**LAWS ON ORGAN AND TISSUE DONATION**

**LAW n° 2004-800 of 6 August 2004, on bioethics (1)**

TITLE I

**ETHICS AND BIOMEDICINE**

**Article 1**

Chapter II of Title I of Book IV of Part I of the Public Health Code reads as follows:

*« CHAPTER II*

*« **Ethics***

« *Art. L. 1412-1.* − The mission of the National Consultative Ethics Committee for Health and Life Sciences[1] is to give opinions on the ethical problems and social issues raised by the advances in knowledge in the fields of biology, medicine, and health.

« *Art. L. 1412-2*. − The Committee is an independent authority which comprises, in addition to its chairman appointed by the President of the Republic for a renewable term of two years, thirty-nine members appointed for a four-year term renewable once:

« 1° Five persons appointed by the President of the Republic, belonging to the main philosophical and spiritual schools;

« 2° Nineteen qualified persons chosen for their competence and interest in ethical issues, namely:

« – one member of the National Assembly and one senator appointed by the presidents of their respective assemblies;

« – one member of the Council of State appointed by the Vice-President of the Council of State;

« – one adviser to the Court of Cassation appointed by the first president of that court;

« – one person appointed by the Prime Minister;

« – one person appointed by the Keeper of the Seals, Minister of Justice;

« – two persons appointed by the Minister of Research;

« – one person appointed by the Minister for Industry;

« – one person appointed by the Minister of Social Affairs;

« – one person appointed by the Minister of Education;

« – one person appointed by the Minister for Labour;

« – four personalities appointed by the Minister for Health;

« – one person appointed by the Minister of Communication;

[1] *Comité consultatif national d'éthique pour les sciences de la vie et de la santé*.

« – one person appointed by the Minister for Family;

« – one person appointed by the Minister for Women's Rights;

« 3° Fifteen persons from the research sector, namely:

« – one member of the Academy of Sciences, appointed by its president;

« – one member of the National Academy of Medicine, appointed by its president;

« – one representative of the *Collège de France*, appointed by its director;

« – one representative of the *Institut Pasteur*, appointed by its director;

« – four researchers belonging to the corps of researchers with tenure at the French National Institute of Health and Medical Research[2] or the French National Centre for Scientific Research[3], and two engineers, technicians or administrative staff of said institute or centre, half of whom shall be appointed by the Director-General of the Institute and half by the Director-General of the Centre;

« – two research teachers or members of the teaching and hospital staff at the university hospital centres, registered on the electoral roll of the National Institute for Health and Medical Research, appointed by the Director-General of this Institute;

« – two research teachers or members of the teaching and hospital staff at the university hospital centres, appointed by the Conference of University Presidents;

« – one researcher belonging to the corps of researchers with tenure of the National Institute of Agricultural Research[4], appointed by the President-Director General of this Institute.

« *Art. L. 1412-3.* – The Committee shall draw up an annual activity report which shall be submitted to the President of the Republic and to Parliament and made public.

« It may issue recommendations on matters within its competence.

« *Art. L. 1412-4.* – The necessary funds for the accomplishment of the missions of the National Consultative Ethics Committee for Health and Life Sciences are included in the budget of the Prime Minister's general services.

« The provisions of the law of 10 August 1922 relating to the organisation of the control of incurred expenses are not applied to their management.

« The Committee shall submit its accounts for audit to the Court of Auditors.

« *Art. L. 1412-5.* – A decree in Council of State specifies the conditions for the appointment of the members of the Committee and defines its referral, organisation, and operation arrangements.

« *Art. L. 1412-6.* – Spaces for ethical reflection are created locally or at inter-regional level; they constitute, in cooperation with university hospital centres, places for training, record, meetings and interdisciplinary exchanges on ethical issues in the health field. They also act as regional or inter-regional observatories of

[2] *Institut national de la santé et de la recherche médicale* (INSERM).
[3] *Centre national de la recherche scientifique* (CNRS).
[4] *Institut national de la recherche agronomique* (INRA).

ethical practices. These spaces partake in the organisation of public debates to promote the information and consultation of citizens on bioethical issues.

« The rules for the constitution, composition and operation of the spaces for ethical reflection are defined by order of the Minister for Health after consulting the National Consultative Ethics Committee for Health and Life Sciences. »

*« TITLE V*

***« COMMON PROVISIONS FOR ORGANS, TISSUES AND CELLS***

*« SINGLE CHAPTER*

« *Art. L. 1251-1.* – Only those persons, regardless of their place of residence, who are registered on a national list may benefit from an organ, cornea or other tissue transplant, the list of which is determined by decree, following the opinion of the Agency of Biomedicine[5]. »

V. – In Article L. 1244-8 of the same code, the words « the Minister for Health » are replaced by the words « the Agency of Biomedicine ».

VI. – In Article L. 1125-2 of the same code, the words « French transplant institute » are replaced by the words « the Agency of Biomedicine ».

VII – Chapter III of Title I of Book I of Part Two of the same code is repealed.

VIII – The provisions of this article shall come into force on the date of publication of the decree appointing the Director General of the Agency of Biomedicine, except for the provisions of VII, which shall come into force on the date of publication of the decrees necessary for the application of the provisions of V of A of Article 12 and of Articles 23 and 24 of this law.

**Article 3**

Under conditions ensuring compliance with the provisions of law n° 78-17 of 6 January 1978 relating to data processing, files and freedoms, the existing files of volunteer haematopoietic stem cells or peripheral mononuclear cells donors for patients who cannot receive a corresponding transplant shall be transferred to the Agency of Biomedicine, after fair and prior compensation, under the terms set by decree in the Council of State within six months of the publication of the decree appointing the Director General of the Agency.

The rights and obligations relating to the constitution and management of the donor register held by the France Bone Marrow Transplant Association[6] are transferred to the Agency of Biomedicine under conditions set by decree in the Council of State. As the Agency is substituted from the date of transfer of the files to the association in its rights and obligations as an employer, the private law personnel recruited by the association prior to this date may opt for the continuation of their contract or for a public law contract governed by the provisions set by regulation.

[5] *Agence de la biomédecine.*
[6] *France greffe de moelle association.*

TITLE III

## DONATION AND USE OF THE PARTS AND PRODUCTS OF THE HUMAN BODY

### Article 7

Title I of Book II of Part I of the Public Health Code is amended as follows:

1° The last two paragraphs of Article L. 1211-1 are replaced by the following paragraph:

« Activities relating to these items and products, as referred to in this Book, including their import and export, shall be for medical or scientific purposes, or be conducted as part of legal proceedings in accordance with the provisions applicable to such proceedings. »;

2° Article L. 1211-2 is completed by two paragraphs worded as follows:

« The use of parts and products of the human body for a medical or scientific purpose other than that for which they were removed or collected is possible, unless the person from whom the procurement or collection was carried out, duly informed beforehand of this other purpose, expresses their opposition. When this person is a minor or an adult under guardianship, the objection shall be exercised by the holders of parental authority or by the guardian. The obligation to inform may be derogated whenever it is impossible to find the person concerned, or if one of the consultative committees for the protection of individuals mentioned in Article L. 1123-1, consulted by the person responsible for the research, does not deem this information necessary. However, these exemptions are not allowed when the elements initially removed consist in germline tissues or cells. In the latter case, any use for a purpose other than that of the initial procurement is prohibited in the event of the death of the person concerned.

« Autopsies are said to be medical when they are performed, apart from investigation or enquiry measures carried out in the course of legal proceedings, with the aim of obtaining a diagnosis on the causes of death. They must be performed in accordance with the requirements for seeking consent and with the other conditions laid down in Chapter II of Title III of this book. However, in exceptional cases, they may be carried out despite the opposition of the deceased person, in the event of an imperative need for public health and in the absence of other procedures enabling a diagnosis on the causes of death to be obtained. An order of the Minister of Health specifies the pathologies and situations justifying the performance of medical autopsies under these conditions. »;

3° Article L. 1211-3 is amended as follows:

*a)* The following words are added to the second paragraph: «, in collaboration with the Minister of National Education »;

*b)* The following paragraph is added to the text:

« Physicians shall ensure that their patients aged between sixteen and twenty-five years are informed of the terms of consenting to organ donation for transplantation purposes and, in absence of that, shall provide them individually with this information as soon as possible. »;

4° Article L. 1211-4 is amended as follows:

*a)* The second sentence is removed;

*b)* The following two paragraphs are added:

« The costs of the procurement or collection shall be borne in full by the health care institution responsible for carrying out the procurement or collection.

