JUSTEL - Established legislation

Dossier number: 1986-06-13/37

Title

June 13th 1986 – law on the removal and transplantation of organs.
Context: integration of amendments in force published up to 21-06-2019 included.
Source: JUSTICE, PUBLIC HEALTH AND ENVIRONMENT
Publication: Belgian Official Gazette of 14-02-1987 page: 2129
Entry into force: 24-02-1987

Index

Text

CHAPTER 1 [fields of application, definitions and general principles][1]

(1) <L. 2012-07-03/08, art. 3, 009; In force: 03-09-2012>
Art. 1 [1 The present law is applied on donation, control and characterisation, the removal, the conservation, the transport and the transplant of organs intended for transplantation.
Whenever these organs are used for research purposes, the present law is applied only if these are designed to be transplanted in human bodies.][1]
---
(1) <L. 2012-07-03, art. 4, 009; In force: 03-09-2012>

Article 1a <inserted by L. 2007-02-25/57, art.2; In force: 23-04-2007>
§1 The King can establish rules and impose conditions or restrictions to the removal, the conservation, the elaboration, the importation, the transport, the distribution and the allocation of organs, (...). <L. 2008-12-19/44, art. 28, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art. 14)>
Every execution of subparagraph 1st subsequent to the entry in force of the programme act 22nd December 2003 will be implemented through a royal assent deliberated within the Council of Ministers.
§2 [1The King can adopt measures to reach an optimum organisation of organs removals as well as to improve the process of identification, selection and management of donors.][1]
---
(1) <L. 2012-07-03/08, art. 5, 009; In force: 03-09-2012>

Art. 1b [1 With the implementation of the present law is meant:
1° “elimination”: the final destination of an organ if it’s not used for the purposes of the transplantation;
2° “donor”: a person who donate one or more organs, whether the donation take place during the life or after the death;
3° “donation”: the fact that organs donation has the purpose of transplantation;
4° “characterisation of the donor”: acquisition of relevant information concerning characteristics of a donor that are necessary to evaluate his suitability to organs donation, so that it’s possible to carry out the evaluation of risks, to reduce risks for the recipient as much as possible and to optimise organs allocation;
5° “European organisation for organ exchanges”: a non-profit organisation, public or private, which deals with national and international exchanges in which the participating countries are mostly European Union member states;
6° “organ”: a differentiated part of a human body, made by different tissues, which maintain, autonomously, its structure, its vascularisation and its capacity to perform physiological functions. A part of an organ is considered equal to an organ if it retains the ability to serve the same purpose of the whole organ within the human body, structure and vascularisation parameters maintained;
7° “organ characterisation”: acquisition of relevant information concerning characteristics of the organ, necessary to evaluate if it is suitable for the transplant, in order to proceed to risks evaluation, risks reduction for the recipient and optimisation of organs allocation;
8° “removal”: a process that allows the availability of donated organs;
9° “conservation”: the process of using chemicals, modifying the environment or using other procedures, in order to prevent or delay the biological or physical deterioration of organs after the removal and until the transplantation;
10° “recipient”: a person who receives an organ transplant;
11° “serious undesirable accidents”: every unwanted and sudden accident linked to one of the steps of the donation process, that can involve the transmission of infectious diseases, that results in the death or the endangering of the patient’s life, involving disability or incapacity to work, causing or extending the hospitalisation or the infectivity;
12° “serious undesirable reactions”: every unwanted reaction which affects the live donor or the recipient, included a transmittable disease, that can be related to one of the steps of the process from the donation to the transplantation, that can be mortal or life-threatening, that involve disability or incapacity to work, that causes or extends the hospitalisation or the infectivity;
13° “operating mode”: written instructions describing the steps of a specific process, including the material and methods to be used and the expected end result;
14° “transplant”: the intended process to restore certain functions of the human body through the transfer of an organ from a donor to a recipient;
15° “transplant centre”: a medical service authorized under the law relating to hospitals and other health facilities, coordinated 10th July 2008;]1
[216° “delegated body”: a body to which tasks have been entrusted in accordance with article 17, paragraph 1, of Directive 1010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs removed for transplantation or a European organ exchange organisation which have been entrusted with tasks in accordance with Article 21 of the aforementioned Directive 2010/53/EU.]2
---
(1) <Inserted through L. 2012-07-03/08, art.6,009; In force: 03-09-2012>
(2) <L. 2014-02-07/13, art.26, 010; In force: 07-03-2014>

