Organ Donation Act

Law of 24 May 1996, the latest amendments entered into force on 01/07/2020

Chapter 1. General provisions

Article 1

The following definitions shall be used in this Act and its provisions:

- a. Minister: Minister of Health, Welfare and Sports;
- b. Organ: part of the human body, including tissues and cells, except for blood and germ cells;
- c. Donor: a person or corpse, from whom or on behalf of whom consent to organ donation has been granted based on this Act, or no objection has been raised to it;
- d. Removal: the removal of an organ, other than for the benefit of the donors themselves;
- e. Implantation: the insertion or application of an organ of a donor into the body of another as a medical treatment;
- f. Hospital: an institution or a department thereof admitted as a hospital or nursing facility under Section 5 of the *Care Institutions Act*;
- g. Transplant center: an institution as referred to in Article 24.

Article 2

It is not permitted to receive compensation for the removal of an organ, if the compensation is higher than the costs, including lost wages resulting directly from the removal of the organ.

Article 2a

For the data processing necessary to carry out what stated in this Act, the citizen service number referred to in Article 1, part b, of the *Citizen Service Number (General Provisions) Act* may be used.

Chapter 2. Provision of organs during life

- 1. An adult who is capable of reasonably evaluating his interests in this matter may consent to the removal of an organ designated by them from their body while alive, for implantation into a specific person.
- 2. The person who will remove the organ shall ensure that the donor is clearly informed, orally and in written form and, if desires, by audio-visual means, of the nature and purpose of the removal and the possible consequences and risks for their health and other living conditions. It shall also

be ensured that the donor has freely given consent, is aware of the consequences and of the provisions of this Act regarding the reimbursement of costs.

3. If it is reasonably plausible that the removal of the organ will have lasting effects on the health of the donor during their life, this shall be done only if the person receiving the organ is in danger of dying and cannot be saved in any other way.

Article 4

- Removal during the life of an organ of an adult who is incapable of a reasonable assessment of their interests in this matter will only take place if it is a regenerating organ and if the removal will not have any lasting consequences for the health of the donor. The removal will take place only if the recipient is a blood relative up to and including the second degree, only if is in danger of life which cannot be otherwise avoided, and if the donor also has a compelling interest in averting the danger to the life of the said relative.
- 2. The removal, as referred to in the first paragraph, only occurs with the permission of the legal representative or, in their absence, of the spouse, registered partner, or other companion or, in their absence, with the permission of a parent or adult child of the donor, as well as by the court.
- 3. The donor shall ensure that the legal representative or spouse, registered partner or other life or parent or child and, if possible, the donor is informed clearly, orally, in written form and, if required, by using audio-visual means, of the nature and purpose of the removal and the possible consequences for the donor. It shall also be ensured that the first and second paragraphs have been complied with.

- 1. Removal during the lifetime of an organ from a minor aged twelve years or older only takes place if it concerns a regenerating organ and the removal will not have any lasting consequences to the health of the donor and only for implantation with a blood relative up to and including the second degree that is in danger of life and whose life cannot be saved in any other way. Removal will only take place after the minor has given consent and obtained the consent of the parents exercising parental authority or the guardian and the juvenile court judge.
- 2. Removal during the lifetime of an organ of a minor who has not yet reached the age of twelve or of a minor who is twelve years old or older and who is incapable of a reasonable evaluation of their interests in this matter can only take place if it is a regenerating organ and if it will not have any lasting consequences for the health of the donor. It may only take place for implantation with a blood relative up to and including the second degree who is in danger of life and whose life danger cannot be otherwise saved, and if the donor also has a compelling interest in averting the danger to the life of that relative. Removal will occur only after obtaining the consent of the parents exercising parental authority or the guardian and the juvenile court judge has been obtained.
- 3. The donor shall ensure that the parents or guardian and, if possible, the donor are clearly informed, orally, in written form and, if desired, by audio-visual means, of the nature and purpose of the removal and the possible consequences for the donor. It shall also be ensured that the first and second paragraphs have been complied with.

