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# **CIT-PART: Report Case Study Netherlands**

**Wyske Versteeg**

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**Research Report**

**CIT-PART  
Report Case Study Netherlands**

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**September 2011**

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## 1 Introduction

In the mid 1990s, xenotransplantation – the process of grafting or transplanting organs or tissues between members of different species – was conceived of as a promising but risky new technology. At the end of that decade several governments in Europe asked their citizens for an opinion about xenotransplantation, while simultaneously acknowledging that it could take years before this technology would be feasible in medical practice. The way in which subsequently decisions were made, and the topic was regulated, varied greatly between countries (see Biegelbauer and Hansen, 2011). This report focuses on the way political judgment and decision-making on xenotransplantation developed in the Netherlands.

Interesting about the way in which the topic was regulated in the Netherlands, first, is that xenotransplantation got formally banned. On May 14, 2002 the First Chamber of the Dutch parliament voted about a change in the Law on exceptional medical procedures. The adjustment voted for implying a ban on xenotransplantation, that is, according to the bill “a treatment, at any moment during which components of an animal are inserted or added to the human body. Not only (parts of) organs are to be regarded as components, but also tissue, (collections of) cells and parts of cells, including cell content”.<sup>1</sup> The reasons for the ban were the risks potentially involved in xenotransplantation for public health: viruses from animal tissue might spread in the human host and human population.<sup>2</sup>

Comparing xeno-related developments elsewhere in Europe and Northern America, this development as such may not seem surprising. In 1999, for instance, Norway promoted a temporary ban on xenotransplantation, while a voluntary moratorium in Sweden ceased clinical trials in this biomedical field (Brown et al., 2010). Yet, interestingly, only four years prior to this change of law, the Dutch cabinet wrote a letter to Parliament that was strongly in favor of stimulating and developing xenotransplantation, notably as a resolution for the shortage of donor organs that was considered too high (Second Chamber, 1998–1999, 26 335, no. 1). What happened in the time lapsed, that such a radical change in perspective was brought about?

A second element of interest in the Dutch handling of xenotransplantation is that it was made the focal topic of a so-called ‘public debate’ that was organized on the initiative of the Health Council and the Dutch parliament. Between December 1999 and December 2001 the public was actively engaged in discussions on the topic of xenotransplantation, and its desirability.

<sup>1</sup> Special Medical Procedures Act (WBMV: Wet op bijzondere medische verrichtingen), as on 17-05-2010, section 2, article 6a.

<sup>2</sup> As is argued in the explanatory note: the change in law is “to avoid medical xenotransplantation procedures to be conducted with humans, without reasonably excluding unacceptable risks for the health of humans. This applies not only to risks for the experimental subject/patient. At least as important is to reasonably exclude unacceptable risks for his environment, and therewith for the public health” (Special Medical Procedures Act). The bill is passed on the nod, without further discussion or voting.

In October 2001, the results of the public debate were presented to the Minister of Health. This public engagement is of interest in particular because an overview of regulation dynamics of xenotransplantation Brown et al. (2010) suggest that nowhere in Europe citizens have been more explicitly and actively involved in debating xenotransplantation. Did this participatory event impact the way the xenotransplantation issue was regulated, and if so, in what way?

These questions are relevant as their answers may shed light on the way so-called 'intractable policy issues' can be dealt with, and on the potentiality of the impact that public engagement in decision-making on such controversial issues may have. Intractable policy issues are controversies that appear on the policy agenda and that entail disagreement about relevant empirical facts, as well as dissent about the normative framework by which to assess the correctness of facts and their relevance (Hisschemöller and Hoppe, 1996; cf. Schön and Rein, 1994). Because these two aspects intersect, such controversies cannot be dealt with, it is assumed, by using the instruments and procedures of routine political debate (Pellizzoni, 2001). The way in which xenotransplantation was dealt with in the Netherlands may be considered an informative example of regulating intractable policy issues. Taking this perspective, the leading questions of this report read:

- How did processes of political judgment and decision-making on xenotransplantation in the Netherlands take place between 1996 and 2003?
- In which ways was the public engaged, and to which extent did that have an impact on judgment and decision-making practices in the policy field at issue?

