medically assisted human reproduction.

3 Articles 36 and 50 to 71 apply to the handling of organs, tissues or cells for autogenic transplantation. The Federal Council may issue regulations on the quality and safety of organs, tissues or cells for autogenic transplantation which are prepared prior to transplantation. Articles 4, 7 paragraph 2 letter b, 49 and 63-65 apply to transplant products for autogenic transplantation.

Art. 3 Definitions

In this Act:

a. *organ* means any part of the body whose cells and tissues together comprise a unit with a specific function; organ parts whose function is similar to that of an organ and parts of the body that consist of different types of tissue and which have a specific function are regarded as equivalent to organs;

b. *tissue* means a structured association of cells, consisting of the same or different types of cells, that has a common function in the body;

c. *cell* means an individual cell, an unstructured cell mass or a cell suspension that consists exclusively of the same type of cell;

d.[3] …

Art. 4 General duty of care

Any person who handles organs, tissues, cells or transplant products must take any measures that may be required in accordance with the current state of scientific and technical knowledge in order not to endanger human health.

Art. 5 Removal for purposes other than transplantation

1 If organs, tissues or cells have been removed for purposes other than transplantation, they may only be stored, transplanted or used to obtain transplant products if the regulations concerning information and consent contained in Articles 8, 12 letter b, 13 paragraph 2 letter f and g, 39 paragraph 2 and 40 paragraph 2 have been complied with.

2 The regulations concerning information and consent in paragraph 1 also apply to the handling of blood stems obtained from umbilical cord blood.

3 Repealed by No I of the Federal Act of 19 June 2015, with effect from 1 May 2016 (AS **2016** 1163; BBl **2013** 2317).

Chapter 2 Human Organs, Tissues and Cells

Section 1 Non-Commercialism and Prohibition of Trade

Art. 6 Non-commercialism of donation

[1] It is prohibited to grant or derive financial gain or any other advantage from a donation of human organs, tissues or cells.

[2] The following are not regarded as financial gain or other advantage:

a. reimbursement of loss of earnings and expenses incurred directly by the donor;

b. compensation for damage incurred by the donor as a result of organs, tissues or cells being removed;

c. a subsequent symbolic gesture of gratitude;

d. a crossover living donation.

Art. 7 Prohibition of trade

[1] It is prohibited:

a. to trade in human organs, tissues or cells in Switzerland or abroad (acting from Switzerland);

b. to remove or transplant human organs, tissues or cells which have been obtained in exchange for payment or by granting advantages.

[2] This prohibition does not apply to:

a. the reimbursement of expenses incurred in the context of transplantation, and in particular costs for removal, transport, preparation, storage and transplantation;

b. transplant products in accordance with Article 49.

Section 2 Removal of Organs, Tissues or Cells from Deceased Persons

Art. 8 Preconditions for removal

[1] Organs, tissues or cells may be removed from a deceased person if:

a. the person has consented before his or her death to the removal;

b. death has been determined.

[2] If no documented consent or refusal by the deceased person is available, the next of kin must be asked whether they are aware of the person having declared an intention to donate.

[3] If the next of kin are not aware of any such declaration, organs, tissues or cells may be removed if the next of kin give consent. The decision of the next of kin shall be guided by what they believe the deceased person would have wanted.

4 If there are no next of kin, or they cannot be contacted, removal is not permitted.

5 The wishes of the deceased person take priority over those of the next of kin.

6 If the deceased person has demonstrably delegated the decision on the removal of organs, tissues or cells to a trusted person, this person shall be consulted instead of the next of kin.

7 Individuals who have reached the age of 16 may declare their intention to donate.

8 The next of kin shall be defined by the Federal Council.

Art. 9 Criteria for death and determination of death

1 A person is dead if the functions of his or her brain, including the brain stem, have ceased irreversibly.

2 The Federal Council shall issue regulations on the determination of death. In particular, it shall specify:

a. which clinical signs must be present so that it can be concluded that the functions of the brain, including the brain stem, have ceased irreversibly;

b. the requirements which must be fulfilled by the doctors who determine death.

Art. 10 Preparatory medical measures

1 Medical measures intended solely to preserve organs, tissues or cells may only be undertaken prior to the death of the donor if the donor has been informed comprehensively and has freely given his or her consent.

2 Such measures are prohibited if they:

a. hasten the death of the patient;

b. may lead to the donor entering a permanent vegetative state.

3 If a person has not declared his or her intention of donating, such measures may be carried out after the death of the patient until the next of kin have reached a decision. The Federal Council shall specify the maximum length of time during which such measures may be carried out.

Art. 11 Independence of persons involved

1 Doctors who determine the death of a person may not:

a. participate either in the removal or the transplantation of organs, tissues or cells;

b. be subject to orders from a medical professional who is involved in such activities.

