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Transplanting Diseases from Organ Donors in Western Europe: Fault Liability or Strict Liability?

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Abstract
This article will examine the problem of disease transmission through organ transplantation from a civil liability perspective. Both fault liability and strict product liability might be possible. These two types of liability will be compared, while applying them to the actions of the central parties involved in organ donation and transplantation, namely the physician/hospital, the donor and the organ exchange organisation. While product liability is generally an easier way to obtain compensation than fault liability, it might nevertheless place too heavy a burden on the transplant professionals.

Keywords
Organ transplantation; liability; Organs Directive; Product Liability Directive

1. Introduction

Organ transplantation is considered to be the most cost-effective treatment for end-stage renal failure and the only available treatment for end-stage failure of organs such as liver, lungs and heart.[1] The success of organ transplantation is reflected by the number of transplants performed annually, as well as the crowded waiting lists.[2] At the same time, these waiting lists reveal a shortage of human organs. The supply of donor organs is clearly insufficient to meet the demand. Organ scarcity has been recognized by the European Commission to be the most important problem of organ transplantation.[3] Not surprisingly, a significant focus of governments and transplant professionals has long been finding ways to increase the number of available organ donors.

However, it must be stressed that donor quantity does not necessarily coincide with donor quality or recipient safety. This is strikingly demonstrated by several cases of (donor derived) disease transmission through organ transplantation (hereafter: DTOT) that have been reported in the past years. Most of these cases centre around two main groups of diseases: infections and malignant neoplasms, better known as cancers. As to infections, organ recipients have already suffered transmission of cytomegalovirus (CMV), human immunodeficiency virus (HIV), hepatitis B, hepatitis C and even rabies, to name a few.[4] Transplanted cancers include for instance melanoma, renal cell carcinoma and lung cancer.[5]

DTOT events are generally quite rare.[6] Nevertheless, they have been recognized as a clinically significant complication.[7] Indeed, DTOT might result in serious morbidity or even the death of the recipient. Moreover, the common practice of multi-organ procurement, in which a single deceased person can donate his organs to different recipients, might only intensify the impact of DTOT, as one donor source will lead to multiple victims.[8] It is thus worthwhile to take a closer look at this type of transplant event. The most interesting legal issue seems to be the question of civil liability for DTOT. Civil liability is a mechanism that aims to compensate losses by transferring the burden of a loss from one person to another. By passing on costs, liability might also deter certain behaviour and effectuate risk management by whoever is considered liable, assuming no one wants to be liable. This way, liability can

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[1] Recital 1, European 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, *O.J. L.* 6-08-2010, 07/14.

[2] See for example: Transplant Newsletter 2014, www.ont.es.

[3] Communication from the Commission – Organ Donation and Transplantation: Policy Actions at EU Level, COM(2007)275, http://eur-lex.europa.eu, 3.

[4] Commission staff working document – Impact Assessment, SEC(2007) 704, http://eur-lex.europa.eu, 64-66; M.G. Ison *et al.*, "The Transmission of Infections" in X (ed.), *NOTIFY: Exploring Vigilance Notification for Organs, Tissues and Cells* (Bologna: Editrice Compositori, 2011) pp. 59-78; A. Srinivasan *et al.*, "Transmission of Rabies Virus from an organ Donor to Four Transplant Recipients", *N. Engl. J. Med.* 352(11) (2005) 1103-1111.

[5] D.C. Strauss and J.M. Thomas, "Transmission of donor melanoma by organ transplantation", *Lancet Oncol.* 11 (2010) 790; J. Chapman *et al.*, "The Transmission of Malignancies" in X (ed.), *NOTIFY: Exploring Vigilance Notification for Organs, Tissues and Cells* (Bologna: Editrice Compositori, 2011) pp. 79-97.

[6] M.A. Greenwald, M.J. Kuenhert and J.A. Fishman, "Infectious Disease Transmission during Organ and Tissue Transplantation", *Emerg. Infect. Dis.* 18(8) (2012) e1; R. Desal *et al.*, "Cancer Transmission From Organ Donors – Unavoidable But Low Risk", *Transplantation* 94(12) (2012) 1200 and 1201.

[7] M.G. Ison and M.A. Nalesnik, "An update on Donor-Derived Disease Transmission in Organ Transplantation", *Am. J. Transpl.* 11 (2011) 1129.

[8] For example: *Baylor University Medical Center* v. *Biggs* [2007] 237 S.W.3d 909 (Tex.App. – Dallas); *Hightower* v. *Baylor University Medical Center* [2011] 348 S.W.3d 512 (Tex.App. – Dallas); *Sanchez* v. *Martin* [2012] 378 S.W.3d 581 (Tex.App. – Dallas). In these three cases, the recipients all received organs from the same rabies infected donor. See also: M.G. Ison *et al.*, "Transmission of Human Immunodeficiency Virus and Hepatitis C Virus From an Organ Donor to Four Transplant Recipients", *Am. J. Transpl.* 11 (2011) 1218-1225.

also prevent losses.[9] To determine how the goals of compensation and prevention are attained with regard to DTOT, we will map and examine the law on DTOT liability of several countries within the Western European region. We have opted for France, Belgium, the Netherlands and the United Kingdom. This selection represents both the continental law and the common law tradition, and encompasses countries which all have a well-developed transplant system. As the case law on DTOT within these countries is rather limited, we will additionally draw inspiration from the United States' experiences as well. Unless mentioned otherwise, this study encompasses DTOT as a result of both living and deceased organ donation procedures.

In general, case law and legal doctrine on disease transmission through transfer of human substances revolves around two types of liability: fault liability and strict (product) liability. So firstly we will take a closer look at the features of fault liability in light of the specifics of organ transplantation (part 2). Hereto, attention must be paid to the *European 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*[10] (hereafter: Organs Directive). Next, we will continue on to the role of strict product liability, which links liability to the condition of a product rather than a faulty behaviour of the liable person (part 3). More specifically, we will examine the strict product liability as prescribed by the *European Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products*[11] (hereafter: Product Liability Directive). Based on the examination of fault liability and strict product liability, we will ultimately conclude by comparing both liability actions in view of providing policy considerations for legislators (part 4).

2. Fault Liability

2.1. ***Fault liability in general***

2.1.1. Overview

DTOT is subject to the general rules of (tortious or contractual)[12] fault liability. Although this type of liability has a different appearance throughout the various European jurisdictions, its core conditions are nevertheless largely common ground.[13] These conditions are threefold: a loss, a fault (violation of the required standard of conduct) and a causal relationship between the loss and the fault. In principle, the plaintiff (*in casu* the recipient) carries the burden of proof in establishing these elements, although courts have allowed

[9] D.H.J. Hermann, "Torts: Private Lawsuits about AIDS" in H.L Dalton and S. Burris (eds.), *AIDS and the law. A Guide for the Public* (New Haven: Yale University Press, 1987) p. 154; R.D. Eckert, "The AIDS Blood-Transfusion Cases: A Legal and Economic Analysis of Liability", *San Diego L. Rev.* (1992) 231; M.J. Miller, "Strict liability, negligence and the standard of care for transfusion-transmitted disease", *Ariz. L. Rev.* (1994) 511; R. Cascao, *Prevention and Compensation of Treatment Injury : A Roadmap for Reform* (The Hague: Boom Juridische Uitgevers, 2005) p. 77.

[10] *O.J. L.* 6-08-2010, 207/14.

[11] *O.J. L.* 7-08-1985, 210/29

[12] Some European jurisdictions differentiate between tort and contractual liability. Apart from some exceptions, this difference however does not seem to be very significant in medical liability cases (see: B.A. Koch, "Medical Liability in Europe: Comparative Analysis" in B.A. Koch (ed.), *Medical Liability in Europe: A Comparison of Selected Jurisdictions* (Berlin: De Gruyter, 2011) pp. 626 and 642). Therefore, we will not go into this distinction in this paper.

[13] *Ibid.* 627. See also the non-binding, but overarching Principles of European Tort Law at www.egtl.org (hereafter: PETL).

several corrections to this principle (alleviating or even shifting the burden).[14] In the following, we will further examine the requirements of loss (*infra* 2.1.2.), fault (*infra* 2.1.3.) and causation (*infra* 2.1.4.) with a focus on the issues common to all DTOT cases. After this, we will be able to go into detail on the fault liability issues that are specific to the different parties involved in organ donation and transplantation, namely the physician/hospital (*infra* 2.2.), the donor (*infra* 2.3.) and the organ exchange organisation (*infra* 2.4.).[15]

2.1.2. The loss

First of all, fault liability presupposes a loss. This requires a material or immaterial harm to a legally protected interest (e.g. life, bodily or mental integrity).[16] As such, DTOT could give rise to compensation of *inter alia* medical expenses, loss of income, physical or moral pain and suffering, or even funeral expenses (as some diseases can lead to the death of the recipient).[17]

In certain DTOT cases however, the existence of a harm can be questioned. More specifically, if the recipient surely would have died without transplantation of the diseased organ (because it was the only organ that could possibly be available in time), then doesn't the surviving recipient appears to be better off with than without the diseased transplant? Such reasoning was apparently followed by the defendants in the French *Calmettes* case, who argued that the plaintiffs did not prove their losses seeing that the infected liver transplant saved the recipient's life. The Parisian court ultimately ruled in favour of the defendants by considering *inter alia* that the recipient would have died without the transplant. However, the French court did not explicitly state that the plaintiffs did not suffer a harm or loss.[18] To predict the course that courts will take in DTOT cases, where absolutely no lifesaving alternative apart from a diseased organ transplant was available, a comparison can be drawn with the case law on wrongful life claims. These revolve around the same question, namely whether life with a disease as the alternative to non-life can constitute a harm.[19] For instance, in Belgium, the possibility of wrongful life claims has recently been rejected by the Supreme court,[20] so a similar course can be expected regarding DTOT. However, if the recipient chose or would have chosen death over living with the transmitted disease, then it will probably be argued on the basis of patient autonomy that the consequences of living with this disease do become a reparable harm (wrongful prolongation of life claim).[21]