The way in which public engagement was given shape in the Netherlands is understood in this report as a manifestation of so-called participatory technology assessment (PTA). As concerns the issue of impact: this was conceptualized in the CIT-PART project's deliverable 2 as 'those changes in the interpretive frames and actions of relevant actors that can plausibly be related to the project taking place, both on the basis of the views of the involved actors themselves and on the basis of reasoned arguments by the investigating outsider' (Biegelbauer et al., 2010). In this report, we will elaborate this perspective on the basis of the Dynamics of Contention-theory, and will discuss the impact of the Dutch xenotransplantation debate in those terms as well (cf. Loeber et al., 2011). It will be argued that an assessment of the impact of a particular debate should not be restricted to a one-off moment in the decision-making processes it seeks to address, if only because such PTA debates do not take place in isolation from wider societal and political deliberation.

This is the reason why, in addition to information on the PTA, information on the Dutch political system in the period under scrutiny (1995-2005) is featured in this report, and on the way in which policy issues that were considered technologically complex and ethically sensitive were regularly dealt with at the time. Hence, contextual aspects of science and (bio)technology-related policy-making practices will be elaborated, in addition to a



chronological description of the xeno-related events against this backdrop, the report will in conclusion formulate an answer to the question:

- To which extent and how does the Dutch handling of the xenotransplantation issue present an example of dealing with intractable policy issues?

Below, we will first give general background information about the Dutch political system (chapter 2) and specifically, the policy field of biomedicine and innovation technology (chapter 3). We will subsequently present a chronological narrative of the development of xenotransplantation as a Dutch policy issue (chapter 4). We will then discuss the case in more detail, focusing on the various social fields and social practices (chapter 5). We proceed with a discussion of the conceptualization of the Dutch public and its right to speak (chapter 6), and of the impact of the PTA (chapter 7) and finish, by way of conclusion, with answering the research questions formulated above (chapter 8).

## 2 The political system

The Dutch political system can be characterized by a striving for consensus and compromise. The government consists of coalitions of usually two or three parties. The parties most often represented within these coalitions from the early 20<sup>th</sup> century onward are the leading confessional parties (since the 1980s merged into the Christian-Democratic Appeal CDA), the liberal conservative (center right) party (the People's party for Freedom and Democracy VVD), the labour party (PvdA), and since the mid 1960s, and D'66 (Democrats '66, a social liberal party).

The legislature consists of two chambers. The lower house or Second Chamber is the best known and arguably the most powerful. Its 150 members are directly chosen by the citizens, via a system of proportional representation based on a party list. The First Chamber or Senate has 75 members, who are indirectly chosen by the Provincial States (provincial councils). Whereas members of the Second Chamber are fulltime politicians and concerned with the details of day-to-day politics, members of the First Chamber are part-timers, who are not bound to a formal government program and focus only on the outlines of policy. The main task of the First Chamber is to revise draft legislation. The Second Chamber has the right of initiative, the right of budget approval, the right to amend bills and to reject aspects of bills. The First Chamber has the right to accept or reject bills, but not to amend them. Members of Parliament get their information from their own, rather modest staff, from the scientific services of the political parties, research institutes such as the Rathenau (see below) and from interest groups and social partners. Although the expertise available to the ministries by far outweighs that to parliament, the number of parliamentary resources has grown since the 1990's (e.g. by the new legal mandate of the Rathenau Instituut in 1994 and the establishment of the parliament's Research and Verification Bureau in 2002; cf. Halfman and Hoppe, 2005)

The executive-legislative relationship is, in theory, characterized by a system of dualism. The Second Chamber is independent: it determines its own agenda and procedural order, chooses its own chair and is responsible for its own budget. Formally, MPs vote without 'last of ruggespraak', that is, independently and without any commitments to anyone else. In practice, however, members of the Second Chamber are bound by a relatively tight party regime and coalition-party-MPs usually follow the government.

The Netherlands has a large and dominant bureaucracy, which, at the time of the xenotransplantation debate was to a large extent relatively directly attached to government. Especially important are several advisory expert committees, part of the highly interwoven corporatist system for consultation and co-optation known as the 'polder model'.

Courts do not exert a significant influence on political decisions. The Netherlands have no Constitutional Court. Together with Finland, the Netherlands is the only EU country in which courts are not allowed to test laws on the constitution. The rationale behind this is that this would inappropriately grant the judges legislative powers. The sole judicial review of importance here is that of the Council of State (*Raad van State*). The importance and depoliticized authority of the Council of State can be exemplified by the common saying that its chair is the viceroy of the Netherlands. Members of the Council of State are appointed by the Crown, that is, the Queen and her ministers. Its members are professors, former politicians, top civil servants and administrators, most of whom are jurists. The Council judges the quality of laws on formal and procedural grounds, thus functioning as the protector of legislative quality. Rulings of the Council of State cannot easily be ignored.