2 Doctors who remove or transplant organs, tissues or cells and associated medical personnel must not pressurise individuals who are caring for the dying person or who determine death or attempt to influence them in any other way.

Section 3
Removal of Organs, Tissues and Cells from Living Persons

Art. 12 Preconditions for removal

Organs, tissues and cells may be removed from a living person if:

a. that person is capable of judgement and has reached the age of majority[4];

b. that person has been informed comprehensively and has freely given his or her consent in writing;

c. there is no serious risk to his or her life or health;

d. the recipient cannot be treated with any other therapeutic method with comparable benefit.

Art. 13 Protection of persons incapable of judgement and minors[5]

1 Organs, tissues and cells may not be removed from persons who are incapable of judgement or who are minors.

2 Exceptions may be permitted for the removal of tissues or cells capable of regeneration if:

a. removal involves only a minimal risk and a minimal burden for the person who are incapable of judgement or minor;

b. the recipient cannot be treated with any other therapeutic method with comparable benefit;

c. no suitable adult donor who is capable of judgement is available;

d. the recipient is a parent, child or sibling of the donor;

e. the donation is likely to save the recipient's life;

f. the legal representative has been informed comprehensively and has freely given his or her consent in writing;

g. the donor who is a minor capable of judgement has been informed comprehensively and has freely given his or her consent in writing;

h. there is no indication that the person incapable of judgement would object to removal;

i. an independent authority has given permission.

3 A person incapable of judgement must be involved as far as possible in the information and consent process.

4 Expression in accordance with Annex No 21 para. 1 of the Federal Act of 18 Dec. 2008 (Adult Protection, Law of Persons and Law of Children), in force since 1 Jan. 2013 (AS **2011** 725; BBl **2006** 7001). This amendment has been made throughout the text.

5 Expression in accordance with Annex No 21 para. 2 of the Federal Act of 18 Dec. 2008 (Adult Protection, Law of Persons and Law of Children), in force since 1 Jan. 2013 (AS **2011** 725; BBl **2006** 7001). This amendment has been made throughout the text.

4 The cantons shall specify the independent authority in accordance with paragraph 2 letter i and shall regulate the process.

Art. 14 Reimbursement of expenses and insurance

1 Any person who removes organs, tissues or cells from a living person must ensure that this person is adequately insured against possible serious consequences of removal.

2 The insurer who would be responsible for the costs of treating the recipient's illness if no living donation were available shall be responsible for:

a. the cost of this insurance;

b. appropriate compensation for loss of earnings or other expenses incurred by the donor in connection with removal.

3 The duty to bear costs stipulated in paragraph 2 shall also apply if the removal or transplantation cannot be carried out. If the recipient's insurer is not known, the Confederation shall bear the costs.

4 The Federal Council shall specify in particular:

a. the serious consequences against which the donor must be insured;

b. the content and scope of the insurance stipulated in paragraph 1;

c. any other expenses for which the donor shall be compensated in accordance with paragraph 2 letter b.

Art. 15 Regulations of the Federal Council

1 The Federal Council shall specify the requirements which information must fulfil under the terms of Articles 12 letter b and 13 paragraph 2 letters f and g.

2 It may specify which other therapeutic methods have no comparable benefit for the recipient.

Section 4 Allocation of Organs

Art. 16 Scope

1 This section concerns the allocation of organs which the donor has not donated for a specific person.

2 The Federal Council:

a. shall specify which organs shall be allocated in accordance with this section;

b. may also declare this section to be applicable to the allocation of tissues and cells.

Art. 17 Non-discrimination

[1] No-one may be discriminated against with respect to the allocation of organs.

[2] The following persons must be treated equally with respect to allocation:

a. persons resident in Switzerland;

b. persons resident in a member state of the European Union, in Iceland or Norway and who in accordance with the Agreement of 21 June 1999[6] between the European Community and its Member States, of the one part, and the Swiss Confederation, of the other, on the free movement of persons or the Convention of 4 January 1960[7] establishing the European Free Trade Association:

1. are required to have mandatory health insurance in Switzerland, or
2. are entitled to international benefits assistance during a stay of limited duration in Switzerland;

c. cross-border commuters under Article 25 of the Foreign Nationals Act of 16 December 2005[8] who at their own request are subject to mandatory health insurance in Switzerland, as well as their family members who are required to have mandatory health insurance in Switzerland.[9]

[3] Persons who do not belong to any of the groups mentioned in paragraph 2 but who are included on the waiting list in accordance with Article 21 paragraph 1 will be allocated an available organ if:[10]

a. the transplantation is medically urgent and there is no-one resident in Switzerland who is in a similar situation; or

b. the transplantation is not medically urgent and no recipient resident in Switzerland can be identified.

[4] There is no fundamental right to allocation of an organ.