- 1. The information referred to in Articles 3, second paragraph, 4, third paragraph, and 5, third paragraph, shall, in any case, include the information referred to in the Annex to Directive 2004/23 / EC of the European Parliament and of the Council of March 31, 2004, setting quality and safety standards for the donation, procurement, testing, processing, storage and distribution of human tissues and cells (PbEU L 102).
- 2. An amendment to the Directive referred to in the first paragraph shall enter into force for the purposes of this Article from the day on which the relevant amending Directive is to be implemented.

The consent referred to in this chapter is granted in advance through a statement that is dated and signed in person. Consent can be revoked at any time before the removal of the organ.

Article 7

Only the costs referred to in Article 2 may be reimbursed to the donor and those who give consent to remove an organ under the provisions of this chapter.

Article 8

Removal of an organ during life is permitted only if consent has been granted under Articles 3, 4, or 5.

Chapter 3. Organ donation after death

§ 1. Consent and objection

- 1. Adults and minors of twelve years of age or older who are capable of reasonably assessing their interests in this matter may consent or object to the removal of their organs or certain organs designated by them after their death. The legal representative of an adult who is unable to reasonably assess their interests concerning organ donation may, on their behalf, consent or object to the removal of their organs or certain organs after their death.
- 2. Consent and objection are expressed through the completion and registration of the form referred to in Article 10. If a person referred to in the first paragraph wishes to leave the decision on the removal of their organs to the closest relative referred to in Article 11, or to another chosen person, he/she can indicate this on the form.
- 3. A previous decision regarding organ donation can be revoked at any time by completing and registering a new donor form.
- 4. Consent or objection to organ donation can be expressed in the will through a written statement that is dated and signed.

5. Revocation of the will, in general terms, does not imply revocation of the statement in the fourth paragraph.

Article 10

- 1. The Minister shall ensure that every resident of the Netherlands (as defined in the *Personal Records Database Act*) receives a donor form upon reaching the age of eighteen. Donor forms will also be made available free of charge by the Minister and by the Municipal Executives upon request.
- 2. To indicate a person's will, there is a donor registry in which consent/objection to organ donation after death is recorded. A record is also kept when the person intends to leave the decision to the next of kin referred to in Article 11 or to a person to be determined by them or that the person concerned has no objection to the removal of his organs after his death. It may also be noted that a disposition of will has been made known by another person on behalf of the subject. The registry is kept by or on behalf of the Minister.
- 3. The registry may be consulted day and night by or on the order of a doctor if this is necessary with a view to the intended removal of an organ.
- 4. When sending the donor form, it is explicitly stated that an adult person by or on behalf of whom no advance directive or will as referred to in Article 9 has been made and provided, six weeks after sending a reminder as referred to in Article 10 a, first paragraph, is registered in the donor registry as a person who has no objection to the removal of his organs after his death. Additional rules will be established by ordinance in council regarding the form, content, and submission of the donor form and the maintenance and accessibility of the donor registry. It may be determined that a donor form shall be sent to persons who have been newly registered as residents after reaching nineteen years of age or who are newly registered as residents in the Personal Records Database.
- 5. Appointment for an order in council under subsection (4) shall not be made until the draft has been submitted to both Houses of Parliament and four weeks have elapsed since that submission.

Article 10 a

- 1. If six weeks after sending the donor form referred to in Article 10, first paragraph, the provisions of Article 9, first and second paragraphs, have not been completed, the Minister shall send a reminder to the person concerned, accompanied by a new donor form and a notification under the provisions of the second paragraph.
- 2. If by or on behalf of the person concerned, no consent/objection has been expressed, following the provisions of Article 9, first and the second paragraph, six weeks after sending the reminder referred to in the first paragraph, the person will be registered in the donor registry as having no objection to the removal of their organs after death.
- 3. The person concerned will receive, within six weeks of the registration referred to in the second paragraph, a confirmation that he/she is registered as having no objection to the removal of their organs after death, accompanied by notification under the provisions of the fifth paragraph.
- 4. If it is clear or plausible that a person referred to in the second paragraph is not capable of a reasonable assessment of their interests, the registered consent is replaced by a record that

the decision is left to his or her legal representative. The person will be informed within six weeks.

5. The person concerned or their legal representative may have teile registration as referred to in the second or fourth paragraph changed at any time by completing and registering a new donor form.

