Leonie Lopp

Regulations Regarding Living Organ Donation in Europe

Possibilities of Harmonisation

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Foreword

This dissertation was accepted by the University of Münster in the summer of 2012. I hope my detailed work on the topic of living organ donation helps make society more aware of the problem of organ shortage and the possibility of living organ donation. I also hope the possibilities presented here to improve the situation serve as an encouragement.

This dissertation has been written under the supervision of Prof. Dr. Thomas Gutmann. I want to thank Prof. Dr. Thomas Gutmann for his ongoing help and valuable advice throughout the entire duration of this dissertation. His support made a significant contribution to the development and completion of this dissertation. Dr. Bijan Fateh-Moghadam was also a great help; he answered several questions, especially with regard to the situation of living organ donation in the United Kingdom. In addition, I want to thank Prof. Dr. Andreas von Arnauld for his written report.

The research leading to these results was funded by the European Commission Seventh Framework Programme (FP7/2010–2012) under the Grant Agreement 242177 Living Organ Donation in Europe (EULOD project). I am grateful to all members of the EULOD project for being open to questions and for helping me to understand the different national legal systems. A special thanks goes to Prof. Dr. Willem Weimar and Ms. Frederike Ambagtsheer for organising the project in such a great way. Furthermore, I also want to thank the members of the ELPAT Working Group on Legal Boundaries, with whom I discussed the several significant points of this work during two EU-funded ELPAT working group meetings in Sofia (2010) and Berlin (2011). ELPAT is the European platform on ethical, legal and psychosocial aspects of organ transplantation. It is an official committee of the European Society for Organ Transplantation (ESOT). The legal experts from this committee, who are cited several times and mentioned in the references, provided me with valuable information about LOD. I want to thank them for sharing their knowledge with me.

Finally, I would like to thank Nicolas Rücker, Oliver Lopp and Rebecca Walsh for reading parts of my dissertation several times and making helpful suggestions. I would also like to thank my parents for their ongoing support and encouragement.

Düsseldorf, June 2012 Leonie Lopp

Contents

Table of Abbreviations

Action plan	Action plan on organ donation and transplantation
Additional Protocol on Transplantation of Organs	Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human origin
Art.	Article
BGHSt	Decisions of the German Federal Supreme Court for criminal cases [Entscheidungen des Bundesgerichtshof in Strafsachen]
BVerfGE	Decisions of the German Federal Constitutional Court [Entscheidungen des Bundesverfassungsgerichts]
cf.	Confer, Latin "compare"
CFI	Court of First Instance
CFREU	Charter of Fundamental Rights of the European Union
CFR-LOD	Common Frame of Reference for European Laws on living organ donation (CFR-LOD)
Commission staff working document, Accompanying document to the Communication	Commission staff working document, Accompanying document to the Communication from the Commission to the European Parliament and the Council, Organ Donation and Transplantation: Policy Actions at EU Level, Impact Assessment

Communication from the Commission	Communication from the Commission to the European Parliament and the Council – Organ Donation and Transplantation: Policy Actions at EU Level
Convention on Human Rights and Biomedicine	Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine
Directive 2004/23/EC	Directive 2004/23/EC of the European Parliament and of the Council on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells
Directive 2010/53/EU	Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation
Directive 2010/53/EU	Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation
e.g.	Exempli gratia, Latin “for example”
EAC	Treaty establishing the European Atomic Energy Community
ead.	Eadem, Latin “the same (man)”
EC	Treaty establishing the European Community
ECJ	European Court of Justice
f.	Following (pages)
i.e.	Id est, Latin “that is”
ibid	Ibidem, Latin “the same place”
LKD	Living kidney donation
LOD	Living organ donation
No.	Number
p.	Page
pmp	Per million people
resolution on organ donation and transplantation	Resolution on organ donation and transplantation: Policy actions at EU Level (2007/2210 (INI))

resolution on the Action plan	Resolution of 19 May 2010 on the Commission Communication: Action plan on Organ Donation and Transplantation (2009–2015): Strengthened Cooperation between Member States (2009/2104 (INI))
Sec.	Section
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
Vol.	Volume
WHO	World Health Organization

Introduction

Transplantation medicine is well developed and the best possibility to cure organ failure. However, too few donor organs are available[1] to entirely utilise the medical progress made in the field of organ transplantation.[2] This causes death every single day. In 2007, about ten people died in Europe every day due to the unavailability of donor organs[3] and about 40,000 people waited for a donor organ.[4] In 2010, even more people waited for a kidney or liver transplant, while less than 20,000 kidney transplantations and about 6,500 liver transplantations were performed during the same year.[5] In Germany, right now about 12,000 people are listed as waiting for an organ transplantation.[6]

The rate of organ donation can be increased by making an effort to ensure that more organs are donated post-mortem or by increasing the rates of living organ donation (LOD).[7] Even though opinion surveys show that the majority of the population is willing to donate organs after death, the actual donation rates are lower.[8] Since it cannot be assumed that the waiting time for donor organs could be

[1] Abbub-Filho et al., in Gutmann et al. (ed.) (2004), p. 149; Broelsch, in Broelsch (ed.) (2006), p. 31; Coppen (2010), p. 9; Esser, in Höfling (ed.) (2003), p. 201; First, Vol. 29 Transplantation Proceedings 67, 67 (1997); Gutmann (2006), p. 4; Norba (2009), p. 55; cf. Oniscu/Forsythe, Vol. 38 Annals Academy of Medicine 365, 367 (2009); Ugowski (1998), p. 2.