The electoral system is proportional and there is no “first pass the post”- rule. This allows small parties to enter parliament. There is an informal rule as not to allow a rest seat to parties who did not attain a seat of their own, amounting to an election threshold of 0,667%

**Table 1 The Dutch political system in terms of WP1 assessment criteria**

Category	Parameter values
Cabinets	coalition government
Legislature	two chambers
Executive-legislative relationship	independent parliament consensual
Bureaucracy	Large directly attached to government dominant
Judicial Review	of limited importance
Party System	numbers of parties in parliament > 3
Interest Group System	Corporatist
Direct Democracy	not important
Political Culture	strong civil society rich tradition in participation closed decision-making
Science Society Relations	strong role of experts
Constitutional division of territorial power	central state
Electoral system	Proportional

Due to this proportional system of representation, the Dutch parliament tends to consist of many political parties. After the election of 1994, no less than twelve parties were

represented in parliament, with their number of seats ranging from 37 for Labour (PvdA) to 1 for a party for senior citizens (Unie55+). By far the dominant parties at the time of and preceding the xenotransplantation debate were PvdA (37 seats), confessional democrats (CDA, 34 seats), the liberal right wing party (VVD, 31 seats), and social-liberal democrats (D'66, 24 seats).

The Netherlands has a corporatist interest group system. Interests of trade unions and employers are represented in the SER (*Sociaal-Economische Raad*, Socio-Economic Council), which is the major advisory council to the government, and consultation partner, on social-economic issues.

No instruments for direct democracy on a national level were provided for at the time of the xenotransplantation-discussion. A proposal for an advisory, corrective, binding referendum failed to win the required two third majority in the First Chamber in May 1999. From 2002 to 2005, there was a temporary referendum law, which led to referendums in three municipalities. Since May 2006, there is a procedure that enables citizens to put a certain topic on the agenda of the Second Chamber – at the time of writing, only one of these citizens' initiatives has made it to the Chamber. Obviously, direct democracy is of limited importance for the Dutch political system.

The political culture is heavily influenced by the corporatist tradition and the associated pillarization, although the traditional religious structures have lost ground to secularization and membership of political parties has decreased drastically. Nevertheless, Dutch civil society can be described as relatively strong. Civil society organizations are present in most sectors and there is a high degree of public spiritedness. In 1998, 66% of the Dutch population claimed to have undertaken some form of non-partisan political action, like writing a letter to a newspaper, signing a petition or attending a demonstration (De Nieuwe Dialog, 2006).

The role of scientific experts and expertise in society and policy-making is significant. The Dutch corporatist tradition of elite rule has led to a large number of advisory councils. This eventually became an issue in itself, with the result that in 1997, a law was accepted that abolished most of the existing advisory councils (with the notable exception of the Socio-Economic Council (SER) and the Council of State), and provided a new framework for the system of councils. It meant to make councils advice on the basis of knowledge rather than interests, and break out from their specific policy niche.

In terms of territorial power, the central state is far more powerful than the provinces: the Netherlands is a decentralized, but unitary state. The main tasks of the provinces are to implement national policies, to take care of spatial planning and environment, and to oversee the municipalities. As was mentioned above, members of the Provincial States elect the members of the First Chamber.

### 3 The policy field: biomedicine and innovation technology

Creating a strong structure for biotechnology research and development had a high political priority in the Netherlands in the 1980's. Industry research was subsidized and two programmes were established to stimulate biotechnological innovations. Between 1979 and 2004, two programmes presented major financial incentives for biotechnological research. Via the Innovation Oriented Research Programme Biotechnology (IOPb), and the Programmatic Industry-related Technology Stimulation on Biotech (PBTS), the Dutch **government** invested more than 178 million Euro's in biotech between 1981 and 1993; between 1994 and 1998, more than 150 million Euro was allocated via various public instruments. The focus on biotech shifted to more generic innovation policies in the 1990's, to shift back to biotech only in 1998. A benchmarking study from Moret, Ernst & Young had alarmed the government, in particular the Ministry of Economic Affairs: whereas in most of the compared countries and regions, the biotechnological sector was "growing", in the Netherlands it only "consolidated". In 1999, the Ministry therefore presented a Life Sciences Action Plan and the Biopartner programme, which aimed to establish at least 75 new life-science startups in the period 2000-2004. The budget for this was 45.3 million Euro. In 2001, the government presented the policy report *Genomics Knowledge Infrastructure*, which would result in the Netherlands Genomic Initiative with a budget of 189 million Euro between 2002 and 2007 (OECD, 2006: 76-77). Despite these investments in medical biotechnology, the general Dutch policy concerning genetic modification of animals tends to be characterized by the principle 'no, unless'.