2.1.3. The fault

Next, the organ recipient must find a person that can be held liable on the basis of a fault, either his own or one of his auxiliaries[22] (e.g. the hospital for the conduct of an employed physician). This is not an easy task, as an organ transplantation procedure entails the actions of several different agents (see *infra* 2.2., 2.3. and 2.4.). The existence of a fault

[14] *Ibid.* 630-634.
[15] This article will not focus on the parties that are not directly involved in the transplantation procedure (e.g. the government or the person whose fault created the need for a transplant), although we do not rule out this liability.
[16] Article 2:101 and 2:102 PETL.
[17] For example: CAA Lyon 20-12-2007, *AJDA* 2008, 826, note D. Marginean-Faure.
[18] CA Paris (1st chamber) 11-02-2000, www.lexisnexis.com.
[19] A *wrongful life claim* is a legal action in which the defendant is sued by a seriously disabled child (represented by its legal guardian) for allowing the child to be born and thus failing to prevent a disabled life. The legal action in which parents sue the defendant for their own damages resulting from this birth is called a *wrongful birth claim*.
[20] Cass. 14-11-2014, no. C.13.0441.N, www.juridat.be.
[21] Compare: C. Lemmens, *Voorafgaande wilsverklaringen met betrekking tot het levenseinde* (Antwerp: Intersentia, 2013) p. 816 *et seq.*; E. Delbeke, *Juridische aspecten van zorgverlening aan het levenseinde* (Antwerp: Intersentia, 2012) p. 692 *et seq.*
[22] Vicarious liability is possible in most European jurisdictions: Article 6:102 PETL; Koch, *supra* note 12, 637.

depends on the standard of conduct (or duty of care) that is required for the agent in question. Generally, the required standard is that of the reasonable person in the circumstances of the case (e.g. value of the protected interest, expertise of that person, foreseeability of the loss, costs of precautions).[23] Underlying this standard is the blameworthiness of that person's conduct, which seems to be commonly accepted as a good reason to pass on the recipient's costs.[24] Reasonableness is of course a very broad template and will need to be specified in the light of the specifics of DTOT.

In this regard, we cannot overlook the European Organs Directive. This directive provides a flexible, but binding legal framework, which compels EU member states to implement some specific quality and safety measures for organ transplantation in their national legislation.[25] It can be accepted in principle that a reasonable person abides by statutory rules. Therefore, rules which prescribe or forbid certain conduct, such as those of the implemented Organs Directive, have to be considered when establishing the required standard of conduct.[26]

As the assessment of a fault pertains to a highly specific and technical matter, expert testimony will be of significant value. However, experiences from the United States reveal that this could be a hurdle. The transplant community is rather small. If expert qualifications were to be drawn too narrowly (e.g. only physicians specializing in transplants) then it might be hard to find an expert willing to testify against a 'colleague' who only did what everyone else was doing.[27]

2.1.4. Causation

Finally, only a fault that caused the loss of the recipient can lead to liability. Causation requires proof that the recipient's loss would not have occurred without the faulty conduct (*conditio sine qua non*).[28] Direct proof of causation exists when it can be demonstrated that the donor derived material was contaminated and that one or more recipients are now inflicted with that same contamination, while this was not yet the case before transplantation.[29]

However, establishing causation in DTOT cases is often considered to be an obstacle, since the damage will usually not present itself immediately upon transplantation, making transplant-unrelated causes (e.g. through sexual contacts) theoretically possible as well.[30] In the absence of direct proof, recipients will thus have to rely on an indirect proof by excluding

[23] Article 4:102(1) PETL.

[24] See also: Koch, *supra* note 12, 628.

[25] According to Article 288 of the Treaty on the Functioning of the European Union (hereafter: TFEU), a directive shall be binding as to the result to be achieved, but shall leave to the national authorities the choice of form and methods. The competence of the EU to enact legislative measures on the quality and safety of organs is contained in Article 168, al. 4 (a) TFEU.

[26] Article 4:102(3) PETL. In the same sense: A.J. Cronin and J.F. Douglas, "Non-standard kidneys for transplants: clinical margins, medical morality, and the law", *Med. L. Rev.* 21 (2013) 459.

[27] M. Bello, "Tainted transplants", *Trial* (2012), 28; X, "Organ Donation and Transplantation" in S. Sanbar, M. Firestone *et al*. (eds.), *Legal Medicine* (St. Louis: Mosby, 2004) p. 286; *Baylor University Medical Center* v. *Biggs* [2007] 237 S.W.3d 909 (Tex.App. – Dallas), where it was stated that qualification requirements should not be drawn narrowly.

[28] Article 3:101 PETL. European jurisdictions nevertheless differ as to the degree of the causal relationship. See: Koch, *supra* note 12, 632-634.

[29] Ison *et al.*, *supra* note 4, 67. For example: *Ravenis* v. *Detroit General Hospital* [1975], 234 N.W.2d 411 (Mich. App.) (Corneal transplant was not performed in aseptic conditions, no prior condition of the recipient explained the infection, both cornea recipients developed the same infection and the donor records revealed some donor risk factors).

[30] Bello, *supra* note 27, 28. See also: C. Dalcq, "La transmission des M.S.T. Responsabilité civile" in M. Vincineau (ed.), *Le SIDA: un défi aux droits* (Brussels: Bruylant, 1991) p. 291; Miller, *supra* note 9, 473.

all reasonable alternatives.[31] When causation still lacks sufficient certainty, a final option would be to invoke the loss-of-a-chance doctrine.[32] For example, if there is an 80% chance that the death of a liver recipient is caused by post-operative thrombosis and a 20% chance that it is caused by a bacterial infection derived from the donated liver,[33] this doctrine would allow damages for 20% of the total loss.

2.2. ***The physician/hospital***

2.2.1. Organ characterisation

Having discussed the three conditions for fault liability, we can now turn to some specific issues relating to the different parties involved, starting with the physicians and hospitals. Throughout the transplantation procedure, they are responsible for performing several actions which might constitute a fault if the standard of conduct is not met. To start, physicians must naturally procure the organ in the donor hospital. According to Article 7, al. 1 of the Organs Directive, this procurement must be accompanied by an action called 'donor and organ characterisation'. This is basically the collection of all relevant information on the donor and the organ necessary to undertake a proper risk assessment and to optimise organ allocation,[34] which of course includes information on disease transmission risks. The duty of characterisation entails several sub-duties: interviewing the donor or his relatives, submitting donor samples to tests in qualified laboratories, a physical examination (e.g. radiological tests or visual inspection) and reviewing the donor medical records.[35] This way, the Organs Directive has clearly established a standard of conduct to which non-compliance could lead to fault liability.

Still, the scope of the characterisation duties is left open for interpretation. Although the Annex to the Organs Directive specifies which information should be gathered, the data in part B of the Annex only needs to be collected if the physicians decides so, taking into account availability of the information and the particular circumstances of the case.[36] The minimum data in part A of the Annex is obligatory, but even when not all minimum data is available, organ transplantation may still be performed when the expected benefits for the recipient outweigh the risks posed by incomplete data.[37] So fault liability for failing to search for and discover donor diseases will only be at hand if the physician fails to strike the right balance between the benefits and risks of further data collection. The large variety of potential pathogens and detection methods precludes a detailed discussion of this balancing act.

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[31] For example: *DeBattista* v. *Argonaut-Southwest Insurance Company* [1981] La., 403 So.2d 26 (Sup. Louis.) (The fact that the blood donor showed no symptoms was not conclusive as the donor testing was not very effective; paid donor, and thus increased risk of disease transmission; no other reasonable risk of transmission for recipient; hepatitis transmission through blood transfusion was common at the time); Ghent 24-04-1998, *T. Gez./Rev. Dr. Santé* (1999-2000) 59-60, note J. Ter Heerdt (The HIV-infected blood recipient did not present any transfusion-unrelated risk behaviour e.g. no homosexual relations, no intravenous drug use, no other medical procedures that could have resulted in disease transmission, and the hospital was known to accept donors of dubious quality).

[32] I. Lutte, "Transplantation d'organe au regard de la jurisprudence de la C.J.C.E." (note under ECJ 10-05-2001), *DCCR* (2002) 70; N. Albert, "Les organes contaminés ne peuvent être assimilés à des 'produits défectueux'" (note under Conseil d'État 27-01-2010), *La Semaine Juridique Administrations et Collectivités territoriales* 23 (2010) 2189. However, this doctrine is not accepted in some jurisdictions (E.g. England or Germany. See: Koch, *supra* note 12, 636-637).

[33] Example derived from: CAA Versailles 25-05-2010, n°08VE02901, www.legifrance.gouv.fr.

[34] Article 3, (f) and (g) Organs Directive.

[35] Article 7, al. 3 and 4 and the Annex to the Organs Directive; Commission staff working document – Impact Assessment, SEC(2007) 704, http://eur-lex.europa.eu, 15.

[36] Article 7, al. 1 Organs Directive.

[37] Article 7, al. 2 Organs Directive. Part A of the Annex mentions *inter alia* the cause of death, the past or present history of intravenous drug abuse, past or present history of malignant neoplasia, present history of other transmissible disease, and (the results of) HIV, hepatitis C and hepatitis B tests.

Instead, we will consider the three main parameters in order to determine whether the DTOT risk should have been known.