« To apply the provisions of Chapter II of Title IV of Book I of Part I of the present code, the procurement of organs, tissues or cells from a living person who donates them for the therapeutic benefit of a recipient is treated as an act of assistance. »;

5° Article L. 1211-6 reads as follows:

« *Art. L. 1211-6.* – Parts and products of the human body may not be used for therapeutic purposes if the risk to the potential recipient, measurable according to the state of scientific and medical knowledge, is greater than the expected benefit to the recipient.

« The procurement of parts and the collection of products of the human body for therapeutic purposes, as well as activities with the same purpose, mentioned in this book and relating to these parts and products, are subject to the health security rules in force, especially as regards tests for transmissible diseases. »;

6° Article L. 1211-7 reads as follows:

« *Art. L. 1211-7.* – Surveillance systems must be implemented for parts and products of the human body, for products, other than medicinal products, derived from them, for medical devices incorporating them, as well as auxiliary therapeutic products in contact with these elements and products. »;

7° In Article L. 1211-8, the word « title » is replaced by the word « book », and the words « Articles L. 1211-2 to L. 1211-6 » are replaced by the words « Articles L. 1211-1 to L. 1211-7 »;

8° Article L. 1211-9 reads as follows:

« *Art. L. 1211-9.* – The following shall be determined by decree in the Council of State:

« 1° The conditions under which doctors provide the information laid down in Article L. 1211-3;

« 2° The terms and conditions of the coverage laid down in Article L. 1211-4;

« 3° The health safety regulations laid down in Article L. 1211-6;

« 4° The conditions under which the surveillance laid down in Article L. 1211-7 is carried out, and in particular the information that users or third parties are required to transmit;

« 5° The list of human body products mentioned in Article L. 1211-8. »

**Article 8**

Chapter I of Title II of Book II of Part I of the Public Health Code is amended as follows:

1° Article L. 1221-4 is amended as follows:

*a)* The words: « under conditions defined by decree » are removed;

*b)* The following two paragraphs are added:

« Blood, its components and their derivatives may be distributed and used for research purposes, for the control of medical biology analyses or for the control of *in vitro* diagnostic medical devices, excluding any administration to humans, before the results of the biological analyses and screening tests laid down in the first paragraph have been obtained.

« The conditions for the application of this article shall be laid down by decree. »;

2° After the word « therapeutic », the end of the second paragraph of Article L. 1221-5 reads as follows: « the request or when an immunologically compatible major donor cannot be found. »;

3° Article L. 1221-8 is amended as follows:

*a)* 2° and 3° become 3° and 4°;

*b)* A new paragraph 2 is inserted as follows:

« 2° Plasma products; »

*c)* 4° and 5° become 5° and 6° and read as follows:

« 5° Cellular products for therapeutic purposes mentioned in Article L. 1243-1;

« 6° Auxiliary therapeutic products pursuant to Article L. 1261-1; »

*d)* Before the last paragraph, a new 7° is included as follows:

« 7° Excipients for pharmaceutical use and substances used in the manufacture of a medicinal product but not included in its composition. »;

*e)* The last paragraph reads as follows:

« Blood and its components, whether or not they have been collected in blood establishments, may also be used to carry out quality checks of medical biology analyses as well as for the production and control of *in vitro* diagnostic medical devices, or for the French Agency for the Safety of Health Products[7] to carry out expert assessments and technical controls on products prepared from blood or its components, in application of Article L. 5311-2. The principles mentioned in Articles L. 1221-3, L. 1221-4 and L. 1221-6 are also applicable in this case. »;

4° After Article L. 1221-8, an Article L. 1221-8-1 is included as follows:

« *Art. L. 1221-8-1.* – Blood and its components may be used in research, whether or not they have been collected by a blood establishment. In this case, the research is conducted using samples taken either for medical purposes, or in the context of biomedical research, or for the purpose of constituting a collection of human biological samples. In the latter case, the blood samples must entail only negligible risks. In any case, the principles mentioned in Articles L. 1221-3, L. 1221-4 and L. 1221-6 shall apply, notwithstanding the provisions of Title II of Book I of this part, whenever blood or its components are collected or used in the context of a biomedical research activity.

« When blood or its components are taken to directly constitute a collection of human biological samples, the provisions mentioned in Articles L. 1243-3 and L. 1243-4 shall apply, as well as the principles of

[7] *Agence française de sécurité sanitaire des produits de santé.*

compensation for harmful consequences and the obligation of insurance as defined, for biomedical research, in Article L. 1121-7.

« When blood samples referred to in the previous paragraph are taken, for the purpose of constituting a collection of human biological samples, from pregnant women, in labour or lactating, from minors or adults subject to a legal protection measure or unable to express their consent, from persons deprived of their liberty, from persons hospitalised without their consent, from persons admitted to a health or social establishment for purposes other than research, the Consultative Committee for the protection of persons referred to in Article L. 1243-3 shall also ensure that the collection is intended for research which could not be carried out on another category of the population with comparable effectiveness »;

5° Article L. 1221-12 is amended as follows:

*a)* After the words « a labile blood product or plasma product », the following words shall be inserted: «, for direct therapeutic use or for the preparation of health products, »;

*b)* The following paragraph is added to the text:

« The import or export of blood, its components or derived products for scientific purposes is subject to the authorisation of the Minister of Research in accordance with Article L. 1245-5. »0

**Article 9**

A. – The first paragraph of Article 16-3 of the Civil Code reads as follows:

« The integrity of the human body may only be violated in cases of medical necessity for the person or exceptionally in the therapeutic interest of others. »

B. – Title III of Book II of Part I of the Public Health Code is amended as follows:

I. – Before Chapter I, two articles L. 1231-1 A and L. 1231-1 B are included as follows:

« *Art. L. 1231-1 A.* – The procurement and transplantation of organs is a national priority.

« *Art. L. 1231-1 B.* – The regulations for the distribution and allocation of grafts must respect the principle of equity. »

II – Chapter I is amended as follows:

1° Article L. 1231-1 reads as follows:

« *Art. L. 1231-1.* – The procurement of organs from a living person who donates them may only be carried out in the direct therapeutic interest of a recipient. The donor must be the father or mother of the recipient.

« Notwithstanding the first paragraph, the following may be authorised to lend themselves to organ procurement in the direct therapeutic interest of a recipient: their spouse, brothers or sisters, sons or daughters, grandparents, uncles, aunts, first cousins, as well as the spouse of their father or mother. The donor may also be any person who can prove that they have lived together with the recipient for at least two years.

« The donor, previously informed by the Committee of experts mentioned in Article L. 1231-3 of the risks and the possible consequences of the procurement, must express their consent before the President of the *Tribunal de Grande Instance* or the magistrate designated by the President, who shall first ensure that the

consent is free and informed and that the donation complies with the conditions set out in the first and second paragraphs. In the event of a life-threatening emergency, consent shall be obtained by any means by the prosecutor. Consent may be revoked informally and at any time.

« The authorisation provided for in the second paragraph is issued, after the expression of consent, by the Committee of experts mentioned in Article L. 1231-3.

«The procurement of organs from the persons mentioned in the first paragraph may also, except in the case of a life-threatening emergency, be subject to the authorisation of this Committee when the magistrate responsible for obtaining consent considers it necessary.

« The Agency of Biomedicine shall be informed, prior to its implementation, of any organ procurement for therapeutic purposes from a living person.