Arguably the most conspicuous involvement of the **legislature** with the policy field was the case of the bull Herman, which had been genetically modified by Gene Pharming Europe. Herman was modified to be born with a human gene. This should allow cows to produce lactoferrin, a human protein, which could be used for medicine. Herman generated a public debate when he was 'born' in 1990, and it was discussed in the Second Chamber whether or not he should be allowed to breed.

Permission was granted, but in 1994, Herman would give rise to a conflict in the **executive-legislative relationship**. It turned out that the nutrition company Nutricia had secretly co-financed the experiment with Herman. Although the Ministry of Agriculture was aware of this sensitive information, it had not informed the Second Chamber. Not informing the Second Chamber meant that members of Parliament were unable to fully exercise oversight on this matter. After all, the Dutch "no-unless" regulation of genetic manipulation implied that no modification of animals was to be allowed unless it would be explicitly allowed, for reasons that it could help provide products of which there was a dire need, and no alternative was available. Because of this ruling GenePharming had creatively formulated the production of high levels of lactoferrin in the milk of Herman's female offspring as a research objective. The protein lactoferrin has antibacterial qualities and is conducive to the transport of iron in

blood. Consequently, in order to get a licence for the development of the GM-animal, this research objective could be qualified as necessary for medical reasons. However, had the involvement of Nutricia, a baby-food producing company, been known, it would have been clear that commercial rather than medical reasons were behind the permission request. In that case, parliament might have decided differently.

Another key debate took place in January 2002, when the Second Chamber and the government debated the white paper on biotechnology. Several speakers concluded that the paper - and thus biotechnology policy in general - lacked a framework by which to weigh ethical, technological and socio-economic questions. The biotechnological policy was characterized as ad hoc, instrumental and shallow. In general, however, the relationship between cabinet and parliament in all sorts of policy domains, including biotechnology, can hardly be called adversarial.

An important reason for this lies in the role of **bureaucracy**. Various expert committees play an important role in deciding about permit requests for biotechnological experiments, thus contributing to a gradual, case-by-case evolvement of a framework of what is or is not allowed. This practice in which the scientific committees are the only ones with sufficient expertise to decide about these permit requests contributes to the depoliticization of the policy field. Important committees in this regard are the CCMO (Central Committee for Research involving Human subjects) and the CBD (Committee for Biotechnology involving Animals). Given this system of expert committees in the tradition of the polder model, the **courts** are not very important for the policy field. There have, however, been some court cases between environmental interest or animal welfare groups and various ministries.<sup>3</sup>

At the time of the xenotransplantation discussion, the **political parties** were represented in Parliament as follows:

**Table 2 Division of seats in parliament 1994 and 1998**

Party	Number of seats 1994	Number of seats 1998
PvdA (labour)	37	45
CDA (confessional)	34	29
VVD (liberal right wing)	31	38
D66 (social-liberal)	24	14
AOV (one-issue / senior citizens)	6	0
GroenLinks (GreenLeft)	5	11
CD (right wing)	3	0
RPF (strict confessional)	3	3

<sup>3</sup> E.g.: Dutch Society for Replacement of Animal Testing *Vereniging Proefdiervrij* versus Ministry of Agriculture, LJN AU4809, Court 's-Gravenhage, AWB 04/1542 WOB (2005); Greenpeace and VoMiGen versus Ministry of Housing, Planning and Environment, Raad van State, 200702758/1 (2008).