A first important parameter is the *urgency* of the procurement procedure. Organ procurement from a deceased donor for transplantation purposes should generally be done as soon as possible, due to the rapid deterioration of organs after death. The less time available, the fewer characterisation measures that can be taken. Otherwise, this might lead to wasting urgently needed organs.[38] In the French *Poussardin* case for example, the *Conseil d'État* rejected the liability of the donor hospital for failing to perform a confirmatory hepatitis C test on a brain-dead heart donor when primary testing inconclusively revealed a number of antibodies, seeing that the transplant was urgently needed.[39] Likewise, the Parisian court decided in the *Véronique* case (hepatitis B infection through liver transplantation) that the lack of confirmatory testing did not constitute a fault, because the recipient urgently needed the liver and the testing would have taken too much time.[40]

Secondly, the *nature of the risk* should be taken into account. This mainly pertains to the risk probability. In general, testing for diseases with low incidence (e.g. rabies)[41] is not cost-effective and is difficult to maintain.[42] However, if signs of such diseases reveal themselves, these diseases can become foreseeable and thus require more extensive examination.[43] Logically, failing to characterize risks that were unknown by medical science (e.g. new diseases or known diseases in a new context) at the time of procurement will not constitute a fault.[44]

Last but not least, a third parameter we wish to highlight is the *effectiveness of characterisation methods*. In general, the causation requirement implies that only the failure to take precautions that could have prevented the harm can lead to fault liability.[45] For some diseases (e.g. HIV and hepatitis C), tests exist, but their effectiveness is limited to a certain stage in the development of the disease. Before this moment, there is a so-called 'window period', in which the disease is already present in and transmissible by the donor, but cannot be discovered yet.[46] Obtaining false negative test results due to the window period – during which in fact no test is available – would not constitute a fault.[47] In general, the standard of conduct does not require the discovery of diseases that cannot be discovered. Not surprisingly, it is said that the risk of false negatives attaches considerable importance to screening for risks through donor history.[48] However, interviewing might also be unreliable, as respondents

[38] P. McMaster and D. Mirza, "Precautions to Prevent Transmission of Infectious Agents in Organ Grafting" in Y. Englert (ed.), *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors* (Dordrecht: Martinus Nijhoff Publishers, 1995) pp. 28 and 29; Bello, *supra* note 27, 28.

[39] Cons. d'État 27-01-2010, no. 313568 and 313712, www.lexisnexis.com. *Contra* to the previous ruling in this case: CAA Lyon 20-12-2007, *AJDA* 2008, nr. 15, 826, note D. Marginean-Faure.

[40] CAA Paris 18-10-2006, *RDSS* 2007, 302, concl. B. Folsheid.

[41] Srinivasan *et al.*, *supra* note 4, 1109.

[42] Ison *et al.*, *supra* note 4, 65-66.

[43] Compare: *Basore* v. *Ayvazian* [2009] 2008 WL 5505489 (Mass.Super.) (Strange lymph nodes noticed during lung procurement; no biopsy performed, which could lead to negligence).

[44] *Kozup* v. *Georgetown University* [1987] 663 F.Supp. 1048 (Distr.Court Col.); *Hoemke* v. *New York Blood Center* [1990] 912 F.2d 550 (2nd Cir.); J. Ter Heerdt, "Aansprakelijkheid bij hiv-besmetting: IPR- en causaliteitsproblemen" (note under Ghent 24-04-1998), *T. Gez./Rev. Dr. Santé* (1999-2000) 66.

[45] *Pittman Estate* v. *Bain* [1994] 1994 CarswellOnt 928 (Supr. Ontar.).

[46] McMaster and Mizra, *supra* note 38, 28; Ison *et al.*, *supra* note 8, 1222.

[47] B. Dickens, "Donation and transplantation of organs and tissues" in A. Grubb (ed.), *Principles of medical law* (Oxford: Oxford University Press, 2004) p. 1073; N. Nefussy-Leroy, *Organes humains: prélèvements, dons, transplantations* (Paris: Eska, 1999) pp. 206-207.

[48] Commission staff working document – Impact Assessment, SEC(2007) 704, http://eur-lex.europa.eu, 15 and 64. See also: *Doe* v. *University Hospital of the New York University Medical Center* [1990] 148 Misc.2d 756 (Sup.N.Y.) (Unavailability of tests does not preclude fault for failure to perform interviews).

might forget to mention things, might not understand the question, or just do not know.[49] Furthermore, visual inspection of the organ cannot always reveal the cancer (e.g. malignancies located deeply inside a large organ or micrometastases).[50] Of course, if the ineffectiveness of the characterisation method is caused by a fault (e.g. mislabelling, test sample mix-up, improperly performing tests, unclear communication[51]), then this might yet lead to liability of the medical team, the laboratory personnel or the hospital.[52]

2.2.2. Organ selection

After having performed the characterisation, the physician will need to decide whether to accept the organ (organ selection).[53] In France and Belgium, some courts established a 'safety obligation' that encompasses the selection and provision of blood and other tissues free of defects such as infections. Such an obligation was considered to be an 'obligation of result', which means that the provider breaches the standard of conduct as soon as the recipient proves that the selected blood or tissue was contaminated. The provider could only escape liability by disproving causation between this fault and the recipient's loss, regardless of whether the contamination could have been discovered.[54] By contrast, the EU Organs Directive supports a rather large margin of appreciation for the clinician to determine the appropriate risk-benefit ratio in accepting an organ for transplantion. It acknowledges that more risks can be accepted than with blood or most tissues and cell-based treatments because overall benefits of organ transplantation are high.[55] This allows for non-standard risk donors (also called 'expanded criteria donors' or 'marginal donors') to be used; a policy choice which is convenient in view of the organ shortage.[56] Thus, transplanting an organ that causes or could cause DTOT is not necessarily faulty conduct.[57] Fault liability will not be withheld unless it is proven that the risk-benefit ratio is unreasonable given the circumstances.

Two sets of parameters are especially relevant for judging the reasonableness of the organ selection decision. The first set relates to the *disease itself*. Attention should be given to

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[49] Ison *et al.*, *supra* note 4, 62.

[50] I. Penn, "Precautions to be Taken to Prevent Transmission of Neoplastic Diseases in the Grafting Process" in Y. Englert (ed.), *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors* (Dordrecht: Martinus Nijhoff Publishers, 1995) p. 54.

[51] See for this: Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, *O.J. L.*, 10-10-2012, 275/27.

[52] X, *supra* note 27, 281; T. Vansweevelt, *Aids en recht. Een aansprakelijkheids- en verzekeringsrechtelijke studie* (Antwerp: Maklu, 1989) p. 78. For example: Corr. Leuven 20-05-2003, *T. Gez./Rev. Dr. Santé* (2004-2005) 228 (liability of lab personnel for mislabelling).

[53] In several countries, the organ characterisation and organ selection will be performed by different physicians.

[54] France: Cass. Fr. 12-04-1995, *JCP* 1995, nr. 22.467, note P. Jourdain (HIV-infected blood); Cass. Fr. 9-07-1996, *D.* 1996, 610, note Y. Lambert-Faivre (HIV-infected blood). Belgium: Rb. Ghent 16-04-2007, *T. Gez./Rev. Dr. Santé* 2007-2008, 370, note C. Lemmens (Infected corneal graft; safety obligation of result based on the assumption that using uncontaminated donor material does not depend on an aleatory result and that the hospital/physician is in fact in a position of power towards the recipient); Liège 15-11-2006, *RGAR* 2008, nr. 14.352 (Hepatits C infected blood; safety obligation of result based on the non-aleatory nature of providing disease-free blood).

[55] Recital 11 and Article 7, al. 2 Organs Directive.

[56] See: Commission staff working document – Impact Assessment, SEC (2008) 2956, http://eur-lex.europa.eu, 81; A. Cronin, "Making the margins mainstream: strategies to maximise the donor pool" in A.-M. Farrell, D. Price and M. Quigley (eds.), *Organ shortage: ethics, law, and pragmatism* (Cambridge: Cambridge University Press, 2011) p. 105.

[57] In this vein, the safety obligation of result for providing disease-free blood and tissues, as mentioned earlier, is apparently not extended to organs. See: Vansweevelt, *supra* note 52, 77; Nefussy-Leroy, *supra* note 47, 214-215. See also: CAA Versailles 25-05-2010, n°08VE02901, www.legifrance.gouv.fr (reference was made to a safety obligation of result, but the considerations of the court for rejecting liability seem to go beyond the thought pattern of an obligation of result).

its treatability. For example, CMV is highly susceptible to transmission and has the potential to cause significant morbidity. Nevertheless, prophylaxis is possible, thereby reducing the actual risk, which pleads in favour of transplantation.[58] Another factor is the transmission probability of the disease. For example, the low foreseeable risk that the donor might be infected with hepatitis B was one of the elements taken into account by the French court in the *Poussardin* case to reject negligence for transplanting an infected heart.[59]

The second set of parameters revolves around the *condition of the recipient*. One of these factors is the pre-existence of the disease in the recipient. Whereas for example a hepatitis C-infected donor should principally be excluded, it is nevertheless accepted that his organs could be used for recipients who are already infected with hepatitis C (viral positive-to-positive transplantation).[60] Similarly, the law in the United States has recently been changed in order to allow HIV-positive donors for HIV-positive recipients in an attempt to reduce organ shortage, even though the risks of this type of matching are still partly unknown.[61] The urgency of the transplantation, which also depends on the lack of alternatives, is a relevant factor as well. For example, the court in the French *Poussardin* case rejected liability for transplanting an infected heart *inter alia* on the ground that, in the absence of therapeutic alternatives, the heart transplant was urgently needed to save the recipient's life.[62] In the Texan *Hightower* case, the court even seems to consider that transplantation of a kidney with a high risk for HIV and hepatitis C is not negligent, because the operation was not unnecessary, although it could have waited as the recipient's kidney failure was under control thanks to dialysis therapy.[63] Indeed, dialysis could serve as an alternative for kidney transplants, but non-standard kidney donors could still provide much better outcomes and might thus be justified, depending on the extent of the risk in the specific case.[64]

2.2.3. Informed consent

While transplanting a diseased organ may prove to be in accordance with the standard of conduct, this does not preclude liability of the transplant physician for failing to fulfil his duty to obtain the recipient's informed consent. This means that he will have to inform the recipient about known or reasonably expectable DTOT risks.[65] However, this duty does not mean that every possible transmission risk should be disclosed in detail as this would be impractical and unnecessary to guarantee self-determination by the recipient. The court decision in *Good* v. *Presbyterian Hospital in the City of New York* provides a good opportunity to clarify the extent of informed consent regarding DTOT. In the *Good* case,