Article 10 b

- 1. The mayor shall ensure that in processing an application for a national passport referred to in section 2, paragraph 1, letter a, of the *Passport Act*, an application for a Dutch identity card referred to in section 2, paragraph 2, of the *Passport Act* or an application for a driver's license referred to in section 107 of the 1994 *Road Traffic Act*, each adult registered as a resident in the *Personal Records Database* is provided with information in written form regarding the donor registry and how their information can be accessed and modified in that registry.
- 2. The written information shall be made available free of charge to the mayor by the Minister.

- If a person has left the decision on organ donation to their next of kin, permission for the removal of organs after the determination of death may be expressed by their spouse, registered partner, or other life companion or, in the absence or inaccessibility of these, by the immediately reachable adult relatives up to and including the second degree or, in the absence or inaccessibility of these, by the immediately reachable adult relatives up to and including the second degree, by their spouses.
- 2. If an adult who is clearly or plausibly incapable of a reasonable evaluation of their interests concerning organ donation, is registered in the donor registry as a person who has given consent to or has no objection to the donation of their organs, after the determination of death, or it after his or her death, this may be confirmed or canceled by their legal representative. In the absence or inaccessibility of this person, the decision can be taken by the next of kin referred to in the first paragraph. In the absence or inaccessibility of all these next of kin, consent or no objection is deemed to be lacking.
- 3. If an adult has left the decision on the removal of their organs to a specific person, consent for the removal of their organs may be granted by that person after the determination of death. In the absence or inaccessibility of that person, consent may be granted by the next of kin referred to in the first paragraph.
- 4. If an adult is not registered in the donor registry, consent for the removal of their organs may be granted by the spouse, registered partner, or another life companion after the determination of death, or, in the absence or inaccessibility of these people, by the immediate reachable adult relatives up to and including the second degree, or, in the absence or inaccessibility of these people, by the immediate reachable adult relatives up to and including the second degree, or, in the absence or inaccessibility of these people, by the immediate reachable adult relatives up to and including the second degree.
- 5. If a minor aged twelve or older has left the decision on the removal of their organs to a specific person, consent to the donation of their organ may be granted by the person named in the will upon determination of death. In the absence or inaccessibility of that person, consent may be given by the parents exercising parental authority, or by the guardian.

- 6. In the absence of a living will as referred to in Article 9, paragraph 4, of a person under twelve years of age or older, consent for organ removal may be granted by the parents exercising parental authority after the determination of death, or by the guardian.
- 7. In the case of a minor under the age of twelve, consent for the removal of their organs may be granted by the parents, exercising parental authority, or by the guardian after the determination of death.
- 8. In the event of a disagreement between blood relatives, relatives, or parents, respectively, as referred to in the first to seventh paragraphs, consent cannot be granted.
- 9. If a person has given consent for the removal of organs after death, but they have expressed neither consent nor objection to the removal of a specific organ, permission for the removal of that organ will be granted with the corresponding application of the first, seventh and eighth paragraphs.
- 10. Only in the event that death is expected to be determined based on cardiological criteria, the consent referred to in the previous paragraphs may already be granted after the information referred to in Article 20, paragraph 6, has been provided.

If a person dies before reaching the age of sixteen and has given consent under Article 9 for the removal of their organs, no removal shall take place if a parent exercising parental authority or the guardian objects. In the absence or inaccessibility of both parents or the guardian, the removal may take place.

Article 13

Unless the person who grants consent (or has no objection) explicitly provides otherwise, consent, as referred to in this section (or lack of objection), is granted for the purpose of implantation, including scientific research aimed at implantation, if the organ after removal is found to be unsuitable for implantation. A governmental decree may determine that granting permission (or having no objection) is not permitted for specific purposes other than medical treatment.