[2] Beckmann, in Broelsch (ed.) (2006), p. 9; Deutsch/Spickhoff (2006), p. 433.

[3] Pühler et al., Vol. 25 Medizinrecht 584, 585 (2007).

[4] Commission oft he European Communities (2007), p. 2; Pühler et al., Vol. 25 Medizinrecht 584, 585 (2007).

[5] Matesanz (ed.), Council of Europe (2011); EULOD WP 2, Living Organ Donation Practices in Europe, p. 5.

[6] Bundestag printed paper 17/9030 (2012), p. 3.

[7] Gutmann/Schroth (2002), p. 1; Norba (2009), p. 24.

[8] Cf. Bundestag printed paper 17/9030 (2012), p. 4; cf. Bundeszentrale für gesundheitliche Aufklärung (2010); cf. Hauptmann/O´Connor, Vol. 336 The New England Journal of Medicine 422, 425 (1997); cf. Kirste, Vol. 81 Der Chirurg 778, 778 (2010); cf. Morgan/Deedat/Kenten, in Weimar/Bos/Busschbach (ed.) (2008), p. 99 f.; cf. Robert Koch-Institut (2003), p. 23.

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Table 1 Living kidney donation (LKD) pmp

Country	LKD in 1992	LKD in 1999	LKD in 2008	LKD in 2009
EU				
Austria	1.6	4.9		8.3
Belgium/Luxemburg	1.1	2.5	Belgium: 4.2	
Bulgaria		2.0	1.6	2.1
Cyprus		48.3	49.0	
Czech Republic		1.7	2.8	2.6
Denmark	8.6	7.8	13.5	16.3
Estonia		0.7	2.2	3.0
Finland	3.4	0.8	1.7	1.1
France	0.8	1.3	3.5	
Germany	1.2 (West Germany)	4.6	6.9	7.3
Greece	6.5	8.5	4.6	3.0
Hungary		0.9	2.4	2.4
Italy		1.4	2.2	2.3
Latvia			0.4	2.6
Lithuania		3.8	1.5	2.6
Malta			12.5	12.5
Netherlands	5.5	8.4	25.2	25.3
Poland		0.3	0.5	0.6
Portugal	0.0	0.9	4.7	6.0
Romania			5.3	5.1
Slovakia		0.4	3.6	
Slovenia				0.5
Spain	0.4	0.4	3.4	5.0
Sweden	10.3	11.8	14.8	17.7
United Kingdom/Ireland	1.6	4.3	UK: 15.3 Ireland: 1.2	UK: 16.0 Ireland: 0.0
Additionally				
Moldova			0.6	
Norway	17.1	18.5	20.5	21.6
Switzerland	3.8	9.0	15.3	13.0

sufficiently reduced by only using organs donated by deceased persons,[9] LOD is a valuable supplement.[10] LOD, hence, seems to be a useful and desirable option, making it a worthwhile focus of concentration.

The (increasing) importance of LOD can be confirmed by the fact that the amount of LODs has risen considerably since the beginning of the nineties in several countries. Table 1 shows the development of living kidney donation per

[9] Cf. Ghods, Vol. 3 Iranian Journal of Kidney Diseases 183, 183 (2009); cf. Price (2010), p. 285.
[10] Cf. Neft, Vol. 20 Neue Zeitschrift für Sozialrecht 566, 566 (2011).

million people (pmp) in the countries selected for this study.[11] The countries that show an increase in the amount of LOD since 1992 (or since the earliest year that the publication of numbers was provided for that particular country) are italicised.

LOD is rather common in most countries considered; it can even be considered an established standard therapy today.[12] It became clear, however, that the rates of LOD differ significantly between the countries, showing that not all countries actually tap the full potential.[13] Not only does the medical development have an influence on the amount of LODs, the legal situation has an influence as well.[14] Legal regulations, while not automatically increasing the amount of LOD, are one important factor among several in influencing LOD numbers. This will be analysed in detail by examining the arguments in favour of and against restricting LOD by law. Such analysis will confirm the statement of some legal experts that LOD regimes create in part an *artificial scarcity*.[15]

By presenting the national transplant laws in the countries considered, possibilities for LOD regulation will be demonstrated. This study will show the extent of similarities and differences in existing national laws. It can be assumed that some regulations are *better* than others. The final aim, therefore, is to figure out the best possible way to regulate LOD in order to make a contribution to solve the problem of organ shortage while adequately adressing the ethical, legal, and political side-constraints of the subject.

A legal comparison of the national transplant laws makes sense to find out which regulations would be best to address the issues of LOD in need of regulation. This is also in accord with the European Unions *Action plan on Organ Donation and Transplantation* which strives "to promote the exchange of best practices of living donation programmes (Priority Action 3)." A legal comparison is, furthermore, a first step to make a harmonisation of the regulations for LOD possible. Since the Member States of the European Union are continually growing more and more together, the field of organ transplantation is as well; such harmonisation is desireable.[16]

[11] The numbers for 1992 are from Jakobsen, in Price/Akveld (ed.) (1997), p. 5. The numbers for 1999 are from Matesanz/Miranda, in Gutmann/Schroth (2002), p. 256 f. The numbers for 2009 and 2010 are from Transplant Procurement Management (2011). The criterion for choosing the countries is connected to the object of investigation (Schnitzer (1961), p. 105; Zweigert/Kötz (1996), p. 40 ff), and the intent of the investigation can be an indication of the selection of the included legal systems (Constantinesco (1972), p. 51; Ebert (1978), p. 38). Since this thesis focuses on the European Union, logically all European Union-Member States are considered. Furthermore, Moldova, Norway and Switzerland are included.