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[58] Nefussy-Leroy, *supra* note 47, 205; Cronin and Douglas, *supra* note 25, 451.
[59] Cons. d'État 27-01-2010, no. 313568 and 313712, www.lexisnexis.com.
[60] Inserm, *Transplantation d'organes – Quelles voies de recherche?* (Paris: Les éditions Inserm, 2009) p. 307; Ison *et al*., *supra* note 8, 1222.
[61] 42 U.S.C. § 274(b)(3), as amended by the HIV Organ Policy Equity (HOPE) Act. See also: P.N. Malani, "New Law Allows Organ Transplants From Deceased HIV-Infected Donors to HIV-Infected Recipients", *JAMA* 310 (2013) 2492-2493.
[62] Cons. d'État 27-01-2010, no. 313568 and 313712, www.lexisnexis.com. See also: the expert testimony in *Kelly* v. *New York Organ Donor Network* [2012] 35 Misc.3d 1212(A) (Supr. Suffolk) (Extreme need could justify using kidney donors with bacterial meningitis) and in *Sanchez* v. *Martin* [2012] 378 S.W.3d 581 (Tex.App. – Dallas) (No life-threatening condition, so no high risk liver transplant justified).
[63] *Hightower* v. *Baylor University Medical Center* [2011] 348 S.W.3d 512 (Tex.App. – Dallas).
[64] Compare: Cronin and Douglas, *supra* note 25, 451, 455 and 463.
[65] OPTN Policy 15.3, www.optn.transplant.hrsa.gov; D. Price, *Legal and ethical aspects of organ transplantation* (Cambridge: Cambridge University Press, 2008) p. 427; Cronin and Douglas, *supra* note 25, 462; *St. Vincent Medical Center* v. *Los Angeles County Superior Court* [2002] 2002 WL 31412763 (Cal.App. 2 Dist.) (Hepatitis B infection through kidney transplant; need for informed consent implicitly acknowledged). The doctrine of informed consent is a generally accepted duty throughout Europe: Koch, *supra* note 12, 644.

liability was sought for failing to inform on the known CMV-positive status of a heart-lung donor. The court dismissed this claim on the basis that a reasonable medical practitioner following the practice of the nationwide transplant community would not have disclosed this risk, as heart-lung donors are rare and a lot of donors are CMV-positive.[66]

Some remarks are necessary. Firstly, the court in *Good* appears to be judging by a professional standard of conduct. We believe that there is no reason to rely solely on professional guidelines and practices to this extent, for this would allow transplant surgeons to make their own rules and could easily undermine knowledgeable decision-making by the recipient. The standard should logically be the reasonable, prudent recipient/decision-maker.[67] Next, the court apparently relied on the high frequency of the (CMV) risk. However, not only risk frequency, but also the seriousness of the risk should reasonably be taken into account.[68] On its own, high risk frequency is rather an argument in favour of disclosing the risk.[69] For example, the fact that a lung donor smoked cigarettes daily for over a decade would appear to be information that a reasonable recipient would like to know with a view to the risks of lung cancer.[70] Therefore, instead of relying on the high prevalence of CMV donors, the court in *Good* would have provided a better argument to dismiss liability by stating that CMV is easily controlled and thus forms a not so serious risk.

Committing a fault by failing to inform the recipient on the DTOT risk is in itself not enough for fault liability. Causation between the lack of disclosure and the organ transplantation is also required.[71] Basically, the recipient has to show that he would not have consented if the missing information had been disclosed.[72] The urgency of the transplant can play an important role in assessing this causation. In the *Poussardin* case for example, failing to inform the heart recipient about the hepatitis B risk did not give rise to fault liability according to the French court, because the recipient would still have undergone the transplantation if informed, as it was urgently needed to save his life.[73] In *Ord* v. *Regents of the University of California*, a lack of causation between CMV-infection and failure to inform on the CMV-positive status of a transplanted lung was found for yet another reason. Since the recipient was advised face-to-face and via a booklet about many serious infections other than CMV, some of which were more serious than CMV, the court held that a reasonable, prudent person in those circumstances would not decline a transplant due to an increased risk of CMV infection.[74]

2.3. ***The Donor***

So far, the possibility of organ donor liability for DTOT does not seem to have been recognized by a court in the examined jurisdictions. Section 18(b) of the US Uniform

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[66] *Good* v. *Presbyterian Hospital in the City of New York* [1996] 934 F.Supp. 107 (South.Distr.N.Y.).

[67] See also: *Baylor University Medical Center* v. *Biggs* [2007] 237 S.W.3d 909 (Tex.App. – Dallas) (rabies-infected kidney transplant); *Grier* v. *University of Pennsylvania Health System* [2009] 2009 WL 1652168 (East.Distr.Penn.) (cancerous lung transplant); *Kozup* v. *Georgetown University* [1987] 663 F.Supp. 1048 (Distr. Court Colom.) (HIV-infected blood transfusion).

[68] Compare to blood transfusion: C.J.J.M. Stolker, "Aansprakelijkheid voor bloedprodukten en bloedtransfusies", *NJB* (1995) 692 and 694; *Valdiviez* v. *United States* [1989] 884 F.2d 196 (5th Cir.) (HIV-infected blood transfusion).

[69] Compare to blood transfusion: *Kozup* v. *Georgetown University* [1987] 663 F.Supp. 1048 (Distr.Court Colom.).

[70] *Grier* v. *University of Pennsylvania Health System* [2009] 2009 WL 1652168 (East.Distr.Penn.).

[71] See *supra* 2.1. on the three conditions for fault liability.

[72] Cronin and Douglas, *supra* note 25, 464.

[73] Cons. d'État 27-01-2010, no. 313568 and 313712, www.lexisnexis.com. See similarly in blood transfusion cases: *Spann* v. *Irwin Memorial Blood Centers* [1995] 34 Cal.App.4th 644 (Super.San Fran.); *Kozup* v. *Georgetown University* [1987] 663 F.Supp. 1048 (Distr.Court Colom.).

[74] *Ord* v. *Regents of the University of California* [2002] 2002 WL 1204331 (Cal.App. 4 Dist.).

Anatomical Gift Act (UAGA 2006)[75] even grants immunity for civil action to the person who makes a deceased donation (the donor or his family) and to the donor's estate for any injury or damage that results from the making or the use of the gift.[76] The comment to section 18 UAGA 2006 explains that donor immunity is based on the view that those who donate have little ability to determine the risks associated with transplantation, so risk assessment should be appropriately left to the medical community. We agree with the idea that the duty for risk assessment should be placed upon those who have superior information, as this would be more efficient in view of risk prevention.[77] We also agree with the view that, as a starting point, the living or deceased donor has insufficient knowledge for adequate risk assessment. However, we believe that this does not necessarily mean that an organ donor can never be liable. If it can be established that the (living) donor knows that his situation implies a risk or should have known this, but fails to alert the medical team during the interview, then this would be a fault which could lead to liability.[78] The same goes for the next of kin (or other persons) who are questioned in view of deceased organ donation.

2.4. ***The organ exchange organisation***

Usually, a designated organ exchange organisation will control the allocation of procured organs to compatible recipients. In the French *Calmettes* case, the plaintiffs addressed the former French organ exchange organisation (France Transplant, represented by the *Établissement Français des greffes*) on the basis of fault liability for a liver transplantation which allegedly caused a hepatitis C infection. The Parisian court held that no fault could be established, seeing that, according to its statutes and government contract, this organisation only had a duty of transferring the necessary information between hospitals and coordinating the procedure, instead of examining the condition of the organ or double-checking the characterisation measures.[79] A similar view was implicitly shared in the US case of *Kelly* v. *New York Organ Donor Network*, where the court considered that the Organ Procurement Organization does not make any clinical judgment but only collects and transfers the medical information between hospitals and coordinates the procedure.[80] For the reasons stated in this case law, it is probably not worthwhile to address organ exchange organisations in DTOT cases on the basis of fault liability. However, this does not preclude their liability completely. If the exchange organisation negligently failed to perform its duties (e.g. correct, bonafide information transfer) and this led to an incorrect clinical judgment, which in turn led to DTOT, then their fault liability does need to be examined. It is imperative to examine the scope of the mission of the relevant exchange organisation in each instance.

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[75] To be found at: http://www.uniformlaws.org.

[76] Similarly, by upholding the principle of anonymity with regard to deceased donors and living donation by strangers, some jurisdictions (e.g. Article 4*bis* Belgian law of 13 June 1986 relating to the removal and transplantation of organs, *BS* 14-02-1987 or Article L1211-5 French *Code de la Santé Publique*), appear to have created a *de facto* immunity, as the recipient might not know who to sue.

[77] See also: Eckert, *supra* note 9, 218-219.

[78] This tallies with the Belgian and Dutch majority position on the liability of blood donors: H.J.J. Leenen, J.C.J. Dute, J.K.M. Gevers *et al*., *Handboek Gezondheidsrecht* (The Hague: Boom Juridische Uitgevers, 2014) p. 502; Stolker, *supra* note 67, 688; G. Genicot, *Droit médical et biomedical* (Brussels, Larcier, 2010) p. 723; Dalcq, *supra* note 30, 287-289. See also: Cronin and Douglas, *supra* note 25, 471.

[79] CA Paris (1st ch.) 11-02-2000, www.lexisnexis.com. Reiterated in: CAA Lyon 20-12-2007, *AJDA* 2008, nr. 15, 826, note D. Marginean-Faure; Cons. d'État 27-01-2010, no. 313568 and 313712, www.lexisnexis.com; CAA Versailles 25-05-2010, n°08VE02901, www.legifrance.gouv.fr.

[80] *Kelly* v. *New York Organ Donor Network* [2012], 35 Misc.3d 1212(A) (Sup.Suffolk).