Party	Number of seats 1994	Number of seats 1998
SGP (strict confessional)	2	3
GPV (strict confessional)	2	2
SP (socialist)	2	5
Unie55+ (senior citizens)	1	0

Thus, although there were some parties represented in parliament with potentially big interests in xenotransplantation (the GreenLeft and the orthodox Christian parties RPF, SGP and GPV), these parties did not have a sufficient number of seats to be of significant influence. The liberal VVD would generally emphasize the importance of stimulating business and industry via the development of new technologies, whereas the Christian democratic CDA was known to have objections against technologies with the potential to transgress moral orders. However, this party is more pragmatic than its orthodox counterparts; its typical stance might be characterized as a very Dutch combination of the minister and the merchant. D66 does have a specific interest in deliberative innovations such as PTA, as the party has always tried to introduce more mechanisms of direct democracy within the standing political system.

As the Dutch biotechnology sector is relatively small – measured in the number of people employed and / or otherwise involved in research activities – the **interest group system** consists of a tight intertwinement of policy and innovation networks. Scientific expertise, policy making and company interests meet, for instance, within the national advisory committee Health Council, which enables intensive, consensus oriented consultation between government and the various experts and other actors involved. Interests of firms specialized in medical biotechnology were and are represented by the interest group and lobbying organization Biofarmind. Despite this, the OECD concluded in 2006 that '[i]n general there is a lack of appropriate dialogue between the main stakeholders in biopharmaceutical innovation' (OECD 2006: 85). One of the systemic failures identified is the large number and heterogeneity of patient organizations, resulting in a lack of coordination that hindered them to reach a critical mass necessary to influence the industrial innovation process or facilitate clinical trials.

In terms of **political culture** and **direct democracy**, a Dutch tradition of arranging participatory technology assessments (PTAs) developed out of a societal call for a 'broadening of the basis for decision making on science and technology' (Ministry OC&W, 1984) resulting in 1983 in a White Paper that sought to enhance the integration of science and technology in society. The paper propagated technology assessment (TA) as a practical instrument to do so. In 1986, in line with the Paper's intentions, the Netherlands Organization for Technology Assessment (NOTA) was founded as an independent advisory institute to the Dutch Parliament. In spite of its conceptual background, the organization in its early years

did not systematically explore possibilities for public participation in opinion forming and decision-making. Rather, in the practice of translating societal concerns into policy advice, an emphasis was put on the consultation of experts on particular technological and societal issues. When in 1993, in an evaluative study after its first five-year period the organization was seen to fail to live up to the original expectations (Van Eijndhoven 2000: 154-155), its mission was re-defined as contributing to social debate and political opinion forming on issues that are the result of, or are connected with, scientific or technological developments, including the ethical aspects of these developments (cf. Rathenau Institute, 1994: 9).<sup>4</sup> With the re-emphasizing of the public's role in the reformulation of this institute's remit, participatory technology assessment became an almost default policy instrument in all Dutch policy-making on technological issues. Within this climate, and given the technology assessment institute's reformulated remit, various societal debates were organized, especially on biotechnological and medical-biological issues: the xenotransplantation debate was preceded by debates about the genetic modification of animals (1993), predictive genetic research (1995) and cloning (1998/1999). Like the xenotransplantation discussion, these debates were state-initiated, and fitted well within the Dutch government's emphasis on actively seeking to involve citizens in processes of policy-making and policy advice of the time (cf. Akkerman et al 2004). Pointing at a certain extent of "self-evidence" in the Dutch inclination towards participatory arrangements, Van der Heijden (ed. 2005) provides an apt image of participation in the Netherlands when he states that "[e]very policy issue in any one phase [of the policy process] requires a suitable interactive process" (2005:21, our translation).

This national folklore of 'engaging the public' was frowned upon by some critiques. A commentator in the national, Guardian type newspaper *De Volkskrant* for instance commented on the 'Public debate on command' (Van Kleef, 1995):

Is it possible to initiate a debate when any germ for such a debate is absent among the public? ... A public debate implies that a broad circle of people acknowledges that something bad is going on. Something like the 'three of Breda' [war criminals that were considered eligible for a release from prison], Poncke Princen [a controversial human rights activist], the recent flooding. That kind of things. The discussion about those themes searches a natural bed in society and ends in The Hague, where the decisions have to be taken.

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<sup>4</sup> A change of name – the organization now was called the Rathenau Institute – accentuated its changed (or rather, re-stated) mission. With the emphasis now clearly put on public debate, positioning research in a more supportive role, the acronym NOTA – of which the final two letters represent the Dutch translation of 'technology assessment' featuring the word 'research' (*technologisch aspectenonderzoek*) – was considered to bear the wrong connotation. Hence the change of name, the new institute being named after Professor Rathenau, who had been one of the pioneers in promoting analysis-supported debate on science and technology.