Art. 1c [1 Gametes, gonads, embryos and bone marrow are not considered as organs by this law.]1
---
(1) <inserted through L. 2012-07-03/08, Art. 7, 009; In force: 03-09-2012>

Art. 2 Upon the advice of the Superior Council of Public Hygiene, the King may extend the application of this Law, which he has designated, to the removal of organs or tissue prior to death, with a view to the

preparation of therapeutic tools which are indispensable for the treatment of serious illnesses or disabilities.

Art. 3 [1 §All medical activities related to organ procurement, such as donor selection and evaluation, are carried out by a doctor, based on their state of health and their clinical history. If the donation from a living person presents an unsustainable health risk for the latter, the doctor must exclude him from the selection.
§ 2 Any removal and transplantation of organs from deceased persons shall be carried out by a doctor of a transplant centre within a transplant centre or within a hospital as provided for in the Law concerning hospitals and other health facilities, coordinated on 10 July 2008, provided that the hospital has concluded a collaboration agreement with a transplant centre which is responsible for the collection and transplantation. By derogation from paragraph 1, the transplantation of a heart or heart-lungs may be performed outside a transplantation centre, by a "cardiac pathology" care team, which has concluded a collaborative agreement with a transplantation centre.
§ 3 Every organ removal and transplantation from live persons shall be carried out by a doctor of a transplantation centre within a transplantation centre.]1
---
(1) <L. 2012-07-03/08, art. 8, 009; In force: 03-09-2012>

Art. 3a [1 A quality and safety structure includes all the steps of the process from donation to transplantation or elimination, where indicated. Healthcare personnel who take part in each of the steps from donation to transplantation or disposal shall be appropriately qualified or trained and competent. Such staff will follow specific training programmes at their disposal.]1
---
(1) <Inserted through L. 2012-07-03/08, art. 9, 009; In force: 03-09-2012>

Art. 3b [1 §1 All organs taken and all donors must be subjected to a characterisation prior to transplantation, in accordance with the model set out in the Annex to this act.
The King can establish additional criteria to this model, which concern the physiological, immunological and histological characterization of donors, the characterization of organ functions, the detection of transmittable diseases and the overall situation of the patient.
§2 All necessary information obtained from live donors must be received.
In the case of a deceased donor, this information shall be obtained from the deceased donor's family or other persons where possible.
All parties are aware of the importance of the rapid transmission of this information.
§3 The analyses necessary for the characterisation of organs and donors shall be carried out in laboratories with suitably qualified or trained and competent personnel and with appropriate facilities and equipment. The King may establish criteria to be met by laboratories within the framework of the analyses necessary for the characterisation of organs and donors.]1
---
(1) <Inserted through L. 2012-07-03/08, Art.10, 009; In force: 03-09-2012>

Art. 3c [1 For the transport of organs, there must be appropriate operational arrangements to ensure the integrity of organs during transport and an adequate duration of transport.]1
---
(1) < Inserted through L. 2012-07-03/08, art.11, 009; In force: 03-09-2012>

Art. 3d [1 All organs taken, assigned and transplanted in Belgium are traced from the donor to the recipient and vice versa, so as to protect the health of donors and recipients. Such traceability implies the implementation of a system of identification of donors and recipients that allows to identify each donation and each of the organs and recipients that are associated with it.
All data required for traceability at every step of the process from donation to transplantation or disposal, as well as information on organ and donor characterisation, should be retained for at least 30 years after donation. Such data may be recorded in electronic form.]1