[12] Price (2010), p. 196; cf. Wagner/Fateh-Moghadam, Vol. 56 Soziale Welt 73, 74 (2005).

[13] Cf. EULOD WP 2 (2012), DOW: Deliverable 4, p. 4.

[14] Gutmann/Schroth (2002), p. 42.

[15] Cf. Evans, Vol. 15 Journal of Medical Ethics 17, 19 (1989); cf. Fateh-Moghadam, (2011); cf. Radcliffe Richards, in Weimar/Bos/Busschbach (ed.) (2011), p. 41.

[16] Cf. Gutmann/Schroth (2002), p. 41; cf. Prechern-Hauptmann, in Höfling (ed.) (2008), p. 97.

Not only have the Member States of the European Union become active in the field of (living) organ donation, but the European Union has also already carried out several actions in this area. It even passed a binding directive in this field: *Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation*. This *Directive* focusses on aspects of quality and safety of LOD (and post-mortem organ donation), but does not (completely) stipulate the requirements for LOD.

Does the European Union have the competence to regulate the requirements for LOD? This will be negated for hard law in chapter "Possibilities of Harmonisation". However, the option to pass soft law remains. The European Union is definitely amenable for such non-legally binding tools, which was confirmed by the *White Paper on Governance*. The *White Paper on Governance* was published by the European Commission in 2001 and promoted using such soft methods.[17] The option of the European Union to pass soft law to *regulate* the requirements for LOD, as being preferable towards no further measures, will thus be considered.

All in all, this thesis considers the national transplant laws, but also actions of the European Union that have already been done in this field and whether it has even further competences. The aim is to analyse the arguments in favour of and against legal restrictions of LOD to establish a best practice proposal in the end.

This thesis starts with an overview of LOD in chapter "Overview About Living Organ Donation". The overview includes an introduction of LOD and defines the relevant terminology. Chapter "Comparative Analysis of European Transplant Laws Regarding Living Organ Donation" compares the national transplant laws from the countries considered. First, it explains the method the comparison of laws will follow, and then actually compares the issues of LOD in need of regulation. It especially focuses on how LOD is restricted in the countries considered. Chapter "Analysis of the Normative Arguments That Dominate the Policy Arena About Necessity and Legitimacy of Legal Restrictions in Living Donor Transplantation" analyses the normative arguments that dominate the policy arena about the necessity and legitimacy of legal restrictions in LOD. The arguments in favour of legal restrictions will be compared with those against such restrictions. LOD has not only been recognised by the national laws, but by the European Union as well, which is active in the field of LOD. The actions the European Union has carried out so far are therefore presented in chapter "Actions of the European Union So Far". Whether the European Union has further possibilities to harmonise the legislation for LOD will be analysed in chapter "Possibilities of Harmonisation". Chapter "Best Practise Proposal for Living Organ Donation in the European Union" will focus on the possible content of a unified regulation for LOD and establish a best practise proposal. In the end, a summary of the entire dissertation will be made.

[17] Stefan, Vol. 14 European Law Journal 753, 760 (2008).

Overview About Living Organ Donation

Before analysing the legal regulations of LOD in the European transplant laws, LOD as such will be introduced. (1) I will start with presenting the underlying problem of organ shortage. (2) Afterwards, I will give the basic facts about LOD. (3) Last, I will clarify the used terminology.

I. Problem of Organ Shortage

The problem of organ shortage has already been presented. Transplantable organs are scarce, because the demand for organs is higher than their supply.[1] (1) Several options seem possible to solve this problem. (2) LOD in particular has a great impact on the amount of donor organs.

1) Possibilities to Serve the Problem of Organ Shortage

Cronin makes the following statement: "Prima facie meeting this demand is good. Why would it not be? Saving life is not only, not in itself immoral, it is also one of the most wonderful things that one individual can do for another."[2]

To solve the problem of organ shortage, several options exist. Those will be explained in the following.

[1] Coppen (2010), p. 14; Hoyer, Vol. 21 Pediatric Nephrology 1364, 1364 (2006); Keller, Vol. XXXII Stetson Law Review 855, 868 (2003); cf. Neuberger/Price, Vol. 327 British Medical Journal 676, 676 (2003); Steinbrook, Vol. 353 New England Journal of Medicine 441, 441 (2005); WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation, Preamble, 1.

[2] Cronin, in Weimar/Bos/Busschbach (ed.) (2008), p. 100.