« The Government shall submit to Parliament every four years a report on the application of this article, and in particular on the derogations authorised under its second paragraph. »;

2° Article L. 1231-3 reads as follows:

« *Art. L. 1231-3.* - The Committee of experts whose intervention is envisaged for in Articles L. 1231-1, L. 1241-3 and L. 1241-4 comes together in two panels of five members appointed for three years by order of the Minister for Health. Three of these members, including two doctors and a person qualified in the field of human and social sciences, belong to both panels. When the board gives its opinion on samples taken from persons of age as mentioned in Articles L. 1231-1 and L. 1241-4, it includes a psychologist and a doctor. When it decides on the procurement of a minor mentioned in Article L. 1241-3, it includes a person qualified in the field of child psychology and a paediatrician. In the event of a life-threatening emergency, the members of the Committee of experts are appointed by the Agency of Biomedicine from among the available members listed in the aforementioned order. The committee thus constituted delivers its authorisation by any means. In this case of emergency, the information laid down in the third paragraph of Article L. 1231-1 is delivered by the practitioner who has proposed the transplant or by any other practitioner of the donor's choice.

« The Committee shall decide in accordance with the general principles set out in Title I of this Book.

« To assess the medical substantiation for the operation, the risks that it is likely to entail for the donor and its foreseeable physical and psychological consequences, the Committee may have access to medical information concerning the donor and the recipient. Its members are obliged to keep secret the information of which they are aware by virtue of their functions.

« The Committee shall not provide reasons for its decisions. »;

3° Article L. 1231-4 reads as follows:

« *Art. L. 1231-4.* – The terms and conditions for the application of the provisions of this chapter shall be determined by decree in the Council of State, and in particular the number of committees mentioned in Article L. 1231-3, their territorial jurisdiction, their composition, the conditions for the appointment and remuneration of their members and their operating procedures, including in the event of a life-threatening emergency. »;

4° Article L. 1231-5 is repealed.

III – Chapter II is amended as follows:

1° Articles L. 1232-1 to L. 1232-3 read as follows:

« *Art. L. 1232-1.* – The procurement of organs from a person whose death has been duly confirmed may only be carried out for therapeutic or scientific purposes.

« This procurement may be carried out if the person has not made known, during their lifetime, their refusal of such procurement. This refusal may be expressed by any means, particularly by registering with an automated national register provided for this purpose. It may be revoked at any time.

« If the doctor is not directly aware of the wishes of the deceased, they must endeavour to ascertain from the relatives any opposition to organ donation that may have been expressed by the deceased during their lifetime, by any means. The doctor shall inform the relatives of the purpose of the planned procurements.

« Next of kins are informed of their right to know what samples have been taken.

« The Agency of Biomedicine shall be notified, prior to its performance, of any procurement for therapeutic or scientific purposes.

« *Art. L. 1232-2.* – If the deceased person was a minor or an adult under guardianship, the procurement for one or more of the purposes mentioned in Article L. 1232-1 may only take place if each of the holders of parental authority or the guardian consents in writing.

« However, if it is not possible to consult one of the holders of parental authority, the sample may be taken provided that the other holder consents in writing.

« *Art. L. 1232-3.* – Samples for scientific purposes may only be taken within the framework of protocols transmitted to the Agency of Biomedicine prior to their implementation. The Minister for Research may suspend or prohibit the implementation of such protocols, when the need for the procurement or the relevance of the research is not ascertained. »;

2° Article L. 1232-4 is amended as follows:

*a)* In the first paragraph, the word « transplant » is replaced by the word « graft »;

*b)* The second paragraph is removed;

3° Article L. 1232-5 reads as follows:

« *Art. L. 1232-5.* – Doctors who have performed a procurement or a medical autopsy on a deceased person are required to ensure the best restoration possible of the body. »;

4° Article L. 1232-6 is amended as follows:

*a)* 1° shall read as follows

« 1° The conditions under which the death report provided for in the first paragraph of Article L. 1232-1 is drawn up; »

*b)* A new 3° is added to the text as follows

« 3° The procedures for banning or suspending the protocols mentioned in Article L. 1232-3 by the Minister for Research as well as the procedures for the transmission, by the Agency of Biomedicine, of the information it has on these protocols. »

IV – Chapter III is amended as follows:

1° The first paragraph of Article L. 1233-1 reads as follows:

« The procurement of organs for donation for therapeutic purposes may only be carried out in health establishments authorised for this purpose by the administrative authority after receiving the opinion of the Agency of Biomedicine. »;

2° In Article L. 1233-2, after the words « organ procurement », the words « for donation » are included;

3° Article L. 1233-3 becomes Article L. 1233-4; in this article, after the words: « organ procurement », the words « for transplantation » are included;

4° Article L. 1233-3 is restored as follows:

« *Art. L. 1233-3*. – In the health establishments holding the authorisation mentioned in Article L. 1233-1, a memorial place shall be created for the expression of gratitude to donors of parts of their body for transplantation. »

V. – Chapter IV is amended as follows:

1° Its title reads as follows: « Organ transplants »;

2° In Article L. 1234-1, the words: « Article L. 1243-1 » are replaced twice by the words « Article L. 1243-2» and the words « Article L. 1243-5 » are replaced by the words « Article L. 1243-7 »;

3° In Articles L. 1234-2 and L. 1234-3, the word « explant » is replaced by the word « transplantation »;

4° The following words are added to the first paragraph of Article L. 1234-2: «, after consulting the Agency of Biomedicine »;

5° After Article L. 1234-3, an Article L. 1234-3-1 is included as follows:

« *Art. L. 1234-3-1.* – The health organisation plan laid down in Articles L. 6121-1 and L. 6121-4 shall be adopted by the competent authority after obtaining the opinion of the Agency of Biomedicine in the case of organ transplants. »

VI. – Chapter V is amended as follows:

1° Article L. 1235-1 reads as follows:

« *Art. L. 1235-1.* – Only health establishments authorised to remove organs pursuant to Article L. 1233-1 may export them for therapeutic purposes.

« Only health establishments authorised to transplant organs pursuant to the provisions of Article L. 1234-2 may import them for therapeutic purposes.

« Only organisations authorised by the Minister for Research, after receiving the opinion of the Agency of Biomedicine, may import or export organs for scientific purposes. »;

2° Article L. 1235-2 reads as follows:

« *Art. L. 1235-2.* – Organs removed during a surgical operation, performed in the interest of the person operated on, may be used for therapeutic or scientific purposes, unless the person concerned expresses their opposition after having been informed of the purpose of such use.

« If this person is a minor or an adult under guardianship, the subsequent use of the organs thus removed is also subject to the absence of opposition from the holders of parental authority or the guardian, duly

informed of the purpose of this use. The refusal of the minor or the adult under guardianship is an obstacle to this use.

« The organs thus removed are subject to the provisions of Title I, with the exception of the first paragraph of Article L. 1211-2, and to those of Chapters III and IV of this title. »;

3° Articles L. 1235-3 and L. 1235-4 become Articles L. 1235-6 and L. 1235-7 respectively;

4° Articles L. 1235-3 and L. 1235-4 are re-established as follows:

« *Art. L. 1235-3.* – Any procurement of organs carried out under the conditions laid down in Chapter III of this Title is a medical activity.

« *Art. L. 1235-4.* – For the implementation of this title, samples taken in the context of biomedical research pursuant of Article L. 1121-1 shall be regarded as samples taken for therapeutic purposes, notwithstanding the provisions of Title II of Book I of this part relating to the protection of persons who undergo biomedical research. »;

5° An article L. 1235-5 is inserted as follows:

« *Art. L. 1235-5* – The rules of good practice that apply to the procurement, preparation, conservation, transport and use of human body organs are drawn up by the Agency of Biomedicine after receiving the opinion of the French Agency for the Safety of Health Products. These rules are approved by order of the Minister for Health.»