Yet, in general in the Netherlands, participation was looked upon in a way similar to milk consumption. With comparable 'automatism' as the Dutch after years of exposure to campaigns that said that 'Milk is a Must' and 'Milk is Good for All' pour their glass-fulls mornings and afternoons, policy-makers and policy advisors embrace participatory approaches to policy formation and advice. An empirical investigation in the late 1990s showed that only some 15 percent of the municipalities had not experimented with 'interactive' policy-making, while 75 percent at the time were planning further interactive projects (Van de Peppel, 2000: 41). This emphasis was echoed in the practices of involving publics on science and technology.

In terms of **science-society relations**, important intermediary organizations between scientists and funding organizations – such as ministries – are the Royal Dutch Academy of Science (KNAW) and the Netherlands Organization for Scientific Research (NWO). There were 18 graduate schools active (to a greater or lesser extent) in biopharmaceutical research in 2003. A mediating organization between science and 'the public' is the 'Foundation Knowledge, Science and Technique' (*Stichting Weten*). The number of dedicated biopharmaceutical firms created in the Netherlands grew from 18 in 1994 to 80 in 2001. Most of these firms had only a small number of employees: the average in 2001 was 23 per firm. There have been a significant number of pre-clinical trials in the Netherlands – 640 in 2002 – although a decrease has occurred since 2000 (OECD 2006: 78-80). There were a few scientists involved in xenotransplantation research in the Netherlands; among these few was the most prominent Frank Grosveld. His research at the Erasmus University in Rotterdam, the Netherlands, was co-financed by Imutran, a British Novartis-owned company, which was leading in xenotransplantation-related research, animal breeding and experimentation. Novartis in turn was a leading party in the development of immuno-suppressing drugs, developments that were quintessential for the prospect of xenotransplantation. Immuno-suppression was among the major research interests of Dutch medical research. Intermediaries between innovation firms and funding organizations were Biopartner and SenterNovem.

With regard to the **demand** for xenotransplantation, one could point to the above mentioned lack of coordination between patient organizations. Furthermore, although patient organizations were cautious not to exclude any future possibilities, they were not very enthusiastic about xenotransplantation, focusing instead on improvements in the donor registration system. Scientists' requests for research permits were a stimulus for the discussion about xenotransplantation. However, this can hardly be called a strong demand.

Within the Netherlands, there is no **territorial** division of any relevance for this policy field.

**EU policies** affect the Dutch political system, but it is hard to quantify to which extent. For instance, Geuijen, 't Hart et al. (2008) conclude: 'although nobody doubts the large and increased significance for how the Netherlands is governed, the number of Dutch central

government bureaucrats actively engaged in EU matters is still modest' (2008: 130). A pilot monitor of EU influence on Dutch regulation observed big differences between different policy fields: whereas in the field of education, at least 6 % of Dutch regulation had been influenced by EU jurisprudence, this was at least 66% in the policy field of environment (Douma et al., n.d.). The percentages given by the monitor are, however, purely quantitative: researching this by qualitative methods might yield more nuanced results. In any case it seems safe to conclude that the level of EU influence is highly dependent upon the policy field involved. To our knowledge, the level of EU influence on the policy field of Dutch biotechnology has not yet been systematically studied.

## 4 The Dutch xeno story: a chronology

The Dutch debate on xenotransplantation is, and should be seen as, part of the wider debate on biotechnology. The public discussion about biotechnology makes an early start when a research group from Leiden University in the second half of the 1980s started to genetically modify a Dutch national symbol par excellence, the cow. This research resulted in the birth of the famous bull Herman in 1990, the genetically modified animal that became emblematic in the Dutch biotechnology discussion. The study received national and international media attention, and caused protests from animal rights activists and questions in parliament. The heated debate led to an exceptional law, which was published in 1992. Whereas previous animal laws allowed actions with animals, unless otherwise specified, the new regulation reversed this principle. The so-called *Gezondheids- en Welzijnswet voor Dieren* (Law on Animal Health and Welfare, GWWD) banned from then on all biotechnological procedures with animals; permits were only to be granted when an important societal interest would be served. This became known as the “no unless”-principle (*nee tenzij*). The GWWD presents a ‘framework law’ (*kaderwet*); it becomes effective only by means of the more detailed regulations formulated within its frame, so that the law can be adjusted relatively easily to new technological and societal developments. In this way, the government reacted to the lack of normative societal consensus concerning biotechnology; the new policy left regulatory space (‘unless’) open for new developments while simultaneously showing respect (‘no’) for the doubts about the possible risks of the new developments, and for the concerns about the intrinsic value of animals. ***This ‘two-faced’ policy implied that expert commissions would play an important role in developing and demarcating the Dutch biotechnology policy practices.*** The exact demarcations of the new policy – when is the ‘unless’ justified? – would be judged **per case** by an expert committee. It was within this regulatory context that the issue of xenotransplantation appeared on the policy agenda.