Art. 18 Decisive criteria

[1] The following criteria in particular shall be observed when allocating organs:

a. the medical urgency of a transplantation;

b. the medical benefit of a transplantation;

c. the waiting time.

[2] When allocating organs, an effort must be made to ensure that patients who, because of their physiological characteristics, are likely to have to wait a very long

6 SR **0.142.112.681**
7 SR **0.632.31**
8 SR **142.20**
9 Amended by No I of the Federal Act of 19 June 2015, in force since 1 May 2016 (AS **2016** 1163; BBl **2013** 2317).
10 Amended by No I of the Federal Act of 19 June 2015, in force since 1 May 2016 (AS **2016** 1163; BBl **2013** 2317).

time have the same probability of being allocated an organ as patients without these characteristics.

3 The Federal Council shall specify the order in which the criteria are to be applied, or shall give them a weighting.

Art. 19 National organ allocation office

1 The Confederation shall create a national organ allocation office.

2 The national organ allocation office:

a. keeps a list of individuals waiting to receive an organ (waiting list);

b. allocates available organs to recipients after consultation with the transplant centres;

c. organises and coordinates at national level all activities relating to allocation;

d. collaborates with allocation organisations in other countries.

3 The national organ allocation office shall document each decision and retain this documentation for ten years.

4 The Federal Council shall regulate the allocation procedure.

Art. 20 Registration of patients

The attending doctor shall register patients for whom transplantation is medically indicated and who have given their written consent at a transplant centre without delay. Patients must also be registered if they are receiving replacement therapy.

Art. 21 Waiting list

1 Persons are placed on the waiting list in accordance with Article 17 paragraph 2. The Federal Council shall determine which persons who do not meet the requirements of Article 17 paragraph 2 are also placed on the waiting list.[11]

2 The transplant centres shall decide whom to place on or remove from the waiting list. They may take only medical reasons into account. Article 17 paragraph 1 applies *mutatis mutandis*.

3 The transplant centres shall communicate their decisions with the necessary data to the national organ allocation office.

4 The Federal Council shall specify in more detail:

a. the medical reasons according to paragraph 2;

b. the necessary data according to paragraph 3.

11 Amended by No I of the Federal Act of 19 June 2015, in force since 1 May 2016 (AS **2016** 1163; BBl **2013** 2317).

Art. 22 Registration of donors

[1] Hospitals and transplant centres shall inform the national organ allocation office, sending the necessary data, of all deceased persons who meet the criteria for organ removal. The Federal Council shall specify in more detail the necessary data.

[2] Doctors, hospitals and transplant centres to whom a person has declared while alive his or her willingness to donate an organ have a duty to register this person with the national organ allocation office.

Art. 23 International exchange of organs

[1] If no recipient can be found for an organ in Switzerland, the national organ allocation office shall offer the organ to a foreign organ allocation organisation. The right to exchange an organ under an international patients' programme in accordance with Article 18 paragraph 2 is reserved.

[2] Offers or organs from other countries may only be accepted by the national organ allocation office.

[3] The national organ allocation office may conclude agreements governing reciprocal organ exchange with foreign organ allocation offices. This shall require the approval of the Swiss Federal Office of Public Health (Federal Office).

Section 5 Removal, Storage, Import and Export, and Preparation

Art. 24 Mandatory notification of removal

[1] Any person who removes organs, tissues or cells must notify the Federal Office of this.

[2] The Federal Council shall specify the content of the notification and the duties of the notifier.

Art. 25 Mandatory authorisation for storage, import and export

[1] Authorisation from the Federal Office is required by any person who:

a. stores tissues or cells;

b. imports or exports organs which are not allocated in accordance with Articles 16–23, tissues or cells.

[2] Storage in a bonded warehouse shall be considered as importation.

[3] Authorisation shall be granted if:

a. the necessary technical and operative requirements have been fulfilled;

b. a suitable quality assurance system is in place.

[4] The Federal Council shall regulate the preconditions for authorisation and the authorisation procedure and shall specify the duties of persons who require approval.

Art. 26 Preparation

The Federal Council may issue regulations governing the preparation of organs, tissues and cells. In doing so, it shall take internationally accepted guidelines and standards into account.

Section 6 Transplantation

Art. 27 Mandatory authorisation

[1] Organs may only be transplanted in transplant centres which have been granted the appropriate authorisation by the Federal Office.

[2] Authorisation shall be granted if:

a. the necessary technical and operative requirements have been fulfilled;

b. a suitable quality assurance system is in place which also ensures that the health status of living donors is followed up;

c. the quality of the transplantations is ensured.

[3] Transplant centres must record, evaluate and regularly publish the outcome of transplantations using standardised criteria.

[4] The Federal Council may make the transplantation of tissues or cells contingent on approval from the Federal Office.

Art. 28 Restriction of the number of transplant centres

The Federal Council may restrict the number of transplant centres in consultation with the cantons and taking developments in transplantation medicine into account.