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First, a machine could artificially carry out the task of the human organ. For example, renal failure can be treated with dialysis,[3] which is an alternative mechanism for the cleansing of the bloodstream.[4] The problem with dialysis is its negative side effects. First, the patient's quality of life is impaired due to several hospital stays. This severely limits his free time activities and could require him to search for other employment.[5] Second, the long-term function of the transplanted kidney is worsened the longer the dialysis is carried out. Therefore, transplantation before even starting the dialysis treatment (preemptive transplantation) is favoured.[6] This is usually only possible with LOD, because waiting time is typically required before receiving an organ donated by a deceased person.[7] Hence, LOD not only enhances the quality of life of the recipient, but even prolongs life or is life-saving. Third, patients that are treated with dialysis have a higher risk for several diseases in comparison to the patients who received a transplantation before dialysis became necessary (e. g., heart attack, high blood pressure, anaemia).[8] The negative aspects of dialysis are intensified in the treatment of diabetes. The life expectancy of a diabetic is exceptionally connected to the amount of time he has to undergo dialysis treatment while waiting for a kidney transplantation.[9] Fourth, the costs incurred for a kidney transplantation are lower than the costs incurred for dialysis.[10] Consequently, a machine artificially carrying out the tasks of the organ is no ideal solution.[11] In addition, several organs, for example the liver, cannot be replaced by artificial machines for a longer period of time.[12] The only life-saving option in

[3] Schutzeichel (2002), p. 61.

[4] Cf. Bundestag printed paper 15/5050 (2005), p. 88; Pschyrembel (1998), p. 345.

[5] Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 148.

[6] Bos, in Weimar/Bos/Busschbach (ed.) (2008), p. 23; Daar et al., Vol. 11 Transplantation Review 95, 102 f. (1997); Godlee, Vol. 343 British Medical Journal (2011); Kasiske et al., Vol. 7 Journal of the American Society of Nephrology 2288, 2295 (1996); Kirste, in Rittner/Paul (ed.) (2005), p. 80; Roodnat et al., Vol. 9 American Journal of Transplantation 2150, 2154 (2009).

[7] Cf. Akkina et al., Vol. 57 American Journal of Kidney Diseases 152, 152 (2011); cf. Hamza et al., Vol. 45 Der Urologe 60, 63 (2006); Health Council of the Netherlands (2003); Kirste, Vol. 81 Der Chirurg 778, 780 (2010); cf. O'Hara et al., Vol. 17 Progress in Transplantation 180, 182 (2007); Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 97.

[8] Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 97.

[9] Passim Wolfe et al., 341, New England Journal of Medicine 1725–1730 (1999).

[10] Bundestag printed paper 15/5050 (2005), p. 14; Mueller/Case/Hook, Vol. 22 Transplantation Review 200, 201 (2008); O'Hara et al., Vol. 17 Progress in Transplantation 180, 180 (2007); Price (2010), p. 21; cf. Robert Koch-Institut, (2003), p. 26; Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 58; Weigend/Zielinska, Vol. 14 Medizinrecht 445, 449 (1996).

[11] Kühn (1998), p. 24 f.; Norba (2009), p. 33.

[12] Bundestag printed paper 15/5050 (2005), p. 13; cf. Dahlke et al., Vol. 46 Psychosomatics 58, 58 (2005); Erim/Malagó/Valentin-Gamazo/Senf/Broelsch, Vol. 35 Transplantation Proceedings 909, 909 (2003); Matas et al., Vol. 343 The New England Journal of Medicine 433, 436 (2000); Mühlbacher (2009), p. 3.

such events is transplantation.[13] Therefore, artificial machines cannot be considered at present as a real substitution for an organ donation.

Second, organ shortages have lead to the attempt to transplant organs from animals into human beings (so-called Xenotransplantation).[14] This procedure is still in the experimental phase and has not yet been performed successfully.[15] Therefore, this cannot be seen as an alternative to organ transplantation.

Thus, organ transplantation is the best option in cases of organ failure. However, to meet the demand of organ shortage, the rate of organ donation must increase.[16] A more extensive use of post-mortem organ donation and the further development of LOD are the two possibilities to increase the amount of donor organs. It has already been explained that it cannot be assumed that the waiting time for donor organs could be sufficiently reduced by using organs donated by deceased persons.[17] LOD is, consequently, a useful and desirable option, making it worthy of consideration.

2) Impact of Living Organ Donation

Increasing the use of LOD is not depicted here as being the only and best option to solve the problem of organ shortage. It should still be made an enormous effort to increase the amount of deceased donation.[18] Because of the existing organ shortage, the extended use of LOD is nevertheless often the only possibility for a patient that suffers from organ failure.[19] Restricting LOD by law also means disabling several patients from receiving a healing donor organ. Many claim that such a restriction artificially increases the existing shortage of donor organs even more.[20] Because of the shortage of donor organs, the legal restrictions on LOD have to be justified and any unjustified barriers to LOD should be removed.[21] The German Federal Constitutional Court, for example, addressed the problem by referring to the German basic

[13] Bock (1999), p. 53; Norba (2009), p. 33; Levinsky, Vol. 343 The New England Journal of Medicine 430, 430 (2000); Pichlmayr, in Toellner (ed.) (1991), p. 22; cf. Reason (1) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

[14] Hofer (2006), p. 24; Keller, Vol. XXXII Stetson Law Review 855, p. 871 (2003); Norba (2009), p. 31; Schutzeichel (2002), p. 273; Ugowski (1998), p. 9.

[15] Hofer (2006), p. 24; Keller, Vol. XXXII Stetson Law Review 855, p. 873 (2003); Kühn (1998), p. 25; Nickel/Schmidt-Preisigke/Sengler (2001), p. 5.

[16] Winter, in Broelsch (ed.) (2006), p. 53.

[17] Cf. Ghods, Vol. 3 Iranian Journal of Kidney Diseases 183, 183 (2009); Price (2010), p. 285.

[18] Kirste, in Rittner/Paul (ed.) (2005), p. 79; Stangl, in Rittner/Paul (ed.) (2005), p. 32.