---
(1) <Inserted through L. 2012-07-03/08, art.12, 009; In force: 03-09-2012>

Art. 3e [1 §1 A notification system must be set in place to allow reporting, to examine, record and transmit the necessary relevant information concerning serious undesirable accidents which could affect the quality and safety of organs which could be attributed to the control, characterisation, the removal, storage or transport of organs, as well as any serious undesirable reactions observed during or after transplantation that may be related to these activities.
§2 An operational algorithm for the management of major accidents and undesirable reactions shall be established.
§3 Operational methods for timely notification shall be implemented to communicate:
a) all serious adverse events or reactions to the European organ exchange organisation or the concerned transplantation centre;
b) management measures in relation to major accidents and undesirable reactions to the european organ exchange organisation.
§4 There must be an interconnection between the notification system referred to in paragraph 1 and the notification system provided for in the Law of 19 December 2008 on the acquisition and use of human body material for medical application or scientific research.]1
---
(1) <Inserted through L. 2012-07-03/08, art.13, 009; In force: 03-09-2012>

Art. 4 [1 §1 Donations of organs from deceased donors and live donors shall be voluntary and unpaid. Neither the donor nor his family can assert a claim against the recipient.
§2 The principle of non-remunerative donation does not prevent living donors from receiving compensation, where this is limited to covering direct and indirect expenses as well as the loss of earnings related to the donation.
The King defines the conditions under which this compensation may be granted and checks that it does not constitute an economic incentive or a profit for a potential donor.
§3 Any measure which makes public the need or availability of bodies whose purpose is to offer or seek economic gain or a comparable advantage shall be prohibited.
§4 Organ harvesting should be on a non-profit basis.]1
---
(1) <Inserted through L. 2012-07-03/08, art.14, 009; In force: 03-09-2012>

Art. 4a [1Unless the donor and the recipient know their identity in the context of a transplant from a living person, the identity of the donor and the recipient cannot be communicated.]1
---
(1) <Inserted through L. 2012-07-03/08, art.15, 009; In force: 03-09-2012>

CHAPTER II _ Removal from living persons

Art. 5 Without prejudice to the provisions of Article 7, a withdrawal (of organs, (...)) from a living person may be performed only on a person who has reached the age of 18 and has previously given his consent. <L. 2003-12-22/42, art. 160, 004; In force: 10-01-2004> <L. 2008-12-19/44, art. 31, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art.14)>
[1No organ removal from a living person may be carried out on a person who has reached the age of eighteen but is not able to express his will.]1
---
(1) <Inserted through L. 2012-07-03/08, art.16, 009; In force: 03-09-2012>

Art.6 §1 Where removal from living persons is likely to have a[1strong]1 impact on the donor or involves non-regenerating tissues (…), it may not be carried out except where the recipient's life is in danger and the transplantation (of organs, tissues or cells) from a deceased person cannot produce an equally satisfactory result. <L. 2003-12-22/42, art. 161, 004; In force: 10-01-2004> <L. 2008-12-19/44, art.32, 008; In force: 01-12-2009 (see L. 2009-09-28/06)>
§2 [1…]1
---
(1) < Inserted through L. 2012-07-03/08, art.17, 009; In force: 03-09-2012>

Art. 7 §1 Where transplantation from living persons cannot normally have serious consequences for the donor (and where it does) for organs (...) that can be regenerated, and where it is intended for a brother or sister, it may be carried out by a person under the age of 18. <L. 2001-12-07/75, art. 2, 003; In force: 10-01-2003> <L. 2008-12-19/44, art. 33, 1°, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art. 14)>
(paragraph 2 repealed) <L. 2008-12-19/44, Art. 33, 2°, 008; In force: 01-12-2009 (see: L. 2009-09-28/06, art. 14)>
§2 [1 The transplantation provided for in paragraph 1 may not be made except on a person who has reached the age of 12, who is able to demonstrate his will and who consents to the transplantation in advance. [1
---
(1) <L. 2012-07-03/08, art.18, 009; In force: 03-09-2012>