The period in which xenotransplantation became a political issue, was an exceptional one in Dutch politics. Confessional parties had been represented in all Dutch Cabinets since 1918, but from 1994 to 2002, liberal and social democratic parties formed the so called Purple Cabinets: Kok I (1994-1998) and Kok II (1998-2002). The coalition between the social-democratic PvdA and the liberal VVD became possible both by changes within the PvdA, and by a shared distrust of the powerful Christian democratic CDA. The third participant in the purple coalitions is D66, the social-liberal party. D66 is known for its liberal perspective on health care themes (e.g. abortion, euthanasia). During the xenotransplantation debate, the Minister of Health, Welfare and Sport (hereafter VWS) was dr. Borst-Eilers from D66.

On December 31, 1996, dr. Borst formally asked the Health Council for an advice regarding xenotransplantation. Her request was prompted by signals that important progress had been made regarding the transplantation of organs of animal origin to humans. In fact, the Health Council was probably itself responsible for one of these signals; in its annual advice

1994/1995 the Council observed a renewed scientific and social interest in xenotransplantation.

The Health Council presented its advice with respect to xenotransplantation on January 21, 1998. The Council points to the problematic rejection of transplanted material, and observes that it is too early for any conclusion regarding the future viability of xenotransplantation as a clinical technique. However, the Council deems it important to consider ethical questions while the technique is still at an early stage of development. The Council believes that, from a human point of view, xenotransplantation is ethically acceptable, and will be capable of alleviating the suffering of people with certain medical conditions. On the other hand, it is recognized that some people may, for cultural or religious reasons, disagree with the committee's conclusions regarding the morality of using animals for xenotransplantation or implanting animal organs into humans. The committee would consequently like to see information made available and the encouragement of public debate on these matters (Gezondheidsraad, 1998).

The Health Council based its opinion in part on three other reports that were published in 1997 and 1996, in the United Kingdom and the United States, by, respectively, the Nuffield Council of Bioethics, the Kennedy Committee and the Institute of Medicine.

On November 27, 1998, the government presented its point of view regarding xenotransplantation to parliament. Referring to the report of the Health Council, the government concluded that restraint regarding the practical (clinical) application to humans was in order, but also that it had not yet been proven that there were other reasonable possibilities for solving the shortage of transplantation organs. The thought that when xenotransplantation would prove to be clinically applicable to humans, and when at that point, there would still be insufficient other possibilities to help patients with badly functioning organs, xenotransplantation would, in principle, be ethically acceptable. The interest in xenotransplantation of patients in need of a replacing organ outweighed the objections that could be formulated against the keeping and using of (genetically modified) donor animals. The government therefore did not want to formulate a (legally regulated) moratorium on xenotransplantation, as had been argued for by, in particular, the Dutch Society for the Protection of Animals (NVBD) respectively the association Proefdiervrij, in reaction to the Health Council advice. The government felt itself supported in its opinion by the content of the reactions to the Health Council advice, as formulated by the Council for Animal Affairs (RDA) and the Dutch Society of Animal Experiment Committees (NVDEC). The shortage of human donor organs justified, according to the government, also the opinion that in principle, further research into other treatment possibilities should be allowed to proceed, such as research into the use of animal organs or artificial organs and research into gene therapeutical treatment options. The government considered it to be self-evident that, when considering respectively permitting concrete research proposals, it had to be judged in advance whether these specific actions were ethically and societally acceptable, and under

which conditions, in accordance with relevant regulations. It specified that this applied both to permits for research involving animals (regulated by the Law on animal experiments or the Health- and Welfare act for animals), to permits within the framework of environmental regulation, and to permits within the framework of the Law medic-scientific research involving humans. For research using animal experiments a specific judgment criterion is the acceptable welfare level for the animals involved, which includes for instance appropriate housing conditions (Second Chamber, 1998-1999, 26 335, no. 1).