**Article 10**

The second paragraph of Article L. 114-3 of the National Service Code is completed by a sentence that reads as follows:

« Information shall be provided on the procedures for consenting to organ donation for transplantation and on the possibility for a person to register their refusal on the automated national register laid down in Article L. 1232-1 of the Public Health Code. »

**Article 11**

The following paragraph is added to Article L. 1233-1 of the Public Health Code:

« All health establishments, whether or not they are authorised, participate in organ and tissue procurement activities by becoming part of procurement networks. »

**Article 12**

A. – Title IV of Book II of Part I of the Public Health Code is amended as follows:

I. – Its title shall read as follows: « Tissues, cells, products of the human body and their derivatives ».

II – Chapter I is amended as follows:

1° Article L. 1241-1 reads as follows:

« *Art. L. 1241-1.* – The procurement of tissues or cells or the collection of products of the human body from a living person for donation may only be performed for therapeutic or scientific purposes or for the production or control of *in vitro* diagnostic medical devices or for the quality control of medical biology analyses or within the framework of expert assessments and technical controls carried out on tissues or cells or on products of the human body by the French Agency for the Safety of Health Products pursuant to Article L. 5311-2, paragraph 1. Only tissues featured in a list drawn up for this purpose may be removed for donation for therapeutic purposes, apart from tissues removed as part of biomedical research.

« The procurement of tissues or cells other than haematopoietic stem cells from the bone marrow, or the collection of products of the human body for donation for therapeutic purposes or for the production or control of *in vitro* diagnostic medical devices or for the quality control of medical biology analyses or within the framework of expert assessments and technical controls carried out on tissues or cells or on products of the human body by the French Agency for the Safety of Health Products pursuant to Article L. 5311-2, paragraph 1 may only take place on condition that the donor, duly informed of the purpose of the procurement or collection and the consequences and risks attached thereto, has given their consent in writing. This consent may be revoked informally and at any time. However, the conditions for expressing consent and obtaining authorisation provided for in Article L. 1231-1 shall apply where the nature of the procurement and its consequences for the donor so justify.

« The procurement of haematopoietic stem cells from the bone marrow for donation for therapeutic purposes may only take place on condition that the donor, having been informed in advance of the risks involved and the possible consequences of the procurement, has expressed their consent before the President of the *Tribunal de Grande Instance* or the magistrate designated by him, who shall first ensure that the consent is free and informed. In the event of a life-threatening emergency, consent shall be obtained by any means by the prosecutor. Consent may be revoked informally and at any time. »;

2° In Article L. 1241-2, after the words « products of the human body », the words « for donation » are inserted;

3° Articles L. 1241-3 and L. 1241-4 read as follows:

« *Art. L. 1241-3.* – Notwithstanding the provisions of Article L. 1241-2, in the absence of any other therapeutic solution, a haematopoietic stem cell sample from bone marrow may be taken from a minor for the benefit of their brother or sister.

« When such a procurement is not possible and in the absence of any other therapeutic solution, the procurement of haematopoietic stem cells from the bone marrow may, exceptionally, be carried out on a minor for the benefit of their first cousin, uncle, aunt, nephew, or niece.

« In any case, this procurement may only be carried out with the consent of each of the holders of parental authority or of the legal representative of the minor who have been informed of the risks incurred by the minor and of the possible consequences of the procurement by the practitioner who made the indication for transplantation or by any other practitioner of their choice. Consent is expressed before the President of the *Tribunal de Grande Instance* or the magistrate designated by them, who ensures in advance that the consent is free and informed. In the event of a life-threatening emergency, consent shall be obtained, by any means, by the prosecutor. Consent may be revoked informally and at any time.

« Authorisation to carry out the procurement is granted by the Committee of experts mentioned in Article L. 1231-3, which ensures in advance that all means have been implemented to find a donor of legal age who is compatible with the recipient and that the minor has been informed of the planned procurement, with a

view to expressing their wishes, if they are able to do so. In this case, the minor's refusal prevents the procurement.

« *Art. L. 1241-4.* – Notwithstanding the provisions of Article L. 1241-2, in the absence of any other therapeutic solution, a sample of haematopoietic stem cells from the bone marrow may be taken from a living person of age who is subject to a measure of legal protection for the benefit of their brother or sister.

« If the protected person is subject to a measure of guardianship, this procurement is subordinate to a decision by the responsible guardianship judge, who shall decide after having obtained the opinion of the person concerned, where possible, of the guardian and of the Committee of experts mentioned in Article L. 1231-3.

« If the protected person is subject to a measure of legal curatorship or judicial protection and if the responsible guardianship judge considers, after having consulted the person concerned, that the protected person has the discretion to consent to the procurement, the procurement is subordinate to authorisation by the Committee of experts referred to in Article L. 1231-3, after the consent of the person concerned has been obtained in accordance with the conditions set out in Article L. 1241-3. Except in cases where the protected person has the option of consenting to the procurement, the procurement may only be carried out under the conditions laid down in the second paragraph of this article.

« In the absence of any other therapeutic solution, the procurement of haematopoietic stem cells from the bone marrow may, exceptionally, be carried out on a protected person for the benefit of their first cousin, uncle, aunt, nephew or niece. However, only protected persons who are under legal curatorship or judicial protection and who have been recognised as having the discretion to consent to the procurement by the responsible guardianship judge after having been auditioned by the latter may undergo an organ procurement. Consent shall be obtained and the authorisation to the procurement shall be issued by the Committee of experts under the conditions laid down in the third paragraph.

« Before drawing up the opinion mentioned in the second paragraph or issuing the authorisations laid down in the third and fourth paragraphs, the Committee of experts mentioned in Article L. 1231-3 shall ensure that all means have been implemented to find a donor of legal age who is compatible for the recipient.

« The refusal of the protected person prevents the procurement. »;

4° Two articles L. 1241-6 and L. 1241-7 are included as follows:

« *Art. L. 1241-6.* – The procurement of tissues and cells and the collection of products of the human body from a person whose death has been duly ascertained may only be performed for therapeutic or scientific purposes and under the conditions laid down in Chapter II of Title III.

« *Art. L. 1241-7.* – The procedures for applying this chapter shall be determined by decree in the Council of State, and in particular:

« 1° The list of tissues mentioned in the first paragraph of Article L. 1241-1 that may be removed from a living person for donation for therapeutic purposes;

« 2° The tissues and cells mentioned in the second paragraph of Article L. 1241-1, the procurement of which is subject to one or more of the conditions laid down in Article L. 1231-1;

« 3° The medical situations and conditions under which the procurement laid down in Article L. 1241-6 is authorised. »

III – Chapter II is amended as follows:

1° Article L. 1242-1 reads as follows:

« *Art. L. 1242-1.* – Tissues from the human body may only be removed for donation for therapeutic purposes in health establishments authorised for this purpose by the administrative authority after receiving the opinion of the Agency of Biomedicine.

« Cells for autologous or allogeneic administration may only be collected in health establishments authorised for this purpose by the administrative authority after receiving the opinion of the Agency of Biomedicine. These same establishments and blood establishments may collect blood cells when they are intended for the preparation of the cellular products for therapeutic purposes mentioned in 5° of Article L. 1221-8.

« Notwithstanding the previous paragraph, the categories of cells appearing on a list drawn up by the Minister for Health, on proposals from the French Agency for the Safety of Health Products and after receiving the opinion of the Agency of Biomedicine, may be collected for autologous administration in all health establishments and by doctors and dental surgeons practising outside health establishments, provided that the samples are taken in compliance with the rules of good practice drawn up in accordance with the same procedures.

« The authorisations laid down in the first and second paragraphs shall be issued for a period of five years. They are renewable. »;

2° In Article L. 1242-2, after the words « tissue samples », the words « and cells for donation » are included;

3° In Article L. 1242-3, the words « which are not intended for gene or cell therapies » are replaced by the words « mentioned in the first two paragraphs of Article L. 1242-1 ».