§ 2. Determination of death

- 1. Before an organ is removed, death shall be determined by a physician who must not be involved in the removal or implantation of the organ. If there is an intention to remove an organ from a corpse, death shall be determined based on the most recent methods and criteria for determining brain death or death based on the cardiological criteria. How brain death has been established shall be recorded in a statement, the model of which shall be included in the Protocol referred to in Article 15, paragraph 1.
- 2. Brain death shall be understood as the complete and irreparable loss of the functions of the brain, including the brainstem and the medulla oblongata. Brain death shall be diagnosed only in the event of a fatal brain injury of which the cause is known and which cannot be cured. This can only occur if there can likely be no other cause underlying the unconscious state.
- 3. Death based on cardiological criteria means an irreversible absence of circulation and breathing.

- 1. With due observance of Article 14, paragraphs 2 and 3, the Health Council shall determine what methods and criteria are applicable for determining brain death or death based on the cardiological criteria with certainty, based on the latest scientific knowledge. This said, the Health Council shall draw up protocols regarding the procedures to be followed in hospitals when determining brain death or death based on the cardiological criteria, and the investigations to be carried out in cases where there is an intention to remove an organ. The protocols shall be established by ordinance in Council.
- 2. A decree adopted under paragraph 1 shall not enter into force until eight weeks after it has been published in the *Official Gazette*. Both Houses of Parliament shall be notified immediately of the publication.

Article 16

When an organ is removed from a corpse, the autopsy as referred to in Article 3 of the *Funeral Services Act* (*Bulletin of Acts and Decrees* No. 133, 1991) shall not be carried out by a doctor involved in the removal or implantation of the organ.

Article 17

In the presence or suspicion of unnatural death, an organ may not be removed until the public prosecutor has given the permission referred to in Article 76, second paragraph, of the *Funeral Services Act*.

§ 3. Notification and allocation of available organs

Article 18

- 1. The officer designated in the Protocol referred to in Article 23 shall immediately report the possible availability of organs to a transplant center.
- 2. The transplant center designates who is eligible for implantation of an organ registered at the center. If immediate designation cannot be made and the organ center considers it necessary for medical reasons, it may determine that an organ eligible by its nature should remain available for implantation.
- 3. Factors other than donor and recipient blood and tissue compatibility, the medical urgency of the recipient, and other circumstances relating to the condition of the organ shall not be considered in the designation of the recipient. If these factors do not make it possible to make a decision, the waiting time of the recipient can be taken into account. Additional rules in this regard may be established by decree in Council.

Article 19

[No longer in force since July 1, 2004]

§ 4. Preparatory acts and organ removal

- 1. When there is a reasonable possibility that a person will die in the near future, and any event as soon as possible after the determination of death, the officer designated in the Protocol referred to in Article 23 shall verify that the person is registered in the donor registry unless it has already been established that the person concerned is not a medically eligible donor.
- 2. The designated officer shall provide proper and immediately accessible family members with information about the registration in the donor registry. In the case of an adult of whom it is clear or plausible that he/she is not able to reasonably assess their interests, the officer also provides information to their legal representative, if present and accessible.
- 3. If the registration does not correspond to any other statement as referred to in Article 9, paragraph 4, the most recent registration or statement will apply.
- 4. If the person concerned is registered in the donor registry as a person has given consent to or having no objection to the removal of his organs after their death and a statement to the contrary as referred to in Article 9, paragraph 4, is present, the latter statement shall prevail, notwithstanding the third paragraph.
- 5. If the person concerned is registered in the registry as a person has given consent to or having no objection to the removal of their organs after their death and there is no other statement, but their next of kin, as referred to in Article 11, first paragraph, shows that it is plausible that this registration does not correspond to the wishes of the person concerned, the decision of the next of kin shall apply.
- 6. If the person concerned is not registered or has made use of the option referred to in Article 9, paragraph 2, second sentence, the designated officer shall, as soon as it is reasonably established that the person concerned will die in the near future, provide adequate information on the possibility of organ donation to the person or persons who, under Article 11, are authorized to grant permission for organ removal. Once death has been ascertained, he/she shall seek their permission for organ removal, unless an objection has already been raised by the authorized person or persons named above. Only if it is anticipated that death will be determined based on the cardiological criteria, the officer may request consent immediately after the information has been provided.
- 7. The designated officer shall inform proper and immediately accessible family members of how the authorization for organ removal will be acted upon.
- 8. If the persons concerned have themselves authorized the removal of organs, the officer designated for this purpose in the Protocol referred to in Article 23 shall inform the proper and immediately accessible family members of how the authorization will be followed up.
- 9. This Article shall be implemented under the rules provided for in the Protocol referred to in Article 23. The officer designated for this purpose in the Protocol referred to in Article 23 shall report on the application by completing a paper or digital form established by the transplant center. Rules directed to the transplant center regarding the provision of information on the application of this Article may be established by ministerial regulation.
- 10. The appointees referred to in this Article shall have access to the patient's file to the extent necessary for carrying out the activities related to the application of this Article.
- 11. It may be determined by ordinance in Council that the rules established in this Article shall not apply to such categories of physicians as shall be designated by such ordinance. In