[19] Frei, Commission printed paper 15/141 (2004), p. 1; cf. Jakobsen, in Price/Akveld (ed.) (1997), p. 4; Land, in Oduncu/Schroth/Vossenkuhl (ed.) (2003), p. 211; cf. Price (2010), p. 20; cf. Roodnat et al., Vol. 10 American Journal of Transplantation 821, 821 (2010).

[20] Fateh-Moghadam (2011), p. 1 ff.

[21] Ibid.

rights. Art. 2 II German *Constitution* guarantees that "[e]very person shall have the right to life and physical integrity." This basic right is violated in cases where a governmental regulation denies a therapy that is medically possible and would be life prolonging or would at least reduce the suffering considerably.[22] The *Charter of Fundamental Rights of the European Union* (*CFREU*), which reflects common values of the Member States,[23] also regulates that "[e]veryone has the right to life"[24] and that "[e]veryone has the right to respect for his or her physical and mental integrity."[25] The *CFREU* does not mention LOD in particular, but these two fundamental rights definitely have to be kept in mind in any examination of LOD.

The following statement by the European Commission, which has been considered the executive branch of the EU,[26] attests to the need for more LODs: "The use of living donors is an increasing alternative given the failure to meet the growing need for organs with cadaver donation."[27] And the Council of the European Union mentions "[t]he promotion of living donation" as one of the "[n]ew alternatives for expanding the donor pool."[28]

It has already been shown that the amount of LODs has risen considerably since the beginning of the nineties in several of the countries considered. Since 2001, the United States of America has even had more living kidney donors than deceased donors.[29]

On the one hand, LOD is an established standard therapy.[30] On the other hand, LOD is very problematic and the subject of a controversy that cannot be ignored. LOD involves two patients instead of only one[31] — one of them being a healthy person.[32] Thus, the ethical principle of nonmaleficence, which asserts the obligation one has to avoid inflicting harm on another, is concerned.[33] To justify this, the principle of autonomy is needed. According to the principle of autonomy, every person has a right of self-determination. He can make his own decisions, which

[22] German Federal Constitutional Court [Bundesverfassungsgericht], 16 March, 1982, Case No. 1 BvR 938/81, in BVerfGE 60, 123, 132; German Federal Constitutional Court [Bundesverfassungsgericht], 11 August, 1999, Case No. 1 BvR 218/98, in Vol. 46 Neue Juristische Wochenschrift 3399, 3400 (1999).

[23] Cf. Calliess, in Ehlers (ed.) (2007), p. 534; Cf. Walter, in Ehlers (ed.) (2007), p. 16.

[24] Art. 2 (1) Charter of Fundamental Rights of the European Union.

[25] Ibid., Art. 3 (1).

[26] Marmor/Freeman/Okma, in Marmor/Freeman/Okma (ed.) (2009), p. 8.

[27] European Commission (2006).

[28] Commission of the European Communities (2008).

[29] Gutmann (2006), p. 3.

[30] Price (2010), p. 196; cf. Wagner/Fateh-Moghadam, Vol. 56 Soziale Welt 73, 74 (2005).

[31] Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 30.

[32] Schreiber (2004), p. 18; Schutzeichel (2002), p. 100; Wagner/Fateh-Moghadam, Vol. 56 Soziale Welt 73, 77 (2005).

[33] Beauchamp/Childress (2001), p. 113.

includes having the right to make a decision about his own body.[34] Consequently, any legal rule on LOD that restrains autonomy infringes on the freedom of both the donor and recipient.[35]

Even if the principle of nonmaleficence and the principle of autonomy are considered to be universal, both maxims are not absolute. If there is a conflict between these two principles, both must be weighed before reaching a judgement in individual cases.[36] As a consequence of this tension, LOD is in need of regulation.[37]

II. Basic Facts About Living Organ Donation

Organ transplantation is defined as the removal of an organ from a donor's body to transplant into a recipient's body; the donor's organ replaces the recipient's failing or absent organ.[38] (1) The donor can either donate the organ while alive or post-mortem. These two existing procedures for organ transplantation will be deliminated. (2) Second, a brief overview about the historical development of LOD will be given. (3) Third, it will be presented which organs can be donated by a living person.

1) Delimitation of Living Organ Donation and Post-Mortem Organ Donation

Organs can be removed either from living or deceased persons. Thus, living and deceased donors must be distinguished.[39] They are classified according to the moment of their death. In compliance with the brain death criterion, a human being is pronounced dead if he exhibits an irreversible end of all brain activity.[40] The criterion of brain death is widely established and is enforced in virtually all

[34] Bundestag printed paper 15/5050 (2005), p. 34; Fischer, in Ahrens et al. (ed.) (1999), p. 545; Forkel, Vol. 23 JURA 73, 78 (2001).

[35] Gutmann, Vol. 15 Medizinrecht 147, 147 (1997); Nickel/Schmidt-Preisigke/Sengler (2001), p. 89.

[36] Beauchamp/Childress (2001), p. 5, p. 18 f.; Gutmann et al., Terasaki (ed.) (1995), p. 356; cf. Lamb, in Price/Akveld (ed.) (1997), p. 43 f.; cf. Price (2000), p. 254.

[37] This area of tension will be explained further in chapter "Analysis of the Normative Arguments That Dominate the Policy Arena About Necessity and Legitimacy of Legal Restrictions in Living Donor Transplantation".