3. Strict product liability

3.1. *Strict product liability in general*

An interesting question is whether strict product liability rules can be applied in situations of a DTOT-victim. As mentioned above, a specific Directive concerning strict product liability is applicable in the EU. The aim of the Product Liability Directive was to adjust the laws of the EU Member States concerning the liability of the producer for damage caused by the defectiveness of his products '*because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property*.'[81] It is clear that consumer protection is one of the main objectives of this Directive.[82]

The application of the Directive would require the recipient to prove that his damage is caused by a defective product and that the addressed person is the producer/supplier of that product.[83] Applied to a situation of DTOT, the victim has to prove that an organ is a product (*infra* 3.2). Secondly, the organ should be considered as being a defective product (*infra* 3.3) Finally, the addressed person should be the producer/supplier of the organ (*infra* 3.4). The issue of damages and the question with regard to causality are already discussed earlier in this article.[84] The European Directive on product liability does not contain a specific definition of the concept of causality so this should get the common (national) interpretation. Concerning the damage, the Product Liability Directive imposed specific conditions with respect to property damage[85] but the remainder is left to the national courts in accordance with their national law.[86] For this reason, we will not further discuss these principles in this part.

3.2. *An organ as a product*

3.2.1. Notion

The first obstacle that the DTOT-victim must overcome, is the proof that an organ is a product within the meaning of the applicable legislation.[87] The regulations on product liability in Europe as well as in the USA logically apply only to products.

The Product Liability Directive defines a product as '*all movables even if incorporated into another movable or into an immovable*'.[88] This way, the Directive applies to a very wide range of products.[89] However, some consider that the Directive can only be applied to industrially manufactured products, as the recitals to the Directive seem to suggest.[90] This

[81] Recital 1, Product Liability Directive. See also: Explanatory memorandum on the proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *Bulletin of the European Communities*, Supplement 11/76, 13-14; D. Wuyts, "The Product Liability Directive – more than two decades of defective products in Europe", *JETL* 5 (2014) 1-2.

[82] A. Van Wassenaer-van Catwijck, *Produktenaansprakelijkheid in Europees verband* (Zwolle: Tjeenk Willink, 1986) pp. 19 and 22.

[83] Article 1 Product Liability Directive.

[84] *Cf.supra*: title 2.1.1 and 2.1.3.

[85] Article 9, b) Product Liability Directive.

[86] See also: Judgment of the Court 10-05-2001, *Henning Veedfald*, C-203/99, *European Court Reports* 2001, page I-3569, recital 27.

[87] J. McHale, M. Fox *et al*., *Health care law: text and materials* (London: Sweet & Maxwell, 2007) p. 1178.

[88] Article 2 Product Liability Directive.

[89] Wuyts, *supra* note 79, 3.

[90] Recital 13 of the Product Liability Directive. See *inter alia*: Opinion of AG Colomer in case C-203/99, *Henning Veedfald* [2000], *European Court Reports* 2001, page I-3569, recital 13 and M. Faure and W. Van Buggenhout, "Produktenaansprakelijkheid. De Europese Richtlijn: harmonisatie en consumentenbescherming (deel 1)?", *RW* 1 (1987-1988) 6.

statement cannot be followed.[91] In the first place, it should be noticed that the clear wording of Article 2 Product Liability Directive does not make a distinction relating to the method of producing a product. Moreover, the European Commission responded explicitly to a parliamentary question that the Directive should for example also apply to craft and artistic products.[92] Finally, we believe it is justified – given the purpose of consumer protection – to argue that the concept of a product should be interpreted very broadly.

Regarding human material, it must be assumed that parts of the body that can be removed – such as blood, tissues and sperm – are undeniably movable goods and therefore fall within the meaning of the product concept.[93] As for France, we can even refer to the hereinafter discussed 'development risk defence'[94] which is explicitly excluded for damage resulting from defective bodily material.[95] *A contrario,* we must conclude that bodily material as such does initially fall within the scope of the Directive.[96] Furthermore, in the well-known English blood case, *A* v. *National Blood Authority*, the judge said that blood and blood products fall within the scope of the Directive.[97] This proposition should be nuanced in that only bodily material which is separated from the human body can be considered as being a product.[98] The person himself cannot be seen as a movable good as long as he is alive. Thus, as long as bodily material is part of the human body, it is not a movable good[99] and consequently not a product within the meaning of the Product Liability Directive. Nevertheless, the fact that the bodily material – for example the organ after the transplantation – becomes a part of the recipient's body does not alter this statement. For example, in several blood cases as well as in cases relating to medicines, it was never stated that a product which caused the damage is no longer a product because of its 'absorption' into the body.[100] In our opinion, the same can be said of an organ transplant.

3.2.2. The internal market argument

Some case law and scholars consider that organs are not products within the meaning of the Product Liability Directive.[101] In their opinion, this allegation can be justified by one of the objectives of the Directive, namely the creation of an internal market. According to them,

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[91] In a similar sense, see: L. Cornelis, "Aansprakelijkheid voor gevaarlijke produkten", *RW* 34 (1987-1988) 1143; J. Peigné, "Quelle responsabilité hospitalière du fait de la greffe d'un organe contaminé" (note under CAA Paris 18-10-2006), *RTDSS* 2 (2007) 298; T. Vansweevelt and B. Weyts, *Handboek buitencontractueel aansprakelijkheidsrecht* (Antwerpen – Oxford: Intersentia, 2009) p. 501.

[92] Question 706/55 G. De Vries, *O.J. C.* 114/42, 8-05-1989.

[93] Van Wassenaer-van Catwijck, *supra* note 80, 41; Cornelis, *supra* note 89, 1143; Vansweevelt, *supra* note 52, 83-84; E.H. Hondius, "Produktaansprakelijkheid in het ziekenhuis", *Tijdschrift voor Gezondheidsrecht* (1990) 414; Stolker, *supra* note 67; 686-687; P.-H. Delvaux and L. Vandenhouten, "La responsabilité du fait des produits de santé", in J. Cruyplants and J.-L. Fagnart (eds.), *Actualités du droit de la santé* (Brussels: Editions du jeune barreau de Bruxelles, 1999) p. 216; L. Dommering-van Rongen, *Productaansprakelijkheid. Een rechtsvergelijkend overzicht* (Deventer: Kluwer, 2000) p. 112; Y.-H. Leleu and G. Genicot, *Le droit médical* (Brussels: De Boeck, 2001) p. 212; J. Herring, *Medical law and ethics* (Oxford: Oxford University Press, 2006) p. 378; Peigné, *supra* note 89, 298; D. Marginean-Faure, note under CAA Lyon 20-12-2007, *AJDA* 2008, nr. 15, (828) 829; Genicot, *supra* note 76, 723; R.P. Wijne, *Aansprakelijkheid voor zorggerelateerde schade* (The Hague: Boom Juridische Uitgevers, 2013) p. 330; Wuyts, *supra* note 79, 7.

[94] *Cf. infra*: title 3.2.3.

[95] Article 1386-12, al. 1 *Code civil*.

[96] In a similar sense, see: Peigné, *supra* note 89, 298; Genicot, *supra* note 76, 724.

[97] *A* v. *National Blood Authority* [2001] 3 All ER 289.

[98] Stolker, *supra* note, 67, 687; Wijne, *supra* note 91, 331.

[99] Leenen, Dute, Gevers *et al*., *supra* note 76, 498.

[100] See *inter alia*: Court Amsterdam 3-02-1999, *NJ* 1999, 621; *A* v. *National Blood Authority* [2001] 3 All ER 289 (2001) and Court of Brussels 10-02-2005, *T.Gez.* 2007-2008, nr. 4, 284.

[101] See *inter alia*: CAA Paris 18-10-2006, *RTDSS* 2007, 290 and Albert, *supra* note 32, 2189.

organ transplantation has little or even nothing to do with this internal market so an organ cannot be regarded as being a product.

This statement cannot find any support. The idea that organs and organ transplantation have nothing to do with the internal market is false. According to the Treaty on the Functioning of the European Union, the EU does have competence within the field of quality and safety of human organs for transplantation, so such services fall within the scope of the internal market.[102] Thus, organ transplantation does fit within the achievement of the internal market. In addition, this reasoning is contrary to the clear wording of Article 2 Product Liability Directive, in which the concept of a product is defined very broadly.[103] Taking into account this definition, it must be accepted that organs – like all other bodily material – are a product.

3.2.3. The product-services distinction

It can be questioned whether an organ transplant is a service rather than a product. This is for example the position in the USA. In most American blood cases, it is stated that the transfusion of blood should be considered as being a service and not as a product.[104] The same can be said in case of organs and organ transplants.[105] The use of bodily material as a product is in fact subordinate to the primary element of the service; in other words: the providing of health care as a service overrides the occasional provision of products.[106] One goes to the hospital to obtain a service – *i.e.* health care – and not to purchase a product.[107] That way, any kind of strict product liability has to be excluded, according to the majority in the American case law and the doctrine. Only in very exceptional – and strongly criticized[108] – cases, bodily material was regarded as being a product.[109] Nevertheless, in most States of America, legislation was enacted to protect hospitals and blood banks from strict liability.[110] These are the so-called 'blood shield statutes'.[111] A reading of this legislation reveals that in most States, other bodily material – such as organs – also falls within the scope of these

[102] Article 168, al. 4, a) TFEU. See also: D.C. Roccam Abbing, "Organ Transplantation: Challenges for the EU" in Y. Englert (ed.), *Organ and Tissue Transplantation in the European Union: Management of Difficulties and Health Risks Linked to Donors* (Dordrecht: Martinus Nijhoff Publishers, 1995) p. 18.

[103] Albert, *supra* note 32, 2189.