Art. 8 §1 Consent to harvesting (of organs, (...)) from a living person must be given freely and consciously. It can be revoked at any time. <L. 2003-12-22/42, art. 163, 004; In force: 10-01-2004> <L. 2008-12-19/44, art. 34, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art. 14)>
§2 Consent must be given in writing before a senior witness. This will be dated and signed by the [1 donor]1 and the senior witness.
§3 Proof of consent must be provided to the doctor who will be responsible for taking the sample.
---
(1) <L. 2014-02-07/13, art. 27, 010; In force: 07-03-2014>

Art. 8a [1Any retrieval from living persons must be subject to prior multidisciplinary consultation between doctors and other carers, with the exception of doctors and carers who take care of the recipient or who carry out the retrieval or transplantation.
The members of the multidisciplinary consultation shall independently assess the potential donor, in particular his ability to consent to an organ procurement.
The King may lay down detailed rules for the application of paragraph 1.]1
---
(1) <L. 2012-07-03/08, art.19, 009; In force: 03-09-2012>

Art. 9 The doctor in charge of the collection (of organs, (...)) must ensure that the conditions of Articles 5 and 8 are complied with. . <L. 2003-12-22/42, art.164, 004; In force: 10-01-2004> <L.2008-12-19/44, art. 35, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art. 14)>
He shall inform the donor clearly and comprehensively [1...] 1 about the physical, mental, family and social consequences of the collection.
He must note that the donor has made his decision with conscience and with an unquestionably altruistic purpose.
---
(1) <L. 2014-02-07/13, art. 28, 010; In force: 07-03-2014>

Art. 9a [1 There must be a register or archive of living donors.
A monitoring system of living donors should be set up to identify, report, and manage any incident potentially related to the quality and safety of the donated organ and, consequently, to the safety of the

recipient, in addition to any serious adverse reaction affecting the live donor, which could result from donation.] [1]

---

(1) <L. 2012-07-03/08, art.20, 009; In force: 03-09-2012>

CHAPTER III _ Removal after the death

Art. 10 §1 (Organs, (...)) intended for transplantation, as well as the preparation, according to the conditions defined in art. 2, of therapeutic substances may be taken from the body of (any person registered in the population register or in the register of foreigners for more than six months) unless it is established that opposition to the collection has been expressed.
<L. 1987-02-17/31, art. unique, 002; In force: 24-04-1987> <L. 2003-12-22/42, art. 165, 004; In force: 10-01-2004> <L. 2008-12-19/44, art. 27, 008; In force: 01-12-2009 (see L.2009-09-28/06, art. 14)>
[[1]The doctor who intends to make the retrieval should inquire about the existence of opposition from the potential donor.] [1]
For persons who are not registered [[1]under paragraph 1e][1], it is mandatory that they have clearly expressed their consent to the withdrawal.
§2 A person who is eighteen years old and capable of expressing his will may only express the opposition provided for in paragraph 1.
If a person is under the age of eighteen but is capable of expressing his will, the opposition may be expressed either by that person or as long as that person is alive (by parents exercising their authority over the minor or by his guardian). <L. 2007-02-25/57, art. 6, 1°, 007; In force: 23-04-2007>
If a person is under the age of eighteen but is unable to manifest his will, the opposition may be expressed as long as he is alive (by one of the parents exercising their authority over the minor or by his guardian). <L. 2007-02-25/57, art. 6, 1°, 007; In force: 23-04-2007>
If a person is unable to express his or her will because of his or her mental state, the opposition may be expressed as long as he or she is present by his or her legal representative, through his or her administrator [[3]…][3] or failing that, by his or her immediate family members.
[[1] §2a Every person capable of expressing their will can alone clearly express their will to be a giver after death.][1]
§3 [[5] The King defines a mode of expression of the opposition to the collection of the potential donor or persons indicated in §2, or of the express consent to the collection indicated in §2a.
To this end, he is entitled, on the basis of the conditions and according to the rules laid down by Him:
1° shall, at the request of the person concerned, have the opposition or the consent expressed through the municipality, by an authorised medical practitioner or by electronic self-registration;
2° regulates the access to this donation in order to inform the doctors who take the samples, respectively, of the opposition or the expressed consent to the collection .][5]
(§3a Opposition to, or consent to, the drawing of documents by the National Registry to the request of (persons competent under this Article on the date of the expression of consent or opposition) ceases to have effect where the person referred to in paragraphs 2 and 3 has reached the age of majority. The person concerned is informed of this cancellation in accordance with the procedures defined by the King. The King invites you, if you wish, to make a choice. <L. 2007-02-25/57, art. 6, 2°, 007; In force: 23-04-2007>
The cancellation indicated in paragraph 1, is not applied to the person indicated in paragraph 4.) <L. 2006-06-14/41, art. 2, 005; In force: indefinite>
(§3 [[6]…][6]
§4 The doctor cannot proceed with the collection:
1° where an objection has been expressed in accordance with the rules laid down by the King;
2° when an objection has been expressed by the donor in another way and provided that it has been communicated to the doctor;
3° (…) <L. 2007-02-25/57, art. 6, 4°, 007; In force: 23-04-2007>
(Paragraph 2 repealed) <L. 2007-02-25, art. 6, 5°, 007; In force: 23-04-2007>