[38] Coppen (2010), p. 10; Joint Council of Europe/United Nations Study (2009); Schreiber (2004), p. 19; Ugowski (1998), p. 8; Wollenek/Wolner, in Brandstetter/Kopetzki (ed.) (1987), p. 10 f.

[39] Kalchschmid (1997), p. 35.

[40] Kienapfel (1990), p. 3 at 11; Mayrhofer, in Brandstetter/Kopetzki (ed.) (1987), p. 55.

countries considered.[41] Therefore, LOD takes place when the donor does not experience brain death, or the irreversible end of all brain activity.[42]

2) Historical Overview

LOD already has a rather long history. The possibility of replacing a sick organ with an organ donated by a living person has been available since the 1950s. The first living kidney transplantation with long-term success took place in 1954 between two identical twins.[43] In 1959, the first kidney-homotransplantation[44] was performed,[45] and, in 1962, the first living kidney transplantation between people who were not genetically related took place.[46] In the meantime, transplantation medicine, and therefore LOD as well, evolved into a common treatment.[47] This was exemplified in Table 1 presented in the chapter "Introduction." The first successful living liver donation was not performed until the late 1980s for the benefit of a child and in the early 1990s for adults.[48] The increasing importance of LOD should not hide the fact that organ demand still far exceeds the amount of organs being donated.[49]

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[41] See Belgium, France, Greece, Italy, the Netherlands, Poland and Switzerland (Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 87); cf. Oniscu/Forsythe, Vol. 38 Annals Academy of Medicine 365, 366 (2009); cf. Nickel/Schmidt-Preisigke/Sengler (2001), p. 7.

[42] Schreiber (2004), p. 52.

[43] Gruessner/Benedetti, in Gruessner/Benedetti (ed.) (2008), p. xvii; Hauptmann/O´Connor, Vol. 336 The New England Journal of Medicine 422, 423 (1997); Jowsey/Schneekloth, Vol. 22 Transplantation Reviews 192, 192 (2008); Keller, Vol. XXXII Stetson Law Review 855, 865 f. (2003); Losse, in Toellner (ed.) (1991), p. 4; Ross/Thistlethwaite, Vol. 122 American Academy of Pediatrics 454, 454 (2008); Schreiber (2004), p. 16; Spital, Vol. 38 American Journal of Kidney Diseases 189, 189 (2001); Zenker, in Kaufmann et al. (ed.) (1979), p. 481.

[44] In this type of organ transplantation, organs from different individuals from the same species are transplanted (Bock (1999), p. 46; Kühn (1998), p. 19 f.; Norba (2009), p. 34; Schreiber (2004), p. 19 f.).

[45] Vogt/Karbaum, in Toellner (ed.) (1991), p. 12.

[46] Schutzeichel (2002), p. 74.

[47] Bock (1999), p. 29; de Klerk (2010), p. 14; Kalchschmid (1997), p. 3; Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 34.

[48] Erim et. al., Vol. 81 Der Chirurg 820, 820 (2010).

[49] Teubner (2006), p. 3.

3) Possible Organs for Living Organ Donation

Not all organs are of use for LOD. To determine which organs could be used for LOD, one must differentiate (1) the medical and (2) the legal situation.

a) Medical Situation

Medically, the liver, the kidney, the lobes of the lung, segments of the pancreas and the small intestine can be donated by a living person.[50]

The liver could be subject to a LOD, because, from a medical point of view, it can regenerate.[51] This means that, after donating part of the liver, the remaining liver normally regenerates quickly and completely.[52] Living liver donation can be considered as a routine matter.[53]

The kidney is a paired organ and therefore one kidney can be donated by a living person.[54] It is the most frequent type of LOD.[55]

Lobes of the lung and segments of the pancreas and of the small intestine can also be donated while alive.[56] Living lung donation cannot be considered routine, though.[57] Because lung diseases usually affect both lungs, two lobes are essential for one to obtain enough volume and function. Two living donors are usually involved,[58] in contrast to an entire lung from a deceased person.[59] In addition, the surgery has a rather big impact on the donor. Her lung function is permanently impaired and she is no longer able to engage in intensive training, sports, or heavy

[50] Bundestag printed paper 15/5050 (2005), p. 8.

[51] Gutmann, in Schroth et al. (ed.) (2005), Sec. 8 at 31; cf. Norba (2009), p. 57; Siegmund-Schultze (1999), p. 110.

[52] Gutmann, in Schroth et al. (ed.) (2005), Sec. 8 at 31; Norba (2009), p. 57.

[53] Cotler et al., Vol. 9 Liver Transplantation 637, 637 (2003); Neumann/Neuhaus/Schmeding, Vol. 81 Der Chirurg 804, 812 (2010); Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 38.

[54] Bundestag printed paper 15/5050 (2005), p. 9; Erim et al., Vol. 81 Der Chirurg 820, 820 (2010); Land, in Oduncu/Schroth/Vossenkuhl (ed.) (2003), p. 212; Schutzeichel (2002), p. 65.

[55] Childress/Liverman (2006), p. 266; Esser (2000), p. 7; Steinberg, Vol. 145 Annals of Internal Medicine 197, 197 (2006); Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 34.

[56] Bundestag printed paper 15/5050 (2005), p. 8; Joint Council of Europe/United Nations Study (2009); Siegmund-Schultze (1999), p. 98.