Art. 29 Mandatory notification

[1] Any person who transplants tissues or cells must notify the Federal Office of this.

[2] The Federal Council shall specify the content of the notification and the duties of the notifier.

Section 7 Duty of Due Diligence

Art. 30 Suitability of donors

[1] Any person who removes or transplants organs, tissues or cells must verify the suitability of donors.

[2] The following must be excluded as donors:

a. any person who has received a transplant of organs, tissues or cells of animal origin or transplant products obtained therefrom;

b. any person other than those mentioned under letter a whose organs, tissues or cells could transmit pathogenic agents or otherwise harm the health of the recipient; Article 31 paragraph 2 letter c applies notwithstanding.

3 The Federal Council shall regulate the requirements regarding donor suitability, responsibility for verifying suitability and the data that shall be recorded in the process.

Art. 31 Mandatory testing

1 Any person who removes or transplants organs, tissues or cells must make certain that these have been tested for pathogenic agents or markers thereof.

2 The Federal Council shall specify in particular:

a. which tests for pathogenic agents or markers thereof must be carried out;

b. which tests may be used;

c. the cases in which organs, tissues or cells may be transplanted in spite of the test results being reactive.

3 It may provide for exemptions from mandatory testing if it can be ensured by other means that infection with pathogenic agents is excluded.

Art. 32 Removal and inactivation of pathogenic agents

The Federal Council may make provision for procedures to remove or inactivate pathogenic agents not to be used until they have received regulatory approval by the Federal Office.

Art. 33 Mandatory labelling

Organs, tissues and cells and associated samples must be labelled in such a way that they can be identified unequivocally.

Art. 34 Mandatory documentation and traceability

1 Any person who handles organs, tissues or cells must:

a. record all procedures and transactions of significance for the protection of health;

b. keep these records in such a way that the data can be traced back as far as the donor and the recipient.

2 In particular, for each instance of removal or transplantation of organs, tissues or cells, the surname, first name and date of birth of both donor and recipient must be recorded.

Art. 35 Mandatory archiving

1 The records specified in Article 34 and all important documents shall be kept for 20 years.

2 If the business activity ends before this period expires, the complete documentation shall be stored safely or, if this is not possible, handed over to the Federal Office.

Section 8 Clinical Trials

Art. 36[12]

1 Clinical trials involving the transplantation of human organs, tissues or cells require authorisation from the Federal Office in advance. For certain trials, the Federal Council may grant an exemption from mandatory authorisation or specify mandatory notification.

2 The Federal Office shall determine whether the organs, tissues or cells used in a clinical trial meet the requirements specified in this Act. It may inspect clinical trials at any time.

3 The Federal Council shall issue regulations concerning the procedure. It may specify mandatory authorisation for changes to clinical trials.

4 It may specify notification or information requirements, in particular with regard to:

a. the completion or discontinuation of a clinical trial;

b. adverse events observed in connection with a clinical trial;

c. the occurrence of circumstances during the conduct of a clinical trial which could affect the safety or health of the participants.

5 In issuing regulations in accordance with paragraphs 3 and 4, the Federal Council shall have regard to recognised international regulations.

6 For clinical trials, the Human Research Act of 30 September 2011[13] is also applicable.

Section 9 Handling Embryonic or Foetal Human Tissues or Cells

Art. 37 Principles and prohibitions

1 The time and method of a termination of pregnancy must be selected independently of subsequent transplantation of embryonic or foetal human tissues or cells.

2 It is prohibited:

a. to keep superfluous embryos alive artificially after the seventh day of development or to keep aborted embryos or intact foetuses alive artificially for the purpose of remove tissues or cells from them for transplantation;

12 Amended by Annex No 4 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).
13 SR **810.30**

b. to transplant embryonic or foetal tissues or cells into a person designated for this purpose by the donor;

c. to use embryonic or foetal tissues or cells from women who are incapable of judgement for transplantation purposes.

Art. 38 Mandatory authorisation

1 Any person who wishes to transplant embryonic or foetal human tissues or cells into humans shall require authorisation by the Federal Office.

2 Authorisation shall be granted for a clinical trial if:

a. a therapeutic benefit can be expected;

b. the necessary technical and operative requirements have been fulfilled;

c. a suitable quality assurance system is in place.

3 Authorisation shall be granted for standard treatment if:

d. a therapeutic benefit has been demonstrated;

e. the recipient cannot be treated with another therapeutic method with comparable benefit;

f. the conditions stated in paragraph 2*b* and *c* have been fulfilled.

Art. 39 Information and consent of donor

1 A woman may not be asked to donate embryonic or foetal human tissues or cells for transplantation purposes before she has taken the decision to terminate the pregnancy.

2 Embryonic or foetal human tissues or cells may only be transplanted if the donor has been informed comprehensively and has consented freely and in writing to the intended use.