[104] See *inter alia*: *Perlmutter* v. *Beth David Hospital* [1954] 123 N.E.2d 729 (App.N.Y.); *Sloneker* v. *St. Joseph's Hospital* [1964] 233 F.Supp. 105 (Distr.Court Color.); *Koenig* v. *Milwaukee Blood Center, Inc*. [1964] 23 Wis.2d 324 (Supr.Wis.); *Whitehurst* v. *American National Red Cross* [1965] 1 Ariz.App. 326 (App.Ariz.); *Lovett* v. *Emory University, Inc*. [1967] 156 S.E.2d 923 (App.Georg.); *White* v. *Sarasota County Public Hospital Board* [1968] 206 So.2d 19 (Supr.Flor.); *Parr* v. *Palmyra Park Hospital, Inc*. [1976] 139 Ga.App. 457 (App.Georg.); *Fogo* v. *Cutter Laboratories, Inc*. [1977] 68 Cal.App.3d 744 (App.Cal.); *Fisher* v. *Sibley Memorial Hospital* [1979] 403 A.2d 1130 (App.Col.); *Roberts* v. *Suburban Hosp. Association, Inc*. [1987] 532 A.2d 1081 (App.Mary.); *Howell* v. *Spokane & Inland Empire Blood Bank* [1990] 785 P.2d 815 (Supr.Wash.).

[105] *Heirs of Fruge* v. *Blood Services* [1973] 365 F.Supp. 1344 (West.Distr.Louis.); L.E. Douglass, "Organ donation, procurement and transplantation: the process, the problems, the law", *UMKC L.Rev.* 65 (1996), 227; X, *supra* note 27, 286.

[106] *Perlmutter* v. *Beth David Hospital* [1954] 123 N.E.2d 729 (App.N.Y.); *Whitehurst* v. *American National Red Cross* [1965] 1 Ariz.App. 326 (App.Ariz.).

[107] Miller, *supra* note 9, 483; R.D. Miller, *Problems in health care law* (Massachusetts: Jones and Bartlett Publishers, 2006) p. 622.

[108] See *inter alia*: X, "A hospital is strictly liable for transfusions of hepatitis-infected blood – Cunningham v. MacNeal Memorial Hospital", *Mich.L.Rev.* 69 (1970-1971) 1171.

[109] *Jackson* v. *Muhlenberg Hospital* [1967] 96 N.J.Super. 314 (Sup.N.J.); *Cunningham* v. *MacNeal Mem. Hosp*. [1970] 47 Ill.2d 443 (App.Ill.); *Hines* v. *St. Joseph's Hospital* [1974] 527 P.2d 1075 (App.New M.); *Moore* v. *Underwood Memorial Hospital* [1977] 371 A.2d 105 (Super.N.J.); *Shortess* v. *Touro Infirmary* [1988] 508 *So.2d* 938 (Sup.Louis.).

[110] For a clear overview, see: X, *supra* note 106, 1179; Miller, *supra* note 9, 488-494.

[111] S.S. Sanbar, M.H. Firestone *et al*., *Legal medicine* (St. Louis: Mosby, 2004) p. 409.

statutes so strict product liability is not possible in those situations.[112] In the Third Restatements on Torts, it is also explicitly mentioned that blood and other human bodily material are not products within the meaning of the Restatements.[113] For example, a heart valve for transplantation cannot be considered as being a product.[114] The policy reasons behind this are to avoid a decrease in the number of donors and to avoid medical science being limited as a result of (too) strict liability.[115] In other words, the blood supply – and by extension any provision of any form of bodily material – may not be jeopardized by the imposition of strict product liability.[116]

Concerning the European Union by contrast, it can undeniably be argued that the Product Liability Directive is applicable when a product is used in the context of a service.[117] This follows from the *Henning Veedfald* case, which was about a kidney that became unsuitable for transplantation after being rinsed with a defective perfusion fluid produced by the hospital itself. In a short but very clear decision, the European Court of Justice ruled that the Product Liability Directive should apply to products used within the context of a service. The Court stated that it is sufficient to observe that the case involved the defectiveness of a product – used in the course of providing a service – and not any defect in the service as such.[118]

When we apply this to the problem of DTOT, it can undeniably be argued that the Directive applies to organs because they are a product as soon as they are separated from the human body.[119] The fact that these are used in the course of providing a service – namely the organ transplantation – does not affect this statement. The Directive is also applicable to these products, as long as the case involves the defectiveness of the product and not any defect in the service as such. The service itself undeniably falls outside the scope of the Directive. However, it should be noted that in practice it will not always be that easy to distinguish between a defectiveness in the product and a defect in the service as such.[120]

3.3. *Organs as a defective product*

3.3.1. The legitimate safety expectations

A second hurdle the plaintiff must overcome is the proof of defectiveness. As already mentioned, the producer is only liable for the damages caused by a defect in his product.[121] The standard of liability is the defectiveness of the product and not the negligence or fault of the producer. According to the European legislator, a form of strict liability is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production.[122] The producer is best placed to bear such costs as he can pass them on to all consumers by increasing the price

[112] Douglass, *supra* note 103, 227; X, *supra* note 27, 286.
[113] §19, c) Restatements of the Law (third) – Product liability.
[114] *Miller* v. *Hartford Hospital* [2006] 2006 WL 2808215 (D.Conn.).
[115] See *inter alia*: Miller, *supra* note 9, 490.
[116] Dommering-van Rongen, *supra* note 91, 112.
[117] J.-L. Fagnart, "Transplantation d'organe et responsabilité du fait des produits défectueux" (note under ECJ 10-05-2001), *JT* (2002) 210; Vansweevelt and Weyts, *supra* note 89, 505; Wuyts, *supra* note 79, 6.
[118] Judgment of the Court 10-05-2001, *Henning Veedfald*, C-203/99, *European Court Reports* 2001, page I-3569, recital 12.
[119] M.A. Jones, *Medical negligence* (London: Sweet & Maxwell, 2008) pp. 815 and 854; A. Grubb, J. Laing and J. McHale, *Principles of medical law* (Oxford: Oxford University Press, 2010) pp. 969 and 995 and Cronin and Douglas, *supra* note 25, 466.
[120] Wijne, *supra* note 91, 334.
[121] Article 1 Product Liability Directive.
[122] Recital 2, Product Liability Directive; D. Wuyts, "Productaansprakelijkheid: een Richtlijn voor (n)iets?", *TBBR* 1 (2008) 9.

of the product.[123] According to the drafters of the Directive, a fair apportionment of risks between the injured person and the producer implies that the latter should be able to free himself from liability in certain exonerating circumstances.[124] Therefore, Article 7 Product Liability Directive provides a limited number of defences that free the producer from liability. In addition, it should be pointed out that the producer cannot invoke any contract limiting or exempting him from liability.[125]

According to Article 6 Product Liability Directive, a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account. Generally, it must be assumed that the defectiveness of a product must be assessed on a case-by-case basis, taking into account all relevant circumstances, on the basis of objective criteria.[126] In doing so, the court has a wide margin of appreciation.[127]

Some scholars – with regard to sperm – believe that one may not have high safety expectations in case of an unknown infection risk so that this risk should be borne by the recipient.[128] In the same vein, other authors pleaded for a separate product liability regime for blood products.[129] This would mean that a blood product can only be considered as defective from the moment the virus can be detected. As long as the situation concerns a known risk that cannot be detected, the producer should only warn of the potential risks.

However, the majority of authors has held that the general public is entitled to expect that transfused blood is completely safe.[130] This doctrine considers that one can speak of flawed blood even if there is an absolutely unknown virus in the infused blood.[131] The same statements can be found in different case law. For example, the English court ruled in the well-known case of *A* v. *National Blood Authority* that the general public has the right to expect that blood is perfectly safe, although one is usually aware of the fact that there is always a (small) risk of contamination.[132] A Dutch court was already of the opinion that the general public may expect that blood products are 100% HIV-free.[133] Some Belgian authors also believed that HIV-contaminated blood should be considered to be defective.[134] Finally the German court – regarding the inevitable risk of the explosion of glass bottles – considered that the public is entitled to expect absolute safety regardless of the fact that certain defects may not always be detectable.[135] In our view, this reasoning will probably also be applied to the situation of DTOT. In other words: the general public may in principle expect that the transplanted organ is free of any defect.

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[123] Explanatory memorandum on the proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *Bulletin of the European Communities*, Supplement 11/76, 14.
[124] Recital 7, Product Liability Directive.
[125] Article 12 Product Liability Directive.
[126] Explanatory memorandum on the proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, *Bulletin of the European Communities*, Supplement 11/76, 16; Jones, *supra* note 117, 855; Wuyts, *supra* note 79, 9.
[127] Wijne, *supra* note 91, 341.
[128] A.M.L. Broekhuijsen-Molenaar, *Civielrechtelijke aspekten van kunstmatige inseminatie en draagmoederschap* (Deventer: Kluwer, 1991) p. 126.
[129] Stolker, *supra* note 67, 694.
[130] *Ibid.*, 693; V. Derckx and H. Roscam Abbing, "Patients' right to health protection and quality and safety of blood(products)", *EJHL* 11 (2005) 161.
[131] *Contra*: Broekhuijsen-Molenaar, *supra* note 126, 126.
[132] *A* v. *National Blood Authority* [2001] 3 All.ER 289.
[133] Court Amsterdam 3-02-1999, *NJ* 1999, 621.
[134] Ter Heerdt, *supra* note 44, 66.
[135] BGH 9-05-1995, *NjW* 1995, 2162.

3.3.2. The presentation of the product

The presentation of the product is one of the specific circumstances that should be taken into account in the safety assessment.[136] This means that the product must be regarded taking into account the packaging, the instructions, the warnings, etc.[137] It is generally accepted that inaccurate, incomplete or missing information renders a product defective.[138] Especially in the case of an inherently dangerous product – such as most medical products – the information about any possible risk is essential in the safety assessment.[139] Applying this to the situation of DTOT, we can argue that the patient should be informed about all known possible dangers inherent to organ transplantation.[140] Comparing this with the above discussed information obligation (informed consent), one might conclude that there is little or no distinction between strict product liability and fault liability. This statement is correct to a certain extent: the provision of incorrect, incomplete or insufficient information is a fault and renders the product defective. However, it should be noted that strict product liability demands that all known risks are communicated, even the very exceptional ones which a normal prudent person would eventually not communicate. For this reason, we believe that the application of the Product Liability Directives offers greater protection concerning the information obligation compared with the fault liability.