addition, it may be determined that the duties assigned to an officer under the first paragraph of this Article shall be performed by another person.

Article 21

Removal of an organ after death is permitted only if:

- a. Under Article 20, it has been established that consent has been given by the deceased or on their behalf, or that there is no objection to this, under this Act;
- b. The designated officer, as referred to in Article 23, has determined that the deceased was mentally competent at the time of the consent was given or when registering as referred to in Article 10a;
- c. Articles 14, 16, and 17 have been complied with;
- d. The organ made available for implantation has been registered with a transplant center under Article 18.

- 1. If a person is registered in the donor registry as a person has given consent to or having no objection to the removal of an organ after death, if it is reasonably established that the person concerned will die in the near future, preparations for implantation shall be made, to the extent that they are not inconsistent with that person's medical treatment and cannot be postponed until after the determination of death. Those preparations may include:
 - a. Examination necessary for the preparation of the implantation;
 - b. Initiating or maintaining artificial respiration;
 - c. Artificially maintaining blood circulation;
 - d. Other measures are necessary to keep organs suitable for implantation.
- 2. If a person is not registered in the donor registry or has exercised the option in Article 9, paragraph 2, second sentence, the preparations referred to in the first paragraph may be made even before death is determined, if:
 - a. It is reasonably certain that person will die in the near future;
 - b. The preparations do not clash with the medical treatment of the person concerned;
 - c. Preparations cannot be postponed until after the determination of death;
 - d. The information procedure, as referred to in Article 20, paragraph 6, has not raised any objection against those preparations by the person or persons who, according to Article 11, are authorized to give consent to the removal of organs.
- 3. If a person is not registered in the donor registry or recourse has been made to the option referred to in Article 9, paragraph 2, second sentence, after death has been determined, as long as the procedure for obtaining the permissions necessary for the removal of organs under this Act has not resulted in the refusal of authorization, the following measures may be taken:
 - Research necessary for the preparation of implantation;
 - Maintaining artificial respiration;
 - Artificially maintaining blood circulation;
 - Other measures are necessary to keep organs suitable for implantation.

§ 5. The protocol

Article 23

- 1. The Board of Directors for a hospital shall be responsible for establishing a Protocol concerning making organs available for implantation and shall ensure compliance therewith.
- 2. The Protocol shall designate officers responsible in the hospital for performing the duties outlined in Articles 18, paragraph 1, and 20, and shall establish rules regarding:
 - a. How it is verified whether a deceased person is eligible as a donor;
 - b. How:
 - i. The donor registry is accessed under Article 20, paragraph 1;
 - ii. The persons referred to in Article 20, paragraph 1, are informed;
 - iii. Information from next of kin, as referred to in Article 20, paragraph 5, is handled;
 - iv. The persons referred to in Article 20, paragraph 6, are asked for permission;
 - v. The persons referred to in Article 20, paragraph 7, are informed;
 - c. The procedure to be followed to inform a transplant center of the availability of an organ;
 - d. How post-transplant care is provided to the persons referred to in Article 20, paragraphs 6 and 7;
 - e. Information about the rules established in the Protocol is shared in the hospital.
- 3. By order in Council, addition rules may be established regarding the content of the Protocol referred to in paragraph 1, and it may be determined that this section does not apply, in whole or in part, to certain categories of hospitals.
- 4. If brain death can be determined in a hospital, the Protocol shall also contain the applicable methods and criteria and the procedures and examinations to be followed in this respect, as determined in Article 15, paragraph 1.
- 5. The proposition for a Decree under subsection 3 shall not be made earlier than four weeks after the draft has been submitted to both Houses of Parliament.