Art. 40 Information and consent of the affected couple

1 A couple may not be asked to donate tissues or cells from a superfluous embryo for transplantation purposes until it has been established that the embryo is superfluous.

2 Tissues or cells from superfluous embryos may only be transplanted if the affected couple has been informed comprehensively and has consented freely and in writing to the intended use.

Art. 41 Independence of medical personnel

The individuals involved in the transplantation must not influence the medical personnel who carry out the termination of the pregnancy or are involved in the reproductive procedure. They may not be involved in either the termination or the reproductive procedure and may not have the authority to give instructions to those involved.

Art. 42 Regulations of the Federal Council

The Federal Council shall specify:

a. the requirements that information provided under the terms of Articles 39 and 40 must fulfil;

b. the duties of the persons requiring authorisation;

c. the preconditions for granting authorisation and the authorisation procedure.

Chapter 3 Organs, Tissues and Cells of Animal Origin

Art. 43 Mandatory authorisation

1 Any person who wishes to transplant organs, tissues or cells of animal origin or transplant products obtained therefrom into humans shall require authorisation from the Federal Office.

2 Authorisation shall be granted for a clinical trial if:

a. a risk of infection for the population can be excluded with a high degree of probability;

b. a therapeutic benefit can be expected;

c. the necessary technical and operative requirements have been fulfilled;

d. a suitable quality assurance system is in place.

3 Authorisation shall be granted for standard treatment if:

a. a risk of infection for the population can be excluded;

b. a therapeutic benefit has been demonstrated;

c. the requirements stipulated in paragraph 2 letters c and d have been fulfilled.

Art. 44 Duties of the holder of the authorisation

The holder of the authorisation has a duty:

a. to examine the recipient regularly and on a long-term basis for pathogenic agents or markers thereof;

b. on the death of the recipient, to examine the cadaver for any signs of infection;

c. to record all information and transactions relevant in terms of protecting the health of the population;

d. to maintain the records in such a way that the data can be traced back to the donor animal, the recipient and the biological samples that were taken;

e. to retain the records and the biological samples and to make them available to the responsible authorities on request;

f. should information come to light which could be relevant in terms of protecting the health of the population, to implement all necessary measures without delay and to inform the competent authorities immediately.

Art. 45 Mandatory testing

Any person who removes organs, tissues or cells from an animal or transplants these or transplant products obtained from them must make certain that they have been tested for pathogenic agents or markers thereof.

Art. 46 Indemnification

In order to protect harmed individuals, the Federal Council may:

a. require any person who places on the market or transplants animal organs, tissues or cells to obtain insurance coverage for the costs for which he is liable or to make provision for another form of indemnification;

b. determine the scope and duration of this indemnification;

c. oblige the indemnifier to notify the Federal Office of the existence, interruption or cessation of the indemnification.

Art. 47 Costs for measures required by the authorities

The perpetrator shall bear the costs of measures implemented by the competent authorities to:

a. prevent or reduce a risk of infection for the population;

b. determine or eliminate harm caused by infections.

Art. 48 Regulations of the Federal Council

[1] The Federal Council shall issue regulations concerning the handling of organs, tissues and cells of animal origin. In particular, it shall specify:

a. requirements concerning the handling of donor animals;

b. requirements concerning the quality of the animal organs, tissues or cells;

c. the requirements concerning tests to monitor the health of recipients and donor animals;

d. the preconditions for authorisation and the authorisation procedure;

e. the duration and nature of retention of recorded data and transactions and biological samples that have been taken;

f. the pathogenic agents or markers for which tests must be carried out;

g. the circumstances in which organs, tissues and cells of animal origin for which the test results are reactive may be transplanted;

h. the labelling of organs, tissues or cells of animal origin which have been obtained from genetically modified animals;

i. the requirements concerning:
   1. information of and consent by the recipient,
   2. information of medical personnel and their consent to measures affecting them, and
   3. information of the recipient's close contacts.

2 The Federal Council may:

a. restrict or prohibit the use of certain species of animals for transplantation purposes;

b. grant exemptions from mandatory testing according to Article 45 if it can be ensured by other means that infection with pathogenic agents can be excluded;

c. specify other duties of the holder of the authorisation and duties of the recipient if required by changing circumstances;

d. declare Articles 6–42 to be applicable to the handling of organs, tissues or cells of animal origin.

Chapter 4 Transplant Products

Art. 49

1 In addition to the provisions of this Act, Articles 3, 5–33, 58–67 and 84–90 of the Federal Act of 15 December 2000 on Medicinal Products and Medical Devices[14] apply *mutatis mutandis* to the handling of transplant products.

2 The Swiss Agency for Therapeutic Products shall also be responsible for inspections according to Article 60 paragraph 2 TPA with respect to transplant products.