Even if information is given, this does not mean that an organ can no longer be considered as defective. It remains possible that the information and warnings do not remove the unsafe nature of the product if the legitimate expectations of the general public were higher.[141] Even the presence of an exhaustive list of warnings and possible dangers does not guarantee that a particular product is safe. For example, the Court of Amsterdam ruled that a blood product contaminated with HIV was defective, although the brochure from the blood bank and various media mentioned the possibility of HIV-infection through blood transfusion.[142]

However, we opt for a more nuanced approach. We believe that sufficient adequate information of all the potential risks of a transplant can transform the initial defective organ into a safe product. This can be justified by the fact that an organ transplantation is very useful and even lifesaving, though it can include some unavoidable risks. Nevertheless, this information requirement should be interpreted very strictly. Thus, we concur with the case law which believes that the producer has to warn of any known side-effect and risk, even if their occurrence is statistically very low.[143] The case law which is satisfied with mentioning the most dangerous risks cannot be followed.[144] Still, we should emphasise that the provision of (sufficient appropriate) warnings in itself is not an absolute defence for the producer. As indicated, it remains possible that the judge finds there is an unsafe product if the legitimate expectations of the public justify this.

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[136] Article 6, b) Product Liability Directive.
[137] Vansweevelt and Weyts, *supra* note 89, 511-512.
[138] Delvaux and Vandenhouten, *supra* note 91, 219; Sanbar, Firestone *et al.*, *supra* note 109, 410-411; Grubb, Laing and McHale, *supra* note 117, 980-981; Vansweevelt and Weyts, *supra* note 89, 512.
[139] Wuyts, *supra* note 79, 16.
[140] M. Kusanovich, "Medical malpractice liability and the organ transplant", *U.S.F.L.Rev.* 5 (1970-1971) 266; Grubb, Laing and McHale, *supra* note 117, 1072.
[141] Vansweevelt and Weyts, *supra* note 89, 513.
[142] Court of Amsterdam 3-02-1999, *NJ* 1999, 621.
[143] *Gober* v. *Revlon, Inc*. [1963] 317 F.2d 47 (U.S.App.); *Sterling Drug, Inc*. v. *Cornish* [1967] 370 F.2d 82 (U.S.App.); *Basko* v. *Sterling Drug, Inc*. [1969] 416 F.2d 417 (U.S.App.); *Cunningham* v. *Charles Pfizer & Co*. [1974] 532 P.2d 1377 (Supr.Okl.); Paris 23-09-2004, *D.* 2005, 1012.
[144] *Merrill* v. *Beaute Vues Corp*. [1956] 235 F.2d 893 (U.S.App.); *Bonowski* v. *Revlon, Inc*. [1959] 251 Iowa 141 and 100 N.W.2d 5 (Supr.Iowa); *Kaempfe* v. *Lehn & Fink Products Corp*. [1964] 21 A.D.2d 197 and 249 N.Y.S.2d 840 (Supr.N.Y.); *Thibault* v. *Sears, Roebuck & Co*. [1978] 118 N.H. 802 and 395 A.2d 843 (Supr. New Hamp.); Cass.fr. 8-04-1999, *JCP* 1999, II, 20721.

3.3.3. The development risk defence

Finally, the producer is not liable if the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered. Within the medical context, in which such risks are inherently present, this so-called development risk defence deserves particular attention.[145] The development risk defence has to be interpreted strictly.[146] According to the European Court of Justice, the producer must prove that the accessible objective[147] state of scientific and technical knowledge, including the most advanced level of such knowledge at the time when the product in question was put into circulation, was not such as to enable the existence of the defect to be discovered.[148] There are three possible interpretations of this defence in relation to bodily material.

In the first instance, there is the French view. In France, the defence is expressly excluded in relation to human body parts and products derived from them.[149] It seems this defence is interpreted too rigorously for the producer.

Secondly, in the blood case *A* v. *National Blood Authority*, the English court held that, since the infection of transfused blood with hepatitis C occurred before and had been clearly documented, the producer knew this danger. For that reason, the development risk defence was not applicable when there is knowledge of the possible existence of the defect even if there are no functional tests available to detect this defect in specific products.[150] The same reasoning was applied in an *obiter dictum* in the case *Richardson* v. *LRC Products* concerning a ruptured condom.[151] Also the German Court – in the case of an exploding water bottle – held that the defence only covered undetectable dangers.[152] To summarize, it can be said that as soon as a possible risk is known, the producer can no longer invoke the development risk defence because of this knowledge of the risk.[153] A technical inability to detect a particular risk does not give rise to the application of this defence.[154] This reasoning can additionally be justified through the objective of consumer protection: the stricter the defence is interpreted, the more protection a victim of a defective product receives. Thus, if a defective organ is transplanted, the producer cannot rely on this defence if the risk of such a defect is known, regardless of whether the defect could be discovered in that particular case.

Finally, the district Court of Amsterdam, dealing with a case of infected blood, did find the fact that the HIV infection could not be detected during a certain phase of the disease, sufficient to allow the development risk defence.[155] Some scholars believe this judgement is wrong as the development risk defence is only about the recognisability of a risk and not about the 'avoidability' of this risk.[156] Nonetheless, the Dutch Court was in our opinion not totally wrong by stating that the development risk defence could be invoked when the defect could not be discovered in a particular case. This can be supported by the clear wording of Article 7, e) Product Liability Directive. It states that the producer is not liable if he proves that the state of knowledge was not such as to enable the '*existence of the defect to be*

[145] Delvaux and Vandenhouten, *supra* note 91, 223.
[146] Explanatory report on the Product liability Act, *Parl.St.* Kamer 1989-1990, 1262/1, 18.
[147] Consequently the specific qualities and capabilities of the producer are not taken into account. See: G. Viney, "Chronique: responsabilité civile", *La semaine juridique* 50 (1997) 520.
[148] Judgment of the Court 29-05-1997, *Commission/United Kingdom*, 300/95, *European Court Reports* 1997, page I-2649, recitals 26-29.
[149] Article 1382-12, al. 1 *Code Civil*. See also: Delvaux and Vandenhouten, *supra* note 91, 226.
[150] *A* v. *National Blood Authority* [2001] 3 All ER 289.
[151] *Richardson* v. *LRC Products Ltd*. [2000] 59 BMLR 185.
[152] BGH 9-05-1995, *NJW* 1995, 2162.
[153] Grubb, Laing and McHale, *supra* note 117, 1001.
[154] Ter Heerdt, *supra* note 44, 66; Dommering-van Rongen, *supra* note 91, 113.
[155] Court Amsterdam 3-02-1999, *NJ* 1999, 621.
[156] Wuyts, *supra* note 120, 27.

discovered'. Linguistically, it can be argued that even in a situation where a certain risk is known but cannot be detected in a specific product, one can rely on the development risk defence.[157]

In summary, we can conclude that the interpretation of this defence is not as clear as it should be. We believe it is up to the European Court of Justice – for example in the framework of a preliminary ruling – to solve this problem by giving a clear interpretation of this defence.

3.4. *The producer/supplier of an organ*

3.4.1. Notion

The final obstacle on the way to compensation is the question of who can be held liable *ratione personae*. Regarding the Product Liability Directive, the recitals make clear that all participants involved in the production process should be held liable.[158] The producer is: the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part, as well as any person who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as its producer.[159] Without prejudice to the liability of the producer, the EU-importer bears the same liability when some specific conditions are fulfilled.[160] Finally, the supplier of a product shall be treated as its producer where the producer of the product or the EU-importer cannot be identified unless the supplier informs the injured person within a reasonable time of the identity of the producer/EU-importer or of the person who supplied him with the product.[161]

Now the question remains of how the foregoing should be applied to the situation of DTOT. Hereafter we will discuss the situation of the donor, the organ exchange organisations and the hospital or the physician.

3.4.2. The donor

Certain legal scholars are of the opinion that a donor cannot be considered as being the producer because he does not manufacture his own bodily material.[162] According to this, bodily material is in their view a product without an initial producer.[163] However, can we really pretend that a person does not produce his own bodily material? For example, one can say that a sperm donor produces his own sperm and thus should for that reason be labelled as the producer.[164] Basically the donor 'produces' at least something.[165]

We believe it can be argued that the mere 'production' of a product in one's own body is not enough to consider someone as being a producer. There should be at least some intervention in the production process and a will to produce something. Thus, we believe it is justifiable to say that the donor cannot be considered as being the producer of his/her bodily material.[166] This statement can also be founded on one of the objectives of the Product Liability Directive, namely the purpose that all participants involved in the production process should be made liable. One can hardly say that the donor is actually a participant in the production process.

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[157] Dommering-van Rongen, *supra* note 91, 52.
[158] Recital 4, Product Liability Directive.
[159] Article 3, §1 Product Liability Directive.
[160] Article 3, §2 Product Liability Directive.
[161] Article 3, §3 Product Liability Directive.
[162] Cornelis, *supra* note 89, 1143. In the same sense, see: Stolker, *supra* note 67, 112; Albert, *supra* note 32, 2189.
[163] Peigné, *supra* note 89, 299.
[164] Vansweevelt, *supra* note 52, 85.
[165] Leenen, Dute, Gevers *et al*., *supra* note 76, 501.
[166] Van Wassenaer-van Catwijck, *supra* note 80, 41-42.