---

(1) <L. 2012-07-03/08, art. 21, 009; In force: 03-09-2012>

(2) <L. 2012-07-03/08, art. 21, 009; In force: indefinite>
(3) <L. 2013-03-17/14, art.208, 011; In force: 01-09-2014 (W 2014-05-12/02, art. 22)>
(4) <L. 2015-07-17/38, art. 100, 012; In force: 27-08-2015>
(5) <L. 2018-03-21/32, art. 2, 013; In force: 22-10-2018>
(6) <L. 2018-03-21/32, art. 3, 013; In force: 22-10-2018>

Art. 10 FUTURE OBLIGATIONS
§1 (Organs, (...)) intended for transplantation, as well as the preparation, according to the conditions defined in art. 2, of therapeutic substances may be taken from the body of (any person registered in the population register or in the register of foreigners for more than six months) unless it is established that opposition to the collection has been expressed. <L. 1987-02-17/31, art. unique, 002; In force: 24-04-1987> <L. 2003-12-22/42, art. 165, 004; In force: 10-01-2004> <L. 2008-12-19/44, art. 27, 008; In force: 01-12-2009 (see L.2009-09-28/06, art. 14)>
[1 The doctor who intends to make the collection should inquire about the existence of opposition from the potential donor.] 1
For persons who are not registered [1under paragraph 1] 1, it is mandatory that they have clearly expressed their consent to the collection.
§2 A person who is eighteen years old and capable of expressing his will may alone express the opposition provided for in paragraph 1.
If a person is under the age of eighteen but is capable of expressing his will, the opposition may be expressed either by that person or as long as that person is alive (by parents exercising their authority over the minor or by his guardian). <L. 2007-02-25/57, art. 6, 1°, 007; In force: 23-04-2007>
If a person is under the age of eighteen but is unable to express his will, the opposition may be expressed as long as he is alive (by one of the parents exercising their authority over the minor or by his guardian). <L. 2007-02-25/57, art. 6, 1°, 007; In force: 23-04-2007>
If a person is not able to express his will because of his mental state, the opposition may be expressed as long as he is alive by his legal representative, through his administrator [3...]3 or, failing that, by his immediate family members.
[1 §2a Every person capable of expressing his will can alone clearly express his will to be a giver after death.]1
§3 [5 The King defines a mode of expression of the opposition to the collection of the potential donor or persons indicated in §2, or of the express consent to the collection indicated in §2a.
To this end, he is entitled, on the basis of the conditions and according to the rules laid down by him:
1° shall, at the request of the person concerned, have the opposition or the consent expressed through the municipality by an authorised medical practitioner or electronic self-registration;
2° regulates the access to this donation in order to inform the doctors who take the samples, respectively, of the opposition or the expressed consent to the collection.] 5
(§3a Opposition to the collection registered in accordance with the procedure laid down by the King at the request of the competent persons, under this Article on the date of the expression of the opposition, ceases to have effect where the person referred to in paragraphs 2 and 3 has reached the age of majority. The person concerned is informed of this cancellation in accordance with the procedures defined by the King. The cancellation referred to in subparagraph 1a shall not apply in respect of the person referred to in § 2, subparagraph 4 Persons who are of legal age at the time this paragraph comes into force are also subject to the cancellation referred to in paragraph 1. <L. 2007-02-25/57, art. 6, 2°, 007; In force: 23-04-2007>
<L. 2006-06-14/41, art. 2, 005; In force: indefinite>
(§3 [6…]6 <L. 2007-02-25/57, art. 6, 3°, 007; In force: 23-04-2007>
§4 The doctor can not proceed with the collection:
1° where an objection has been expressed in accordance with the rules laid down by the King;
2° when an objection has been expressed by the donor in another way and provided that it has been communicated to the doctor;
3° (…) <L. 2007-02-25/57, art. 6, 4°, 007; In force: 23-04-2007>
(Paragraph 2 repealed) <L. 2007-02-25, art. 6, 5°, 007; In force: 23-04-2007>