[57] Dahlke et al., Vol. 46 Psychosomatics 58, 61 (2005); Swiss Dispatch of 12. September 2001 on a Federal Law on Transplantation of Organs, Tissues and Cells, p. 39.

[58] Bowdish et al., Vol. 79 The Annals of Thoracic Surgery 418, 418 (2005); Bundestag printed paper 15/5050 (2005), p. 12; Hodson, Vol. 26 Journal of Medical Ethics 419, 419 (2000); Information from M. Bos; Norba (2009), p. 57; Price (2010), p. 204.

[59] Bowdish et al., Vol. 79 The Annals of Thoracic Surgery 418, 418 (2005).

work.[60] Furthermore, the surgery itself is rather risky for the donor.[61] The Netherlands, for example, reacted to this danger by abolishing this procedure for the most part. Instead, unilateral and bilateral lung transplants are performed by using lungs from post-mortem donors.[62] LOD with segments of the pancreas and of the small intestine are medically possible, but seldom take place.[63]

This review of the medical practice has shown that living kidney and living liver donation are the most common types of LOD. These two types will therefore be the focus in this doctoral thesis.

b) Legal Situation

The national transplant laws often differentiate between regenerative organs and non-regenerative organs. With regard to living kidney and living liver donation, this leads one to assume that the kidney is classified as a non-regenerative organ, while the liver is categorised as a regenerative organ. However, the distinction between regenerative and non-regenerative organs is primarily used to distinguish between bone marrow, which is regenerative, and kidneys, which are non-regenerative.[64] This is, for example, the case in Finland.[65] This thesis only focuses on solid organs; bone marrow donation is excluded from consideration.

A separate assessment of the liver is therefore necessary. As already stated, from a medical point of view, the liver is a regenerative organ. That does not automatically have an impact on its legal classification, though. In Germany, for example, the distinction between regenerative and non-regenerative organs used to be relevant with regard to the donor-recipient relationship, since only the LOD of non-regenerative organs was restricted. Whether this restriction applied to living liver donation was highly controversial. Several legal experts argued that the wording of the restriction only applied to non-regenerative organs. They claimed that the restriction did not apply to living liver donation because the liver, from a medical point of view, can regenerate.[66] In contrast, the parliamentary Enquete-Commission designated the liver as non-regenerative, causing it to be included in the restriction. They argued that the remaining part of the liver grows again, but the structure differs in comparison to the former liver. Therefore, according to the Enquete-Commission, the liver is a

[60] Information from M. Bos; Price (2010), p. 204.

[61] Hodson, Vol. 26 Journal of Medical Ethics 419, 420 (2000).

[62] Information from M. Bos.

[63] Bundestag printed paper 15/5050 (2005), p. 12.

[64] Cf. Gutmann, in Schroth et al. (ed.) (2005), Sec. 8 at 31.

[65] Information from K. Salmela.

[66] Esser, in Höfling (ed.) (2003), p. 217; Gutmann (2006), p. 21; Gutmann, in Schroth et al. (ed.) (2005), Sec. 8 at 31.

The dissenting view holds that the liver is also non-regenerative, since the removed parts of the liver do not regenerate with regard to the liver of the donor (Nickel/Schmidt-Preisigke/Sengler (2001), p. 99).

non-regenerative organ.[67] Meanwhile, this debate has become obsolete since the German *Act on the donation, removal and transplantation of organs* was amended in 2007. Because of this amendment, the restriction of the donor-recipient relationship currently applies to living kidney donation, the donation of a part of the liver and living donation of other non-regenerative organs.[68] Therefore, in Germany, the liver is viewed as a regenerative organ,[69] but is still treated with the same strictness as non-regenerative organs. The Swedish *Transplant Act* also contains different regulations for regenerative and non-regenerative organs. However, the *Guidance of the provisions* clarifies that provisions which contain regulations for non-regenerative organs apply to the partial transplantation of the liver.[70] This is similar in Finland, where "non-regenerative organs" means solid organs, including the kidney, but also part of the liver.[71] The situation is similar in the Netherlands as well, where the liver, in general, is not considered as regenerative.[72] In England, an organ is defined as "a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy."[73] Regenerative and non-regenerative organs are not differentiated; rather, parts of organs are generally included. Consequently, living liver donation is included in the restrictions concerning LOD.[74]

In conclusion countries with less strict rules for regenerative organs do not apply those rules to living liver donation and other countries do not even differentiate between regenerative and non-regenerative organs. The distinction is relevant, however, if one is to distinguish the donation of solid organs (which includes living liver donation and living kidney donation) and bone marrow donation. This thesis only deals with the LOD of solid organs, not with bone marrow or blood donation, though. As just seen, the legal distinction between regenerative and non-regenerative organs is, from a legal perspective, irrelevant for the LOD of solid organs. Therefore, living kidney donation and living liver donation are treated rather equally from a legal perspective, making a legal distinction between regenerative and non-regenerative organs for the LOD of solid organs absurd.

[67] Bundestag printed paper 15/5050 (2005), p. 21.

[68] Cf. Fateh-Moghadam (2008), p. 259; cf. Norba (2009), p. 216 f.

[69] Gutmann (2006), p. 21.

[70] The Ministry of Health and Social Affairs Sweden 1997, The Swedish Transplant Act, Guidance on the provisions, Sec. 7.

[71] Information from K. Salmela. (In Finland, no living liver donation has happened so far.)

[72] Information from M. Bos.

[73] Reg. 2 (6) Human Tissue Act Regulations 2006.