Nevertheless, it should be noted that the donor is always the supplier of his/her bodily material. However, this still does not mean that the donor will be held liable in practice.[167] In order to achieve full protection of the donor and to avoid a decrease in the number of donors, one can argue that the donor may at any time invoke the defence of Article 7, c) Product Liability Directive.[168] One is not liable when he proves that the defective product was neither manufactured by him for sale or for any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business. As the donor's body parts are not produced/supplied for any form of distribution for economic purpose – having regard to the prohibition of the commercialisation of human bodily material[169] – nor distributed in the course of any business, the donor cannot be held liable under the Directive. This defence can be invoked regardless of whether the donor is considered as being the producer or the supplier. Even if the donor would receive a reimbursement for expenses and income loss, this does not mean that the donor distributes the product for economic purposes.[170] However, in the exceptional case of criminal organ trade, the donor cannot invoke this defence anymore. In that situation, the donor will after all act with an economic purpose. This is justified from the perspective that in this way the Product Liability Directive has a deterrent effect on organ trafficking.

3.4.3. The organ exchange organisations

Further, we can briefly discuss the status of the so-called allocation organisations. It must be assumed that they are neither a producer nor a supplier within the meaning of the Product Liability Directive. This can be derived from certain case law which has shown that these organisations usually have a coordinating and administrative function without really being involved in the removal and/or transplantation of organs.[171] For this reason, it is not recommended to consider these organisms as producers/suppliers.

3.4.4. The physician and the hospital

Some scholars believe that the hospital or physician who provides an organ can be considered as being the supplier of the product, as it is impossible for the patient to determine who is the producer of this bodily material.[172] Other authors believe that it would be 'perverse' to say that the prevailing or transplanting hospital/physician should be considered as being the producer of the organ.[173]

However, in several blood cases, the blood bank was usually held liable as a producer of the blood.[174] Furthermore, some scholars have even argued that any agent that procures bodily

[167] J.-L. Fagnart, "La directive du 25 juillet 1985 sur la responsabilité du fait des produits", *Cah.Dr.Eur.* (1987) 20.
[168] Vansweevelt, *supra* note 52, 85; Stolker, *supra* note 67, 689; Delvaux and Vandenhouten, *supra* note 91, 231; Dommering- van Rongen, *supra* note 91, 79.
[169] Article 3, al. 2, c) Charter of Fundamental Rights of the European Union; Article 13 European Directive 2010/53/EU. See also: Article 4 Belgian law of 13 June 1986 relating to the removal and transplantation of organs *BS* 14-02-1987 1987; Article L1211-4 French *Code de la Santé Publique*; Articles 2 and 7 Dutch law of 24-05-1996 on organ donation, *Stb.* 1996, 370; section 32 UK Human Tissue Act 2004; 42 U.S.C. §274e.
[170] Dommering-van Rongen, *supra* note 91, 79; Wijne, *supra* note 91, 379.
[171] *Cf.supra*: title 2.5.
[172] Vansweevelt, *supra* note 52, 84; Ter Heerdt, *supra* note 44, 66; Peigné, *supra* note 89, 300-301.
[173] Albert, *supra* note 32, 2189.
[174] See *inter alia*: *Rostocki* v. *Southwest Florida Blood Bank* [1973] 276 So.2d 475 (Supr.Flor.); Cass. Fr. 12-04-1995, *JCP* 1995, II, 22467, note P. Jourdain; Paris 28-11-1991, *D.* 1992, 85, note A. Dorsner-Dolivet; CAA Lyon 20-12-2007, *AJDA* 2008, nr. 15, 826, note D. Marginean-Faure; Trib. Paris 1-07-1991, *JCP* 1991, II, 21762; Van Wassenaer-van Catwijck, *supra* note 80, 41-42; Vansweevelt, *supra* note 52, 85; J. Foyer and L. Khaïat, *Droit et sida: comparaison internationale* (Paris: CNRS Editions, 1994) p. 236; Stolker, *supra* note 67, 687; P. Jourdain, "La responsabilité civile des centres de transfusion sanguine et des cliniques en cas de

material, in view of providing this to a patient, should be considered as being the producer within the meaning of the Product Liability Directive.[175] It is also accepted that the physician who mixes certain drugs for an injection has to be seen as the producer of this finished product.[176] In the same way, it is stated that the doctor who changes an intravenous drug has to be regarded as being a producer.[177] Even a laboratory that distributes human bodily material within the framework of its professional activities must be regarded as being the producer of this material.[178] Finally, we can mention the European Product Safety Directive, which entails a lot of preventive and corrective measures to ensure the safety of the users and to avoid risks or correct them.[179] Within the meaning of this Directive, the producer is every professional in the supply chain, insofar as his activities may affect the safety properties of a product.[180] As the Product Safety Directive and the Product Liability Directive have a complementary function – namely harmonizing the rules for producing and marketing safe products and achieving a high level of consumer protection[181] – an identical scope for both Directives seems to be desirable.

Based on this, we can state that the physician and/or the hospital must be regarded as being the producer of an organ in the context of organ transplant.[182] In a similar way, it has already been argued that a person acquires the status of producer by processing bodily material or parts of it.[183] The physician and the hospital process an organ before transplantation in the way, for example, that they store and rinse the organ (with certain fluids) before it can actually be transplanted. This preparation of the organ should be considered as part of the production process so it seems plausible to consider the hospital/the physician as a producer.[184] By processing the organ, the hospital/the physician 'manufacture' a finished product for transplantation.[185] It will probably be the team that procures the organ that should be considered as being the producer but it can also be the transplanting team. In other words: the team that processes the organ can be considered as the producer; otherwise they can only be considered as the supplier.

Unlike the donor, the hospital/the physician do act with an economic purpose and within the framework of their business so they cannot rely on the defence of Article 7, c) Product Liability Directive. Furthermore, they cannot invoke the defence of Article 7, a) Product Liability Directive which states that the producer is free from liability if he did not put the product into circulation. In the *Henning Veedfald* case, it has explicitly been held that a product is put into circulation when it is used during the provision of a specific medical service, consisting of preparing a human organ for transplantation, though it never left the medical sphere of control.[186] Thus, the use of a product for the benefit of a third party means

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contamination de transfusés par le VIH: la cour de cassation prend position", *La semaine juridique* 29 (1995), 288-290; Delvaux and Vandenhouten, *supra* note 91, 231; Leleu en Genicot, *supra* note 91, 212; Leenen, Dute, Gevers *et al*., *supra* note 76, 501.

[175] Delvaux and Vandenhouten, *supra* note 91, 231.

[176] Grubb, Laing and McHale, *supra* note 117, 994.

[177] Jones, *supra* note 117, 853.

[178] Fagnart, *supra* note 165, 20.

[179] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, *O.J. L.* 15-01-2012, 11/4; S. Van Camp, "Productveiligheid en Product recall", *TBH* 6 (2010) 454.

[180] Article 2, e), iii) Product Safety Directive.

[181] C. Hodges, M. Tyler and H. Abbott, *Product safety* (London: Sweet & Maxwell, 1996) p. 96; D. Van de Gehuchte, *Productaansprakelijkheid in België* (Ghent: Mys & Breesch, 2000) p. 77.

[182] In the same sense, see: Wijne, *supra* note 91, 334.

[183] Cornelis, *supra* note 89, 1143.

[184] Peigné, *supra* note 89, 300.

[185] Wijne, *supra* note 91, 334.

[186] Judgment of the Court 10-05-2001, *Henning Veedfald*, C-203/99, *European Court Reports* 2001, page I-3569, recitals 17-18.

that this product is put into circulation.[187] Since the European Court of Justice said that a perfusion fluid used to prepare a human organ for transplantation is put into circulation, it must be assumed that the (flawed) organ itself – which is prepared for transplant – is also put into circulation.[188] After all, it is not relevant that the product did not leave the hospital.[189] For that reason, we believe that the producer of a defective organ may not rely on this defence.

4. Overall conclusion

The purpose of this article was to determine how the liability goals of compensation and prevention are attained with regard to DTOT in order to provide policy considerations for legislators. For this, we examined both fault liability regimes and the European strict product liability regime. As to the application of fault liability for DTOT, we can conclude that this is not a particularly recipient-friendly means of providing compensation for the loss of the recipient. The burden of proof relating to faulty conduct and causation is quite heavy. Locating faulty conduct is especially hampered by the complexity of the organ transplantation procedure. A lot of different parties are involved and many of their actions are technical actions which require expert insight in order to be verified. The parties most easily targeted for liability claims are obviously the medical teams and hospitals. However, they are generally granted a rather wide margin of appreciation, which often makes it difficult to label their conduct as faulty. Furthermore, the fact that often other factors than the organ transplant could theoretically explain the disease contraction provides an easy defence for the defendant. Consequently, achieving prevention of DTOT risks is possible, but limited by these hurdles as well.

As to the application of strict product liability for DTOT, the recipient might still have difficulties in establishing causation. Yet, the recipient will no longer carry the burden of proving faulty conduct. Instead, he will have to establish the defectiveness of the organ, which will be easier. As we have seen, it will probably be rather difficult for the medical team or the hospital to free themselves from strict product liability for DTOT. Thus, it appears that strict liability will be much more recipient-friendly in view of providing compensation for the DTOT related losses. Consequently, strict product liability will provide a stronger incentive for prevention of DTOT risks. However, the European product liability regime might even lead to the liability of the medical team or hospital when it was impossible to prevent DTOT. Instead of creating beneficial incentives for prevention, strict product liability might thus deter transplant professionals from performing some transplants entirely, which could be detrimental to patients on the organ waiting lists.[190] A more flexible interpretation of the requirements for product liability would lower deterrence, but would lower chances for recipient compensation at the same time. We hope that these insights may guide legislators in defining their policy on quality and safety of human organs for transplantation.

[187] Fagnart, *supra* note 115, 212; Vansweevelt and Weyts, *supra* note 89, 537.
[188] In the same sense, see: Peigné, *supra* note 89, 299 and Albert, *supra* note 32, 2189.
[189] Wijne, *supra* note 91, 377.
[190] Compare: *Hutchins* v. *Blood Services of Montana* [1973] 506 P.2d 449 (Supr.Mont).