IV – Chapter III shall read as follows:

*« CHAPTER III*

***« Preparation, preservation and use of tissues, cells and their derivatives***

« *Art. L. 1243-1.* – With the exception of labile blood products, human cells used for autologous or allogeneic therapeutic purposes, whatever their level of processing, including their derivatives, are cellular products for therapeutic purposes.

« When these cellular products for therapeutic purposes are pharmaceutical specialities or other industrially manufactured medicinal products, they are regulated by the provisions of Title II of Book I of Part Five. In other cases, they are preparations for cell therapy regulated by the provisions of this chapter, even when human cells are used to transfer genetic material.

« *Art. L. 1243-2.* – Establishments and organisations authorised for this purpose, after receiving the opinion of the Agency of Biomedicine and the French Agency for the Safety of Health Products, which ensures compliance with the provisions of Title I of this Book, may prepare, store, distribute and transfer tissues and their derivatives and cell therapy preparations, for autologous or allogeneic therapeutic purposes.

« The authorisation shall be granted for a period of five years. It shall be renewable.

« Any change to the elements contained in the initial authorisation must be subject to a new authorisation.

« *Art. L. 1243-3.* – Any organisation that has made a preliminary declaration to the Minister for Research may, for the needs of its own research programmes, ensure the preservation and preparation for scientific purposes of tissues and cells from the human body as well as the preparation and conservation of organs, blood, its components, and their derived products. These activities include the establishment and use of collections of human biological samples. If the organisation is a health establishment, the declaration is made jointly to the Minister for Research and the director of the regional hospital agency with territorial jurisdiction.

« The expression "collections of human biological samples" means the collection, for scientific purposes, of biological samples taken from a group of persons identified and selected on the basis of the clinical or biological characteristics of one or more members of the group, as well as the derivatives of these samples.

« The organisations mentioned in the first paragraph shall submit their draft declaration for the prior opinion of a consultative committee for the protection of individuals, defined in Chapter III of Title II of Book I of this part, whose task is to assess the quality of the information provided to the participants, the methods of obtaining consent and the ethical and scientific relevance of the project. The declaration is sent to the Minister for Research and, where relevant, to the director of the regional hospital agency with territorial jurisdiction, at the same time as it is submitted to the consultative committee for the protection of individuals for its opinion on the declaration. The opinion of the latter shall be sent to them without delay.

« The Minister for Research and, where relevant, the director of the regional hospital agency with territorial jurisdiction may object, within a period of notice set by law, to the pursuit of the above-mentioned activities if the conditions of supply, conservation and use of tissues and cells from the human body do not provide sufficient guarantees to ensure compliance with either the provisions of Title I of this book, or the rules in force concerning the safety of persons carrying out an on-site professional activity, or the provisions enforceable to environmental protection. They may also object to the pursuit of the above-mentioned activities on the basis of the quality of the information provided to participants, the procedures for obtaining consent and the ethical and scientific relevance of the project.

« The Minister for Research and, where relevant, the director of the regional hospital agency with territorial jurisdiction may at any time suspend or stop activities that no longer meet these requirements.

« Prior to the decision to object, suspend or interdiction, the Minister for Research shall obtain the opinion of the Consultative Committee on information processing in the field of health research, laid down in Article 40-2 of Law N° 78-17 of 6 January 1978 relating to information technology, files and freedoms.

« Notwithstanding the preceding paragraphs, the activities referred to in the first paragraph are regulated by the provisions of Title II of Book I of this part, when they are implemented as part of a biomedical research project pursuant to Article L. 1121-1.

« The French Agency for the Safety of Health Products is informed of conservation or preparation activities for scientific purposes of tissues and cells of the human body carried out on the same site as activities of the same nature performed for therapeutic purposes. In this case, the suspension or interdiction of exercising the stated activities is automatic when requested by the French Agency for the Safety of Health Products for health safety reasons.

« The organisations referred to in the first paragraph may transfer the human body tissues and cells that they store or prepare solely to another establishment or organisation that has itself declared similar activities.

« *Art. L. 1243-4.* – Any organisation that ensures the conservation and preparation of tissues and cells of the human body for their transfer within a commercial activity, for scientific use, including genetic research purposes, must hold an authorisation issued by the Minister for Research, after obtaining the opinion of the Consultative Committee regarding the processing of information relating to research in the field of health, laid down in Article 40-2 of the aforementioned Law n° 78-17 of 6 January 1978. Authorisation must be obtained under the same conditions by any organisation that ensures the conservation and preparation of tissues and cells from the human body for their free-of-charge transfer for scientific use. When the organisation is a health establishment, the authorisation is issued jointly by the Minister for Research and the director of the regional hospital agency with territorial jurisdiction.

« The provisions of this Article shall apply to organisations involved in activities of conservation and preparation of organs, blood, its components and their derived products.

« *Art. L. 1243-5.* – Tissues and their derivatives used for therapeutic purposes and cell therapy preparations are subject to authorisation by the French Agency for the Safety of Health Products after evaluation of their preparation and storage processes and of their therapeutic indications.

« Any change to the elements contained in the initial authorisation must be subject to a new authorisation.

« The Agency of Biomedicine shall be informed of the authorisations issued pursuant to this article.

« *Art. L. 1243-6.* – Tissue transplants and the administration of cell therapy preparations may only be carried out in health establishments. When these activities are of high cost or require special provisions in the interest of public health, they may only be carried out in health establishments authorised for this purpose, after receiving the opinion of the Agency of Biomedicine, under the conditions laid down in Chapter I of Title II of Book I of Part 6.

« However, cell therapy tissues and preparations appearing on a list drawn up by the Minister for Health on a proposal from the French Agency for the Safety of Health Products and after receiving the opinion of the Agency of Biomedicine may be used by doctors and dental surgeons outside health establishments, provided that they are used in compliance with the rules of good practice approved in accordance with the same procedures.

« The following may be authorised to carry out haematopoietic cell allografts, in accordance with the provisions of Chapter II of Title IV of Book I of Part VI: health establishments which carry out medical teaching and medical research activities, as well as health establishments linked by agreement to the aforementioned within the framework of the public hospital service. The responsible administrative authority shall issue the authorisation after receiving the opinion of the Agency of Biomedicine.

« Composite vascularised tissue transplants are assimilated into organ transplants and are subject to the same provisions.

« *Art. L. 1243-7.* – The granting of the authorisations laid down in Articles L. 1243-2, L. 1243-5 and L. 1243-6 is subject to technical, health or medical conditions and, where necessary, financial conditions, as well as conditions to ensure that they operate in accordance with the general principles set out in Title I of this Book.

« *Art. L. 1243-8.* – The health organisation plan laid down in Articles L. 6121-1 and L. 6121-4 shall be adopted by the competent authority after receiving the opinion of the Agency of Biomedicine when it concerns the activity of haematopoietic cell allografts.

« *Art. L. 1243-9.* – The terms and conditions for the application of this chapter shall be determined by decree in the Council of State, and in particular:

« 1° Activities of high cost or requiring special provisions in the interest of public health as laid down in Article L. 1243-6;

« 2° The conditions and procedures for issuing the authorisations laid down in Articles L. 1243-2, L. 1243-5 and L. 1243-6, as well as the conditions for modification, suspension or withdrawal of these authorisations by the competent administrative authority;

« 3° Where necessary, the rules, in particular financial and economic rules, ensure compliance with the provisions of Title I of this Book applicable to the preparation, preservation, processing, distribution and transfer of tissues and cell therapy preparations. »

[…]

VI. - Chapter V shall read as follows:

*« CHAPTER V*

*« **Common provisions***

« *Art. L. 1245-1.* – Any violation observed in an establishment or organisation, and due to the latter, of the legislative and regulatory requirements relating to the procurement and transplantation of organs, the procurement of tissues and cells, the preservation and preparation of tissues or cell therapy preparations, as well as the transplantation of these tissues or the administration of these preparations, shall result in the suspension or withdrawal of the authorisations provided for in Articles L. 1233-1, L. 1234-2, L. 1242-1, L. 1243-2, L. 1243-4, L. 1243-5, L. 1243-6 and L. 1244-5.