---
(1) <L. 2012-07-03/08, art. 21, 009; In force: 03-09-2012>
(2) <L. 2012-07-03/08, art. 21, 009; In force: indefinite>
(3) <L. 2013-03-17/14, art.208, 011; In force: 01-09-2014 (W 2014-05-12/02, art. 22)>
(4) <L. 2015-07-17/38, art. 100, 012; In force: 27-08-2015>
(5) <L. 2018-03-21/32, art. 2, 013; In force: 22-10-2018>
(6) <L. 2018-03-21/32, art. 3, 013; In force: 22-10-2018>

Art. 11 The death of the donor must be ascertained by three doctors, except those who take care of the recipient or who will perform the collection or transplantation.
These doctors rely on the state of the art scientific knowledge to determine death.
These doctors mention in a record dated and signed, the time of death and the method of its finding. Such records and, where appropriate, any documents annexed thereto shall be kept for ten years.

Art. 12 The removal (of organs, (...)) and the suture of the body must be carried out respecting the body and managing the best feelings of the family.
<L. 2003-12-22/42, art. 166, 004; In force: 10-01-2004> <L. 2008-12-19/44, art. 27, 008; In force: 01-12-2009 (see L. 2009-09-28/06, art. 14)>
The funeral chamber will take place as quickly as possible in order to allow the family to make funeral services to the deceased as quickly as possible.

Art. 13 §1 In the event of a violent death, the doctor who carries out the removal (of organs, tissues or cells) must draft a report which he sends without delay to the King's Procurator. <L. 2003-12-22/42, art. 167, 004; In force: 10-01-2004>
This report should include data on the condition of the deceased person's body and body parts taken and which may be important for determining the cause and circumstances of death. In this report the data which can no longer be examined due to the process of transplantation must be clearly expressed.
§2 In the event of a death the cause of which is unknown or suspected, the removal (of organs, tissues or cells) may not be carried out, except unless the King's Procurator, in the district where the collection facility is located, was informed and did not raise any objection.<L. 2003-12-22/42, art. 168, 004; In force 10-01-2004>
If necessary, the magistrate shall instruct a doctor of his choice to go immediately to the establishment to attend and report the collection.

CHAPTER III/1 [[1]Provisions concerning the allocation of organs][1]

---
(1) <Inserted through L. 2012-07-03, art. 22, 009; In force: 03-09-2012>

Art. 13a [[1] §1 The King defines the European organ exchange organisation responsible for activities relating to organ exchanges within Belgium and abroad, as well as for subsequent functions under the quality and safety framework defined in this Act:
1° shall maintain a system of traceability and identification of donors and recipients;
2° shall maintain and operate a system of notification and management of major accidents and undesirable reactions;
3° shall maintain and operate a register and a tracking system for living donors;
[[2] 4° the maintenance and management of the information collected for the characterisation of the organs collected and of the donors.][2]
The organization defined by the King pursuant to paragraph 1, is responsible for the processing within the meaning of Article 1, §4, of the law of 8 December 1992 concerning the protection of privacy with regard to personal data, for the personal data mentioned in paragraph 1, 1° to 3°.
§2 Within the framework of its function as an organ exchange, the European organ exchange organisation defined by the King shall ensure:
1° ensure high compatibility between the organs removed and the applicant recipients;