3 In addition, Articles 36-41 and 53-57 TPA also apply *mutatis mutandis* to the handling of transplant products obtained from human organs, tissues and cells.

4 Any person who removes organs, tissues or cells for the manufacture of transplant products must verify the suitability of the donor as stipulated in Article 36 TPA.

5 Article 86 paragraph 1*d* TPA also applies to the handling of human transplant products.

Chapter 5 Enforcement

Section 1 Confederation

Art. 50 Principle

1 The Confederation shall enforce this Act unless it declares this to be the responsibility of the cantons.

14 SR **812.21**

2 The Federal Council shall issue the implementing regulations.

Art. 51 Monitoring

1 The Confederation shall monitor the enforcement of this Act by the cantons.

2 It shall coordinate their enforcement activities if it has an interest in enforcement being standardised throughout Switzerland. To this end it may, in particular:

a. oblige the cantons to inform it about their enforcement activities;

b. prescribe activities for the cantons to ensure standardised enforcement.

Art. 52 International cooperation

The Confederation shall employ measures to facilitate the exchange of information and the rapid and safe exchange of organs, tissues or cells and to fight illegal trade in organs.

Art. 53 Continuing and in-service training of medical personnel

The Confederation may carry out or support continuing and in-service training programmes that enable medical personnel to provide appropriate care for donors and their families.

Art. 54 Delegation of enforcement duties

1 The Federal Council may delegate enforcement duties to organisations and persons under public or private law.

2 This applies in particular to:

a. the allocation of organs in accordance with Article 19;

b. the keeping of a stem cell register in accordance with Article 62;

c. monitoring in accordance with Article 63.

3 The Federal Council shall ensure that the delegated duties are remunerated.

Art. 55 Evaluation

1 The Federal Office shall ensure that the enforcement and impact of this Act are evaluated scientifically.

2 These evaluations shall focus on:

a. the influence of the Act on the situation, attitude and behaviour of the population and medical personnel;

b. the practice of allocating organs, the quality of transplantations, and the availability of organs, tissues and cells for transplantation.

3 The Federal Department of Home Affairs shall report the results of completed evaluations to the Federal Council and shall make a recommendation on the next course of action to the Federal Council.

Section 2 The Cantons

Art. 56 Organisation and coordination

1 The cantons shall organise and coordinate activities relating to transplantation in:

a. hospitals that care for donors;

b. transplant centres.

2 In particular, they shall ensure that at each of these hospitals and at the transplant centres:

a. one person is responsible for local coordination;

b. the necessary continuing and in-service training programmes for the medical staff are provided.

3 The person responsible for local coordination shall ensure in particular that:

a. donors and their families receive appropriate care;

b. donors are reported to the national organ allocation office (Art. 22).

Section 3 Duty of Confidentiality and Provision of Data

Art. 57 Duty of confidentiality

All persons charged with enforcing this Act shall be bound to maintain confidentiality.

Art. 58 Confidentiality of data

The confidentiality of the data compiled as a result of this Act merits protection, and the data must accordingly be treated confidentially.

Art. 59 Disclosure of data

1 Where no overriding and conflicting private interest exists, data may, in individual cases and following a written, justified request, be provided to:

a. civil courts if the data is required to judge a court case;

b. criminal courts and criminal investigation authorities if the data is required to investigate a felony or misdemeanour.

2 Where no overriding and conflicting private interest exists, data may be provided to:

a. the offices within the Confederation and cantons responsible for enforcing this Act and organisations or persons under public or private law if they require the data to fulfil the duties assigned to them under this Act;

b. criminal investigation authorities if required to prosecute or prevent a felony or an offence under this Act.

3 Data which is of general interest and relates to the application of this Act may be published. The individuals concerned must not be identifiable.

4 In other cases, data may be provided to third parties as follows:

a. data not relating to specific persons, provided that there is an overriding interest in this data being made available;

b. personal data, provided that the individual concerned has given written consent in each case.

5 Only data necessary for the intended purpose may be provided.

6 The Federal Council shall regulate the details of the provision of data and the information that shall be given to the individuals concerned.

Art. 60 Exchange of data with foreign authorities and international organisations

1 The Federal Council shall regulate responsibilities and the procedures for exchanging data with foreign authorities and institutions and with international organisations.

2 Confidential data may only be provided to foreign authorities and institutions or to international organisations if:

a. required by agreements under international law or resolutions passed by international organisations;

b. necessary to avert an imminent danger to life or health; or

c. this would enable illegal trade or other serious offences under this Act to be exposed.

Section 4 Informing the Public

Art. 61

1 The Federal Office and the cantons shall regularly inform the public about matters concerning transplantation medicine. To this end they may collaborate with organisations and persons under public or private law.