« Withdrawal may only take place at least a month after the formal notice sent by the administrative authority to the establishment or organisation, specifying the complaints made against it. In the event of an emergency relating to the safety of the persons concerned, a provisional suspension may be pronounced as a precautionary measure.

« The withdrawal decision is published in the Official Journal of the French Republic.

« The temporary or definitive withdrawal of the authorisations mentioned in Articles L. 1233-1, L. 1242-1 and L. 1243-4 is automatic when requested by the French Agency for the Safety of Health Products.

« *Art. L. 1245-2.* – Tissues, cells and products of the human body, removed during a surgical operation carried out in the interest of the person operated on, as well as the placenta, may be used for therapeutic or scientific purposes, unless the person concerned expresses an objection after having been informed of the purposes of this use.

« When this person is a minor or an adult under guardianship, the subsequent use of the elements or products thus removed is subject to the absence of opposition which may be expressed by any means by the holders of parental authority or the guardian, duly informed of the purposes of this use. The refusal of the minor or the adult under guardianship shall preclude such use.

« The tissues, cells, products of the human body and placenta thus removed shall be subject to the provisions of Title I, apart from the first paragraph of Article L. 1211-2, and from those of Chapter III of this title.

« *Art. L. 1245-3.* – Any procurement of tissues and cells for donation carried out under the conditions laid down in Chapter II of this title is a medical activity.

« *Art. L. 1245-4.* – In application of this title, procurements performed for the purposes of transplantation or administration in the context of biomedical research pursuant to Article L. 1121-1 shall be regarded as procurements for therapeutic purposes, notwithstanding the provisions of Title II of Book I of this part relating to the protection of persons who undergo biomedical research.

« In the case of biomedical research involving the cell therapy preparations mentioned in Article L. 1243-1, the authorisation to carry out the research also implies the authorisation, for this research, of the procurement, storage, preparation, and administration mentioned in Articles L. 1242-1, L. 1243-2 and L. 1243-6 and it is equivalent to the import and export authorisation mentioned in Article L. 1245-5.

« *Art. L. 1245-5* – Notwithstanding the provisions of Article L. 1221-12 and of the second paragraph of Article L. 5124-13, the import and export of tissues, their derivatives, cells of the human body, whatever their level of preparation, and cellular products for therapeutic purposes are subject to authorisation and only organisations authorised by the French Agency for the Safety of Health Products may carry out these activities.

« However, health establishments authorised to collect haematopoietic cells from the bone marrow for donation in application of Article L. 1242-1 may export unprocessed bone marrow for therapeutic purposes. Health establishments authorised to transplant bone marrow cells pursuant to the provisions of Article L. 1243-6 may import unprocessed bone marrow for therapeutic purposes.

« Manufacturers of reagents, manufacturers of auxiliary therapeutic products and manufacturers of pharmaceutical products may import and export tissues and cells of human origin intended for the manufacture of reagents, auxiliary therapeutic products, patented medicinal products or industrially manufactured medicinal products, as appropriate.

« Only persons whose activity involves medical biology analyses, anatomical-cytopathology examinations, forensic examinations, routine testing, or quality assessments, particularly of reagents, may import or export biological samples.

« Only organisations authorised by the Minister for Research may import or export tissues and cells for scientific purposes.

« *Art. L. 1245-6*. – The rules of good practice that apply to the procurement, preparation, storage, transport and use of tissues, cells, and cell therapy preparations as well as products of the human body used for therapeutic purposes are drawn up by the French Agency for the Safety of Health Products after consultation with the Agency of Biomedicine. These regulations are approved by decree of the Minister for Health.

« *Art. L. 1245-7.* – The terms and conditions for the application of this chapter shall be determined by decree in the Council of State.

« *Art. L. 1245-8*. – The provisions of this title shall apply to army hospitals. A decree in Council of State shall determine the adjustments that may be made, with regards to these hospitals, to the authorisation procedures applicable to health establishments. »

B. − 1. In Article L. 1425-1 of the same code, the words « in Article L. 1421-1 » are replaced by the words «in Articles L. 1421-1 and L. 5313-1 ».

2. In the second sentence of the first paragraph of Article L. 1125-4 of the same code, the words « in the second paragraph of Article L. 1243-4 » are replaced by the words « in Article L. 1243-6 ».

C. − The first sentence of the fourth paragraph (4) of Article 38 of the Customs Code is amended as follows:

1° After the words « labile blood products defined by the Public Health Code », the words « and the plasma pastes mentioned in 1° and 2° of Article L. 1221-8 of the same code, » are included;

2° The words « to organs, tissues, cells or gametes from the human body mentioned in Articles L. 1235-1, L. 1244-8 and L. 1245-4 of the Public Health Code » are replaced by the words « to organs, tissues, cells, gametes from the human body as well as cell therapy preparations mentioned in Articles L. 1235-1, L. 1243-1, L. 1244-8 and L. 1245-5 of this code, to embryonic or foetal tissues or cells mentioned in Article L. 2151-6 of the same code ».

**Article 13**

The following paragraph is added to Article L. 1123-7:

« In addition to the tasks entrusted to them, in terms of biomedical research, in the previous paragraph, the committees are also called upon in the event of the constitution of a collection of biological samples under the conditions laid down in Article L. 1243-3 and, in the event of the use of elements and products of the human body for scientific purposes involving a substantial change in purpose compared to the consent initially given, under the conditions laid down in Article L. 1211-2. »

**Article 14**

The Public Health Code is amended as follows:

1° Title VI of Book II of Part One is amended as follows:

*a)* Its heading shall read as follows: « Provisions on auxiliary therapeutic products »;

*b)* Chapters I and II are repealed;

*c)* Chapter III becomes a single chapter and Articles L. 1263-1, L. 1263-2 and L. 1263-3 become Articles L. 1261-1, L. 1261-2, and L. 1261-3 respectively;

*d)* Article L. 1263-4 is repealed;

2° Part V is amended as follows:

*a)* At the end of the first sentence of the first paragraph of Article L. 5124-11, the words « of the products mentioned in Article L. 1261-1, the authorisation laid down in Article L. 1261-2 » are replaced by the words « of the products mentioned in Article L. 1243-1 and in 12° and 13° of Article L. 5121-1, the authorisation laid down in Articles L. 1243-2, L. 4211-8 and L. 4211-9 »;

*b)* The last paragraph of Article L. 5311-2 shall read as follows:

« 5° Is responsible for the operation of the Transparency Commission. »

**Article 15**

Chapter I of Title I of Book V of the Criminal Code is amended as follows:

1° Article 511-3 reads as follows:

« *Art. 511-3.* – The procurement of an organ from a living person of age, including for therapeutic purposes, without the consent of the latter having been obtained under the conditions set out in the third paragraph of Article L. 1231-1 of the Public Health Code or without the authorisation laid down in the second and fifth paragraphs of the same article having been issued, is punishable by seven years' imprisonment and a €100,000 fine.

« The same penalties shall apply to the procurement of an organ, tissue or cells or the collection of a product for donation from a living minor or a living adult who is subject to a legal protection measure, except for the cases laid down in Articles L. 1241-3 and L. 1241-4 of the Public Health Code. »;

2° Article 511-5 reads as follows:

« *Art. 511-5.* – The procurement of tissue or cells or the collection of a product from a living person of age without that person having expressed their consent under the conditions set out in the second and third paragraphs of Article L. 1241-1 of the Public Health Code is punishable by five years' imprisonment and a €75,000 fine.

« The procurement of haematopoietic cells from the bone marrow from a living minor or a living adult who is subject to a legal protection measure without having complied with the conditions provided for in Articles L. 1241-3 or L. 1241-4 of the Public Health Code, as the case may be, is punishable by seven years' imprisonment and a €100,000 fine. »;

3° Two articles 511-5-1 and 511-5-2 are included as follows:

« *Art. 511-5-1*. – Carrying out procurements for scientific purposes from a deceased person without having transmitted the protocol laid down in Article L. 1232-3 of the Public Health Code is punishable by two years' imprisonment and a €30,000 fine.