[74] Fateh-Moghadam (2008), p. 281.

III. Terminology

The used terminology needs to be clarified. While doing this, the exercised types of LOD are outlined as well. The terminology for the different types of LOD itself is quite problematic,[75] but will not be discussed any further here. Rather, the following terms will be taken as a basis. A rough distinction is made between specified LOD and unspecified LOD. The term specified LOD comprehends all LODs with the intent to help a specific recipient. This includes direct LOD, but indirect LOD as well. Direct LOD means that a person donates directly to the intended recipient, for example, a parent's donation to his child or a child's donation to his parent. Indirect LOD means that a person donates to help a specific recipient, but the donation is only indirect. The organ from the related donor is not directly transplanted into the recipient. The donation still allows the recipient to receive an organ, because he receives an organ from a stranger in return for the donation of the relative which is given to another person as well. This type of LOD includes cross-over LOD, unbalanced living paired exchange, living paired cascade exchange, pool donation and list-paired exchange. The opposite of specified LOD is unspecified LOD. In such a case, a person donates an organ to an anonymous recipient.[76] This is LOD to a stranger. Directed altruistic LOD can either be classified as indirect LOD or as unspecified LOD. Another type of LOD, namely, unspecified non-directed donation catalysing cascade exchanges, connects indirect LOD and unspecified LOD. As seen, several types of LOD exist.[77]

[75] Hilhorst et al., in Weimar/Bos/Busschbach (ed.) (2008), p. 380.

[76] With respect to the used terminology see Dor et al., 2011 Transplantation 1 ff.

[77] The different types of LOD will be explained and analysed below.

Comparative Analysis of European Transplant Laws Regarding Living Organ Donation

As seen in Table 1 in the chapter "Introduction," the rates of LOD are very different in the countries considered. It can be assumed that various reasons contribute to these differences, the legal situation being one of those.[1] The different national transplant laws will hence be compared. (1) How the comparison of laws takes place will be presented, before (2) the issues of LOD in need of regulation are compared.

I. Comparison of Laws

Comparative law is the comparison of different legal systems.[2]

The legal regulations of organ donation — including of LOD — are not uniform in the European Union Member States. This discrepancy in the national transplant laws leads to several problems. (1) Hence, reasons why a comparison of laws is necessary are presented. (2) The approach of the following comparison of laws is described. (3) The countries that are included in the comparison have already been listed in Table 1 in the "Introduction."[3] In addition, the national sources of law that are considered will be listed and (4) relevant European and international documents.

[1] Cf. Fateh-Moghadam (2011), p. 1; cf. Radcliffe Richards, in Weimar/Bos/Busschbach (ed.) (2011), p. 41.

[2] Constantinesco (1972), p. 107 f.; Zweigert/Kötz (1996), p. 2.

[3] P. 2.

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1) Reasons for a Comparison of Laws

First, a comparison of laws can be viewed as a necessary step towards a unification of different laws.[4] The Member States of the European Union continually grow more and more together. This goes hand in hand with the increasing level of cooperation between them. *Klein* correctly states: "None of us can escape the bombardment of information about what is happening in other countries."[5] This also applies to the field of organ transplantation. Strengthening the states' cooperation in this subject matter and finding common solutions for the problems connected to this issue is recommended.[6] This is only possible after the similarities and differences have been brought to light through a comparison of the national transplant laws.[7] This is accomplished in this chapter. The final aim of this thesis is to formulate a *best practise proposal for LOD*. This will take place in the drafting style of the Common Frame of Reference for European Private Law, thus by "expressing our ideas, of summarising what we found in the existing national laws [. . .], and of testing whether it is possible to draft at least *one* coherent set of rules [. . .]."[8] Therefore, a comparison of laws serves as a contribution to the unification of laws.[9]

Second, if all countries regulate organ donation differently, they will have differences in quality and safety requirements.[10] If the laws were adjusted, though, a similar high level of protection could be guaranteed, without restraining the development of LOD.[11] According to the *Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (Directive 2010/53/EU)*, this "would help to reassure the public that organs procured in another Member State carry the same basic quality and safety guarantees as those obtained in their own country."[12]

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[4] Cf. Beck/Burchhard/Fateh-Moghadam, in Beck/Burchhard/Fateh-Moghadam (2011), p. 5; Zweigert/Kötz (1996), p. 16.

[5] Klein, in Marmor/Freeman/Okma (ed.) (2009), p. 305.

[6] Cf. Gutmann/Schroth (2002), p. 41; cf. Prechern-Hauptmann, in Höfling (ed.) (2008), p. 97. The following statement has been made with respect to health care in general, but can be applied to LOD as well "Increased pressure for policy change in health care and, with that, the inclination to look abroad for promising solutions of domestic problems" (Marmor/Freeman/Okma, in Marmor/Freeman/Okma (ed.) (2009), p. 1 f.).

[7] This is in accord with Ehlers who states that knowledge of the foreign law is necessary for a legal comparison (Ehlers, in Großfeld et al. (ed.) (2006), p. 38).

[8] von Bar (2008), p. 4.

[9] Cf. Marmor/Freeman/Okma, Vol. 7 Journal of Comparative Policy Analysis 331, 333 (2005); Zweigert/Kötz (1996), p. 16.

[10] Reason (5) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

[11] Guillod/Perrenoud, in Gutmann et al. (ed.) (2004), p. 168.

[12] Reason (6) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.