2 This information shall cover:

a. explanation of the ways in which an individual can express his or her wishes concerning the donation of organs, tissues or cells and the consequences of expressing such wishes;

b. the legal situation and practical aspects, i.e. explanation of the preconditions for the removal, allocation and transplantation of organs, tissues and cells in Switzerland.

3 The Federal Council may determine that a declaration of volition to donate organs, tissues or cells may be recorded on a suitable document or information storage medium.

Section 5 Stem Cell Register

Art. 62

1 The Federal Office shall keep a stem cell register.

2 The purpose of the stem cell register is to find suitable stem cells for a specific recipient. The data recorded in this register may only be used for this purpose.

3 The data stored in the stem cell register are those necessary to determine the tissue match of:

a. stored stem cells;

b. persons who have declared their willingness to donate.

4 Any person who processes data of the type referred to in paragraph 3 must report them to the register. These data should only be reported in conjunction with a person's name if required by the purpose of the register.

5 A person entered in the register may request the deletion of data referring to him or her at any time.

6 The Federal Council shall specify the types of stem cells for which a register will be kept.

Section 6 Monitoring and Measures

Art. 63 Monitoring

1 The Federal Office shall monitor compliance with the provisions of this Act. In particular it shall carry out periodic inspections to this end.

2 It may, free of charge, take the necessary samples, request the necessary information or documents and request any other assistance required. It may instruct the customs authorities to obtain samples.

3 It may enter sites, establishments and premises and search vehicles in pursuit of its duties.

Art. 64 Duty of cooperation

Any person who handles organs, tissues or cells or transplant products obtained therefrom must, without remuneration, assist the Federal Office in the pursuit of its duties. In particular he or she must:

a. permit samples to be taken or provide samples on request;

b. provide information;

c. grant access to documentation and premises.

Art. 65 Measures

[1] The Federal Office may take any measures necessary to enforce this Act.

[2] In particular it may:

a. issue notices of non-compliance and set an appropriate deadline for rectification of the situation;

b. seize and destroy organs, tissues and cells or transplant products that endanger health or do not comply with the requirements of this Act;

c. forbid the use of premises or establishments or close plants;

d. suspend or revoke authorisations or approvals.

[3] The Federal Office may take necessary precautionary measures. In particular it may seize or hold organs, tissues or cells or transplant products which are deemed to be non-compliant or in the event of a reasonable suspicion.

[4] Where an infringement of the terms of this Act is suspected, the customs authorities shall be entitled to retain shipments containing organs, tissues, cells or transplant products at the border or in bonded warehouses and to involve the Federal Office. The Federal Office shall carry out subsequent investigations and instigate the necessary measures.

Section 7 Funding

Art. 66 Division of tasks

The Confederation and the cantons shall bear the costs of enforcing this Act in their respective jurisdictions.

Art. 67 Fees

[1] Fees shall be levied in respect of:

a. the granting, suspension or revocation of authorisations;

b. the conduct of inspections;

c. the ordering and performance of measures.

[2] The Federal Council shall set the fees for enforcement by the federal authorities.

Section 8 Right of Appeal

Art. 68[15]

[1] Appeals may be filed with the Federal Administrative Court with respect to rulings derived from this Act and its implementing ordinances.

[2] If an appeal against a ruling on the allocation of organs is justified, the Federal Administrative Court shall only determine the degree to which federal law has been infringed by the contested ruling.

[3] The right of appeal shall otherwise be governed by the general provisions on the Administration of Federal Justice.

Chapter 6 Criminal Provisions[16]

Art. 69 Misdemeanours

[1] Provided that no more serious offence has been committed under the Criminal Code[17], a term of imprisonment or a fine of up to 200,000 francs shall be imposed on anyone who wilfully:

a. grants or accepts a financial gain or other advantage for the donation of human organs, tissues or cells (Art. 6 para. 1);

b. places human organs, tissues or cells on the market in Switzerland or abroad (acting from Switzerland) in exchange for payment, or removes or transplants human organs, tissues or cells which have been obtained in exchange for payment or advantages (Art. 7 para. 1);

c. removes organs, tissues or cells from a deceased person without consent having been given (Art. 8);

d. infringes the regulations governing preparatory medical measures (Article 10);

e. removes organs, tissues or cells and in so doing creates a serious risk for the life or health of the donor (Art. 12 let. c);

f. removes organs, tissues or cells from living persons who are incapable of judgement or who are minors without the preconditions for this having been met (Art. 13 para. 2 and 3);

15 Amended by No I 11 of the Ordinance of the Federal Assembly of 20 Dec. 2006 on the Amendment of Legislation in accordance with the Provisions of the Federal Supreme Court Act and the Administrative Court Act, in force since 1 July 2007 (AS **2006** 5599; BBl **2006** 7759).