« The same penalties shall apply to the implementation of a protocol suspended or prohibited by the Minister responsible for research.

« *Art. 511-5-2.* – I. - Punishable by five years' imprisonment and a €75,000 fine are the storage and modification of organs, tissues, cells or blood, its components, and their derived products for scientific purposes, including genetic research:

« 1° Without having prior declaration as provided for in Article L. 1243-4 of the Public Health Code;

« 2° Where the Minister for Research has objected to the carrying out of these activities or has suspended or prohibited them.

« II. – The same penalties shall apply to the act of preserving and processing, with a view to their transfer for scientific use, including for genetic research purposes, of organs, tissues, cells or blood, its components and derived products, without having first obtained the authorisation provided for in Article L. 1243-4 of the Public Health Code or while this authorisation is suspended or withdrawn. »;

4° Article 511-7 reads as follows:

« *Art. 511-7.* – Carrying out organ procurements or organ transplants, tissue or cell procurements, tissue transplants or administration of cell therapy preparations, the conservation or processing of tissues or cell therapy preparations in an establishment that has not obtained the authorisation provided for in Articles L. 1233-1, L. 1234-2, L. 1242-1, L. 1243-2 or L. 1243-6 of the Public Health Code, or after the withdrawal or suspension of this authorisation, is punishable by two years of imprisonment and a €30,000 fine.» ;

5° Article 511-8 reads as follows:

« *Art. 511-8.* – Carrying out the distribution or transfer of organs, tissues, cellular products for therapeutic purposes or human products for donation without compliance with the health safety rules required under the provisions of Article L. 1211-6 of the Public Health Code is punishable by two years' imprisonment and a €30,000 fine. »;

6° Article 511-8-1 reads as follows:

« *Art. 511-8-1.* – Carrying out the distribution or transfer of tissues or cell therapy preparations for therapeutic use in violation of the provisions of Article L. 1243-5 of the Public Health Code is punishable by two-year imprisonment and a €30,000 fine. »;

7° Article 511-8-2 reads as follows:

« *Art. 511-8-2.* – Importing or exporting organs, tissues, cells and cellular products for therapeutic purposes in violation of the provisions adopted pursuant to Articles L. 1235-1 and L. 1245-5 of the Public Health Code is punishable by five years' imprisonment and a €75,000 fine. »

**Article 16**

In Chapter II of Title VII of Book II of Part I of the Public Health Code, two articles L. 1272-4-1 and L. 1272-4-2 are included as follows:

« *Art. L. 1272-4-1.* – As stated in Article 511-5-1 of the Criminal Code, set out below:

« Art. 511-5-1. – *Carrying out procurements for scientific purposes from a deceased person without having transmitted the protocol laid down in Article L. 1232-3 of the Public Health Code is punishable by two years' imprisonment and a €30,000 fine.*

*« The same penalties shall apply to the implementation of a protocol suspended or prohibited by the Minister responsible for research. »*

« *Art. L. 1272-4-2.* – As stated in Article 511-5-2 of the Criminal Code, set out below:

« Art. 511-5-2. – *I. – It is punishable by five years' imprisonment and a €75,000 fine the storage and modification of organs, tissues, cells or blood, its components, and their derived products for scientific purposes, including genetic research:*

*« 1° Without having drawn up the prior declaration provided for in Article L. 1243-4 of the Public Health Code;*

*« 2° Where the Minister for Research has objected to the performance of these activities or has suspended or prohibited them.*

*« II. – The same penalties shall apply to the act of preserving and processing, with a view to their transfer for scientific use, including for genetic research purposes, organs, tissues, cells or blood, its components and derived products, without having first obtained the authorisation provided for in Article L. 1243-4 of the Public Health Code or while this authorisation is suspended or withdrawn. »*

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TITLE II

**ORGANS AND CELLS**

**Article 7**

I. – Chapter I of Title III of Book II of Part I of the Public Health Code is amended as follows:

1° Article L. 1231-1 is amended as follows:

*a)* The following words are added to the second sentence of the second paragraph: « and any person who can provide proof of a close and stable emotional relationship with the recipient for at least two years »;

*b)* After the same paragraph, a new paragraph is included as follows:

« In the event of incompatibility between the person having expressed the intention to donate and the person in whose interest the procurement may be carried out by virtue of the first or second paragraphs, making transplantation impossible, the potential donor and recipient may be offered recourse to cross-organ donation. This consists of the potential recipient benefiting from the donation of another person who has expressed an intention to donate and who is also incompatible with the person in whose interest the procurement may be carried out under the first or second subparagraph, while the latter benefits from the donation of the first donor. In the case of cross-donation, the procurement and transplantation procedures are carried out simultaneously on the two donors and the two recipients, respectively. Anonymity between donor and recipient is respected.»;

*c)* In the first sentence of the third paragraph, the words « and of the possible consequences of the procurement, must express their consent » are replaced by the words «, the possible consequences of the procurement and, if applicable, the modalities of cross-donation » and the references « first and second paragraphs » are replaced by the words « first, second and, eventually, third paragraphs »;

*d)* In the fourth paragraph, the word « provided for » is replaced by the words « of the procurement from a person mentioned »;

2° Article L. 1231-3 is amended as follows:

*a)* In the last sentence of the first paragraph, the word « third » is replaced by the word « fourth »;

*b)* In the first sentence of the third paragraph, the words « of the operation, the risks involved » are replaced by the words « of an organ procurement and transplantation, the risks involved » and the word « potential » is added;

3° In Article L. 1231-4, after the words « and in particular », the words « the provisions applicable to cross-organ donations, » are included.

II. – In the first paragraph of Article 511-3 of the Criminal Code and in the second paragraph of Article L. 1272-2 of the Public Health Code, the words « third » and « fifth » are replaced by the words « fourth » and «sixth » respectively.

III. – In 7° of Article L. 1418-1 of the Public Health Code, after the words « theirs and », the words « that of the register of pairs associating living donors and potential recipients who have consented to a cross-organ donation as well as » are included.

IV. – The following words are added to the second sentence of Article 225-3 of the Criminal Code: « or that they are based on consideration of the consequences for the state of health of organ procurement as defined in Article L. 1231-1 of the Public Health Code ».

**Article 8**

The following article L. 312-17-2 is added to Section 9 of Chapter II of Title I of Book III of Part II of the Education Code:

« *Art. L. 312-17-2.* – Information is provided in secondary schools and higher education establishments of the legislation relating to organ donation for transplantation purposes and on the means of making one's position known during one's lifetime either by registering on the automated national register provided for in Article L. 1232-1 of the Public Health Code, or by informing one's relatives. These sessions may involve staff responsible for the school healthcare as well as outside speakers, particularly from associations campaigning for organ donation. Similarly, blood donation awareness is taught in secondary schools and higher education establishments, possibly with the assistance of outside speakers. »

**Article 9**

The first sentence of the first paragraph of Article L. 1111-14 of the Public Health Code is completed by the words: « and containing the words: “has been informed of the law on organ donation” ».

**Article 10**

The National Day of Reflection on Organ Donation and Transplantation is renamed « National Day of Reflection on Organ Donation and Transplantation and Recognition of Donors ».

**Article 11**

After Article L. 1211-6 of the Public Health Code, a new Article L. 1211-6-1 is included as follows:

« *Art. L. 1211-6-1.* – No one may be excluded from donating blood unless there are medical contraindications.»

**Article 12**

An article L. 111-8 is added to Chapter I of Title I of Book I of the Insurance Code to read as follows:

« *Art. L. 111-8.* – Any direct or indirect discrimination based on the consideration of an organ donation as a factor in the refusal of an insurance contract or in the calculation of premiums and benefits for the donor resulting in differences in premiums and benefits is prohibited. »

**Article 13**

The second sentence of II of Article L. 161-31 of the Social Security Code is completed by the words: « as well as the words: "Has been informed of the legislation relating to organ donation" ».