Chapter 4. Transplant Center

Article 24

- 1. The operations of procurement, typing, and transportation of organs, as well as the allocation of these organs to a suitable recipient, may be carried out only by a transplant center that has obtained a license from the Minister.
- 2. The granting of the license referred to in paragraph 1 shall be the responsibility of the subjects envisaged by the *Framework Law on Independent Administrative Bodies*, except for Article 22 of the same Law.

- 1. A license can only be granted to a legal person whose activities are not aimed at making a profit and that is not an institution as referred to in Article 1, first paragraph, letter k, of the *Safety and Quality of Body Materials Act*.
- 2. A license shall be denied if provisions of or under this Act are not complied with, or are not reasonably expected to be complied with, or if it is reasonably expected that there will be no effective supply of organ needs or no effective cooperation with other institutions or transplant centers referred to in Article 1, first paragraph, part 1, of the *Safety and Quality of Human Materials Act* is not insured.

- 1. A permit can be subject to restrictions. Permit conditions may include:
 - a. Staff competencies;
 - b. Board composition;
 - c. Registration of potential recipients of organs;
 - d. Disclosure of standards for registering potential recipients and for allocating organs to a recipient;
 - e. Protection of organ donors and recipients' privacy;
 - f. Equipment and accessibility of the organ center;
 - g. Reporting on the activities.
- 2. A restriction or regulation can be amended or withdrawn. Even after the permit has been granted, restrictions or conditions may be applied to it.

Article 27

A permit may be withdrawn if the provisions under this Act or to the *Human Body Material Safety and Quality Act* or the conditions attached to the permit are no longer complied with, or if a restriction under which the permit was granted has been violated.

Article 28

[No longer in force since July 1, 2004]

Article 29

[No longer in force since July 1, 2004]

Article 30

[No longer in force since July 1, 2004]

Article 31

[No longer in force since July 1, 2004]

Chapter 5. Final provisions

Article 31a

Officers of the Youth Health and Welfare Inspectorate shall be responsible for supervising compliance with the provisions of this Act under this Act.

Article 31b

The Minister is authorized to impose an order subject to administrative coercion to enforce the obligation under Section 5, Article 20, paragraph 1, of the *General Administrative Law Act*.

Article 32

- 1. Whoever deliberately violates the provisions of Articles 8 and 21 shall be punishable by imprisonment of up to one year or a fourth-class fine.
- 2. The same penalty is given to:
 - a. A person who intentionally causes or induces another person to grant consent to a third party for the removal of an organ during the lifetime, for which the compensation exceeds the costs referred to in Article 2, or who induces another person to act violating Article 7;
 - b. Persons who either openly offers compensation that exceeds the costs referred to in Article 2 for receiving an organ, or offers themselves as a donor for such compensation, or offers services consisting of conduct punishable under letter *a*;
 - **c.** Those who raise awareness of the need for organs or the availability of organs to offer or obtain financial or comparable benefits;
 - d. A person who deliberately causes or promotes the use of organs from a corpse or a person whose brain is completely or almost completely absent, for the purpose of transplantation into another person's body as a medical treatment.
- 3. Whoever violates the provisions of Articles 22 and 24 is punishable by imprisonment up to six months or a fine of category 5.
- 4. The violations referred to in paragraphs 1 to 3 shall constitute a crime.

Article 33

- 1. The Minister shall ensure that information about organ donation contained in Chapters 2 and 3 are public.
- 2. The information referred to in the first paragraph shall be shared under a governmental decree.
- 3. The proposal for setting general administrative rules under paragraph 2 shall not be made until four weeks after the draft has been submitted to both Houses of Parliament.

Article 34

[No longer in force since January 01, 2007]

- 1. This Act shall come into force on a date to be determined by Royal Decree, which may be different for different articles or parts of articles.
- 2. Within three years, and then after five years and seven years after the entry into force of this Act, the Minister shall send to the States General a report on the effectiveness and impact of this Law in practice.

This Law can be cited as Organ Donation Act.