2° ensures an appropriate balance between the number of organs exported from Belgium and the number of organs imported;
3° take charge of the health emergency, the actual waiting times of the receiving candidates and the distance between the centre where the organ is taken and the centre where it is transplanted.
§3 [2 The King may clarify the functions attributed to the European Organ Exchange Organisation, particularly in regards to the definition of the information procedure for the exchange of data such as those referred to in §1, paragraph 1, 1°, 2°, 4° with the competent authorities or delegated bodies of the Member States of the European Union, with procurement bodies or transplantation centres, as well as for the registration and making available of the above information. The exchange, registration and making available of the above information are intended to achieve a high level of public health during the stage of organ exchange within the European Union. The information referred to in paragraph 1 refers to donations that are collected in application of this law and its executive acts, regarding characterization, traceability, accidents and serious undesirable reactions.]2
§4 The designated European Organ Exchange Organisation undertakes to comply with the provisions of this Law, the Law on Hospitals and Other Health Facilities, coordinated on 10 July 2008, the Law of 8 December 1992 on the protection of privacy with regard to personal donation treatments, and the Law of 4 July 1962 on official statistics, as well as for the acts implementing them.]1
---
(1) <L. 2012-07-03/08, art. 23, 009; In force: 03-09-2012>
(2) <L. 2014-02-07/13, art. 29, 010; In force: 07-03-2014>

Art. 13a/1 [1 the exchange of organs with third countries with respect to the European Union is not authorised unless the organs are traceable by a donor to the recipient and vice versa, and whether the organs meet standards of quality and safety equivalent to those laid down in Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.]1
---
(1) <Inserted through L. 2012-07-03/08, art. 24, 009; In force: 03-09-2012>

Art. 13/b <inserted through L. 2007-02-25/57, art. 8; In force: 23-04-2007> To be registered [1...]1 as a candidate recipient within a Belgian transplant centre, each person must either have Belgian citizenship or [2 be registered with the population or with foreigners for a period of at least six months]2 or have the nationality of a State which shares the same body for the allocation of organs or has been resident there for at least six months.
---
(1) <L. 2012-07-03/08, art. 25, 009; In force: 03-09-2012>
(2) <L. 2015-07-17/38, art. 101, 012; In force: 27-08-2015>

Art. 13c <Inserted through L. 2007-02-25/57, art. 9; In force: 23-04-2007> The King may define the conditions of exception to the application of Article 13b.

Art. 14
<Repealed by L. 2012-07-03/08, art. 26, 009; In force: 03-09-2012>

CHAPTER IV _ Final and penal dispositions

Art. 15 The King defines the rules for the expression of consent provided for in Articles 5 to 9.

Art. 16 (Federal Public Health Service officials, Safety of the Food and Environment Supply Chain or the Federal Agency of Medicines and Health Products and Personnel who are associated by contract of indefinite employment to this Federal Public Service or to this Federal Agency, which are) Instructed by the King to monitor the application of this Law and of acts adopted in implementation thereof. <L. 2006-12-27/32, art. 238, 006; In force: 07-01-2007>

They have access to hospitals at all times.
Without prejudice to the powers conferred on judicial police officers, they shall trace infringements and establish them by means of legally binding reports unless it is proved otherwise.
A copy of the report shall be sent to the offender within 48 hours of the discovery of the offence.
They may arrange for all the information and documents necessary for the performance of their duties to be supplied and may make all necessary observations.
In case of violent death or in case of death whose causes are unknown or suspect, the (doctors who are officials or staff members as indicated in paragraph 1) can take samples and proceed to the analysis under the conditions and following the modalities defined by the King. <L. 2006-12-27/32, art. 238, 006; In force: 07-01-2007>
(The King may lay down the specific rules concerning the training and qualifications of officials and members of staff provided for in paragraph 1.) <L. 2006-12-27/32, art. 238, 006; In force: 07-01-2007>