**Article 14**

The second sentence of the second paragraph of Article L. 114-3 of the National Service Code is replaced by two sentences worded as follows:

« General information is provided on blood, platelet, bone marrow and gamete donation and on organ donation for transplantation purposes. With regard to organ donation, specific information is provided on the legislation in force, on presumed consent and on the possibility for a person to register his or her refusal on the automated national register provided for in Article L. 1232-1 of the Public Health Code. »

**Article 15**

Before October the 1st, 2011, the Government shall submit to Parliament a report on the improvement of compensation, by the office mentioned in Article L. 1142-22 of the Public Health Code, of persons suffering damage as a result of the donation of organs, tissues and cells of the human body, and its financial consequences on the accounts of the health insurance.

**Article 16**

Before October the 1st, 2011, the Government shall submit to Parliament a report on the improvement of the conditions of refund of all costs incurred by living donors of human organs, tissues, and cells in connection with their procurement or collection.

**Article 17**

I. – At the beginning of Title II of Book II of Part I of the Public Health Code, an Article L. 1220-1 is added as follows:

« *Art. L. 1220-1.* – This Title applies to blood, its components and labile blood products, except for haematopoietic stem cells and blood mononuclear cells which are covered by Title IV of this Book. »

II. – Title IV of Book II is amended as follows:

1° Article L. 1241-1 is amended as follows:

*a)* In the first sentence of the second paragraph, the words « from the bone marrow » are removed;

*b)* At the beginning of the first sentence of the last paragraph, the words « The procurement of haematopoietic stem cells from the bone marrow for donation for therapeutic purposes » are replaced by the words « The procurement, for donation for therapeutic purposes, of haematopoietic stem cells collected from the bone marrow or the peripheral blood »;

2° Article L. 1241-3 is amended as follows:

*a)* In the first paragraph, the words « derived from the bone marrow » are replaced by the words « collected from the bone marrow or the peripheral blood »;

*b)* In the second paragraph, after the word « therapeutic » the word « appropriate » is included;

*c)* In the first sentence of the last paragraph, after the word « prior », the following words are inserted: « that, in particular with regard to the rules of good practice referred to in Article L. 1245-6, the conditions for carrying out the procurement do not involve any risk for the minor in view of their age or development, » and, after the word « adult », the word « sufficiently » is included;

3° Article L. 1241-4 is amended as follows:

*a)* In the first paragraph, the words « derived from the bone marrow » are replaced by the words « collected from the bone marrow or the peripheral blood »;

*b)* In the first sentence of the fourth paragraph, after the word « therapeutic », the word « appropriate » is included;

*c)* In the penultimate paragraph, after the word « of age », the word « sufficient » is included;

4° The fifth paragraph of Article L. 1245-5 is deleted.

III. – In 3° of Article L. 222-1 of the Research Code, the word « eighth » is replaced by the word « seventh ».

**Article 18**

Title IV of Book II of Part I of the Public Health Code is amended as follows:

1° The following paragraph is added to Article L. 1241-1

« The procurement of haematopoietic stem cells from the cord blood and the placental blood as well as cord and placental cells may only be carried out for scientific or therapeutic purposes, for anonymous and free donation, and on condition that the woman, during her pregnancy, has given her written consent to the procurement and use of these cells, after having been informed of the purposes of this use. This consent may be revoked informally at any time before the donation has taken place. By way of derogation, the donation

may be intended to the child born or to the brothers or sisters of this child in the event of a proven therapeutic need duly justified at the time of the procurement. »;

2° The last paragraph of Article L. 1243-2 reads as follows:

« Only cord blood and placental blood cells as well as cord and placental cells collected under the conditions mentioned in the last paragraph of Article L. 1241-1 may be prepared, stored, distributed or transferred. Each of these establishments devotes a part of its storage to the intended donation mentioned in the previous paragraph. »;

3° In the first paragraph of Article L. 1245-2, the words « as well as the placenta » are replaced by the words « with the exception of cord blood and placental blood cells as well as cord and placental cells, ».

**Article 19**

I. – The second paragraph of Article L. 1242-1 of the same code reads as follows:

« Cells for autologous or allogeneic administration may only be collected in health establishments authorised for this purpose by the Director General of the Regional Health Agency[8] after receiving the opinion of the Agency of Biomedicine. Blood cells intended for the preparation of cellular products for therapeutic purposes mentioned in Article L. 1243-1 may also be collected by the French Blood Institute[9] either in its blood transfusion establishments, if they have been authorised under the conditions applicable to health establishments, or in authorised health establishments. »

II. – Article 511-5 of the Criminal Code is amended as follows:

1° In the first paragraph, the words « second and third » are replaced by the words « last three »;

2° In the second paragraph, after the word « bone », the words «, whether they are collected by bone procurement or in the peripheral blood, » are included.

III. – Article L. 1272-4 of the Public Health Code is amended as follows:

1° In the second paragraph, the words « second and third » are replaced by the words « last three »;

2° In the last paragraph, after the word « bone », the following words are inserted: «, whether they are collected by bone sampling or in peripheral blood, » are included.

**LAW n° 2016-41 of 26 January 2016, on the modernisation of our health system**

**Article 192**

[8] *Agence régionale de santé.*
[9] *Établissement français du sang.*

I. – The last two paragraphs of Article L. 1232-1 of the Public Health Code are replaced by two paragraphs that read as follows:

« The practitioner shall inform the relatives of the deceased, prior to the planned procurement, of its nature and purpose, in accordance with the good practices established by the Minister for Health on the proposal of the Agency of Biomedicine.

« This procurement may be carried out on a person of age if they have not made known, during their lifetime, their refusal of procurement, mainly by registration in an automated national register provided for this purpose. This refusal may be revoked at any time. »

II. – The second paragraph of Article L. 1232-6 of the Public Health Code reads as follows:

« 2° The methods by which the refusal laid down in the last paragraph of the same article may be expressed and revoked, as well as the conditions in which the public and users of the health system are informed of these methods; ».

III. – I and II shall come into force six months after the publication of the decree in Council of State provided for in II, and at the latest on January the 1st, 2017.

**LAW No. 76-1181 of 22 December 1976 on the procurement of organs (1)**

Art. 1°. – In the event of a transplantation for therapeutic purposes on a human being, a procurement may be carried out on a living, mentally sane person of age who has freely and explicitly consented to it.

If the potential donor is a minor, the procurement can only be carried out if it is on a brother or sister of the recipient. In this case, the procurement may only be carried out with the consent of the legal representative and after authorisation by a committee comprised of at least three experts and including two doctors, one of whom must have twenty years' experience in the medical profession. This committee shall decide after examining all the foreseeable consequences of the procurement, both physical and psychological. If the opinion of the minor can be obtained, their refusal to accept the procurement will always be respected.

Art. 2 – Procurements may be carried out for therapeutic or scientific purposes from the corpse of a person who has not made known during their lifetime their refusal of such a harvesting.

However, if it is the body of a minor or of an unfit to plead person, the procurement for transplantation can only be carried out after authorisation from the legal representative.

Art. 3 – Apart from the reimbursement of any expenses that they may cause, the procurements referred to in the previous articles shall not lead to any monetary compensation.

Art. 4 - A decree in the Council of State shall determine:

1° The procedures by which the donor referred to in Article 1, or their legal representative, is informed of the possible consequences of their decision and the procedures by which the donor can express their consent;

2° The terms by which the refusal or authorisation referred to in Article 2 above is to be expressed;

3° The conditions that must be met by healthcare facilities to be authorised to carry out the procurements referred to in Article 2 and to be included on a list drawn up by the Minister of Health;

4° The procedures and terms by which death must be established.

Art. 5 – The provisions of the present law do not prevent the application of the provisions of law n° 49-890 of 7 July 1949 relating to corneal transplantation and those of the single Chapter of Book VI of the Public Health Code relating to the therapeutic use of human blood, its plasma, and their derivatives.

The present law shall be enforced as state law.