16 As of 1 January 2007 penalties and prescriptive periods shall be interpreted and/or amended in application of Art. 333 para. 2-6 of the Criminal Code (SR **311.0**) in accordance with the Federal Act of 13 Dec. 2002 (AS **2006** 3459).

17 SR **311.0**

g. discriminates against persons with respect to inclusion in the waiting list or the allocation of organs (Art. 17 and 21 para. 2) or fails to allocate organs in accordance with the decisive criteria (Art. 18);

h. infringes the regulations concerning the special duty of care (Art. 30–35 and 45) in so doing puts the health of people at risk;

i. carries out clinical trials which do not comply with the requirements of this Act and in so doing endangers the health of people (Art. 36);

j. determines the time and method of the termination of a pregnancy to coincide with the transplantation of embryonic or foetal human tissues or cells (Art. 37 para. 1);

k. obtains superfluous embryos after the seventh day of their development or keeps aborted embryos or intact foetuses alive artificially in order to remove tissues or cells from them for transplantation purposes (Article 37 para. 2 let. a);

l. transplants embryonic or foetal tissues or cells into a person who has been designated for this purpose by the donor (Art. 37 para. 2 let. b);

m. uses embryonic or foetal tissues or cells from women who are incapable of judgement for the purpose of transplantation (Art. 37 para. 2 let. c);

n. infringes the regulations governing the information and consent of the donor or the couple concerned (Art. 39 and 40).

2 If the act is committed for commercial gain, the penalty shall be up to five years' imprisonment or a fine of up to CHF 500,000.

3 If the act is committed through negligence, the penalty shall be up to six months' imprisonment or a fine of up to CHF 100,000.

Art. 70 Contraventions

1 A term of detention or a fine of up to CHF 50,000 shall be imposed on anyone who, without having committed a misdemeanour under Art. 69, wilfully or negligently:

a. infringes the regulations governing the removal of organs, tissues or cells for purposes other than transplantation (Art. 5);

b. infringes the regulations concerning the independence of the persons concerned (Art. 11 and 41);

c. removes organs, tissues or cells from a living person even though the recipient could have been treated with a different therapeutic method with comparable benefit (Art. 12 let. d);

d. infringes a duty of notification (Art. 20, 21 para. 3, 22, 24, 29, 36 and 62 para. 4);

e. accepts without authorisation organs offered from another country (Art. 23 para. 2);

f. performs without authorisation acts which require authorisation or fails to fulfil conditions attached to such authorisation (Art. 25, 27, 38 and 43);

g. breaches the duty of confidentiality, provided that neither Article 320 nor Article 321 of the Criminal Code[18] has been infringed (Art. 57);

h. breaches the duty of cooperation (Art. 64);

i. commits an offence according to Article 69 paragraph 1 letter h or i without endangering the health of any people;

j. contravenes an implementing regulation where such a contravention has been declared by the Federal Council to be an offence, or contravenes a ruling to which he or she is subject that makes specific reference to the penalties under this article.

2 Attempts and aiding and abetting are also offences.

3 The right to prosecute the foregoing contraventions and execute the penalties therefor are subject to a five-year prescriptive period.

4 In particularly minor cases, the requirement to report, prosecute or penalise the offence may be waived.

Art. 71 Jurisdiction and administrative criminal law

1 The cantons have jurisdiction for the prosecution and judgement of offences.

2 Articles 6, 7 (offences committed within a business) and 15 (forgery of documents, obtaining a false certificate by fraud) of the Federal Act of 22 March 1974[19] on Administrative Criminal Law apply.

Chapter 7 Final Provisions

Art. 72 Repeal of current legislation

The Federal Decree of 22 March 1996[20] on the Control of Transplants is repealed.

Art. 73 Amendment of current legislation

…[21]

Art. 74 Transitional provision

1 Anyone who has already begun an activity within the meaning of Articles 24 and 29 must notify this to the Federal Office within six months of the commencement of this Act.

18 SR **311.0**
19 SR **313.0**
20 [AS **1996** 2296, **2001** 1505 2790 Annex No 7, **2002** 3335 Art. 1, **2005** 4779]
21 The amendments may be consulted under AS **2007** 1935.

2 Anyone who has already begun an activity within the meaning of Articles 25 and 27 must submit an application for authorisation to the Federal Office within six months of the commencement of this Act. He or she may continue to pursue the activity until the Federal Office reaches a decision.

3 Authorisations granted in accordance with Articles 18 and 18*a* of the Federal Decree of 22 March 1996[22] on the Control of Transplants shall remain valid until the period of authorisation expires.

4 The Federal Office reserves the right to instigate measures in accordance with Article 65.

Art. 75 Referendum and commencement

1 This Act is subject to an optional referendum.

2 The Federal Council shall determine the date on which this Act comes into force.

Commencement date: 1 July 2007[23]

22 [AS **2001** 1505]
23 Federal Council Decree of 16 March 2007 (AS **2007** 1960)