Art. 17 §1 Infringements [1 to Articles 3 to 3e]1 shall be punishable by imprisonment of between three and six months and a fine [3 of 500 euros to 5000 euros]3, or one of these penalties.
§2 Infringements of [2 Article 4a]2 and of the acts implementing[2 Article 1e, §1]2 shall be punishable by imprisonment from [3 six months to two years and a fine of 250 euros to 1000 euros]3, or one of these penalties.
§3 Infringements of [2 Articles 4, 5 to 11, 13, 13b and 13c]2, as well as of acts carried out by the latter, shall be punishable by imprisonment [3 from one to five years and a fine of 1000 euros to 10000 euros]3, or by only one of these penalties.
He who knowingly prevents the opposition to collection from being known shall be punished with the same punishments provided for in Article 10, whatever the form in which such opposition is expressed.
---
(1) <L. 2012-07-03/08, art. 27, 009; In force: 03-09-2012>
(2) <L. 2014-02-07/13, art. 30, 010; In force: 07-03-2014>
(3) <L. 2019-05-22/19, art. 16, 014; In force: 01-07-2019>

Art. 18 The sentences may be doubled in the event of recidivism during the five years following the final judgment on the conviction of the infringement procedure of this law or of the acts put into effect.

Art. 18/1 [1 In the event of a conviction, the court may also prohibit the pursuit of a professional or social activity linked to the commission of infringements provided for in Article 17, §3, for a period of between one year and five years.]1
---
(1) <Inserted through L. 2019-05-22, art. 17, 014; In force: 01-07-2019>

Art. 19 Chapter VII of Book 1 and Article 85 of the Penal Code are applicable to infringements of this law and to acts put into effect thereof.

ANNEX [[1] Annex to the Law of 13 June 1986 on the collection and transplantation of organs

Characterisation of donor and organs
Minimum set of data to be collected as part of the characterization of donors and organs, in accordance with Article 3b, §1, of this Act.
1° Structure within which the collection takes place and other donations of a general nature
2° Type of donor
3° Blood type + HLA type
4° Sex
5° Cause of death
6° Date of death
7° Date of birth
8° Weight
9° Height
10° Intravenous drug use (previous or current condition)
11° Malignant neoplasia (previous or current condition)
12° Other communicable diseases (previous or current condition)
13° HIV, HCV, HBV, CMV tests
14° Basic information to evaluate the functioning of the donated organ
15° General donations
Contact details of the care facility where the collection takes place, necessary for the coordination, organ allocation and their traceability from the donor to the recipient and vice versa.
16° Data related to the donor
Demographic and anthropometric data required to ensure satisfactory pairing between donor, organ and recipient.
17° Previous medical treatment of the donor
Previous medical treatment of the donor, in particular the conditions that could affect the extent to which organs are susceptible to transplantation and may involve the risk of transmitting a disease.
18° Physical and clinical data
Data resulting from a clinical examination that are necessary for the assessment of the physiological maintenance of the potential donor as well as any findings that reveal conditions that have not been detected during the examination of previous medical treatments of the donor and that may affect the extent to which organs are susceptible to transplantation and involve the risk of transmission of a disease.
19° Laboratory parameters
Data necessary for the evaluation of the functional characterization of organs and for the detection of potentially transmissible diseases and possible contraindications to organ donation.
20° Medical diagnostics
Exploration through medical diagnostics to assess the morphological status of organs intended for transplantation.
21° Therapy
Treatments administered to the donor which should be taken into account when assessing the functional status of organs and their suitability for organ donation, in particular the use of antibiotics, isotropic support or transfusions.
22° Hot or cold ischemia.][1]

---

(1) <Inserted through L. 2012-07-03/08, art. 28, 009; In force: 03-09-2012>