With regard to the organization of a public debate, the government stated in its letter:

The Government agrees with the Health Council that it is important that society is well informed about the aspects that play a role in xenotransplantation. It therefore wants to follow up on the argumentation of the Health Council to give adequate information and to have a societal discussion about the use of animals for xenotransplantation goals, of about implanting an animal organ in a human. We will therefore consider if it is possible to start with giving general information about this topic. We expect that this information campaign will give rise to a public debate about this topic. The discussion about xenotransplantation will then as much as possible be conducted in connection to the previously announced societal debate about medical-ethical questions (Kamerstukken II, vergaderjaar 1997- 1998, 25600, no. 8). However, the results of such a public debate are not expected any time soon. The Government does not want to wait for these results, but wants to take the measures as mentioned (...), so that further research will occur under utmost security for the animals and humans concerned (Second Chamber, 1998-1999, 26 335, no. 1).

The Government also emphasized its trust in the role of expert commissions within ethical deliberation and public debate:

The Government wants to point out that in certain cases, there are already possibilities for a public debate. If for instance to the benefit of xenotransplantation research in the Netherlands biotechnological actions are performed on animals, the Health- and Welfareact for Animals requires that a permit has to be granted for those actions by the Ministry of Agriculture, Nature and Fishery. Criteria for judgment in this regard, are that the actions should have no impermissible consequences for the health and welfare of the animals, and that there are no ethical objections against the actions. The chosen exhaustive, public procedure aims for an optimal societal contribution to the process of judging the permit requests (Second Chamber, 1998-1999, 26 335, no. 1).

Deliberation about the appropriate governmental attitude regarding xenotransplantation also took place in several intergovernmental and supranational organizations, to which Dutch policy makers have close connections. For instance, the World Health Organization organized a consultation on xenotransplantation in October 1997 (WHO 1997: WHO/EMC/ZOO/98.2). In May 1996, the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology had already formulated an opinion on the ethical aspects of genetic modification of animals, e.g. as an alternative source of tissues and organs for xenotransplantation (Schroten et al., 1996). The responsible *rapporteur* was prof. Schroten, chairman of the Dutch Committee on Biotechnology involving Animals. According to Schroten, the Dutch approach to the issue was quite unique, worldwide, as nowhere else requests for research permits were assessed not only on the basis of criteria regarding animal health and welfare, but also regarding “infringements on the integrity of the animal” as the Dutch CBD did (pers. comm. interview 2; see section 5.2.3).

In March 1998, the OECD organized a workshop about xenotransplantation, which was attended by participants from 26 countries. In January 1999, the Parliamentary Assembly of the Council of Europe published a recommendation, which advised the Committee of Ministers to work on the rapid introduction of a legally binding moratorium on clinical xenotransplantation in all member states. One of the *rapporteurs* was mr. Dick Dees, at the time also a (VVD) member of the Dutch First Chamber.

When the Minister of Health meets with the First Chamber in March 1999 - the first purple Cabinet has by then made way for the second, but dr. Borst-Eilers remains minister - the recommendation is discussed, because ‘Mr Dees was surprised and also somewhat worried about the fact that there is no plan for a legal moratorium, also because of the unanimous recommendation of the Council of Europe’ (First Chamber, 1998-1999). Minister Borst discusses in her answer the desirability of a legal moratorium. One of the recommendations of the Health Council was that the Central Committee for Research involving Humans (hereafter CCMO) – which is to be established as the result of the new Law on medical-scientific research involving humans – should judge the protocols in clinical cases of xenotransplantation, and the Minister agrees with this. The Minister posits:

The difference between Mr. Dees – and maybe Mrs Tuinstra as well – and me, is in the following. I think that, when we have such a central committee, in which we have put people that we consider to be capable of judging whether or not a study is acceptable, we should trust that committee. When we say that the opinion of the committee is not that important, because we will legally impose a moratorium, this testifies of limited trust in respect of the committee (First Chamber, 1998-1999).

In May 1999, the Minister further clarified the government’s point of view regarding xenotransplantation. She announced that she has given a subsidy to the Foundation

Consumer and Biotechnology (*Stichting Consument en Biotechnologie*, C&B) for the implementation of two phases of a public debate on xenotransplantation and medical biotechnology, i.e. for conducting a ‘quick-scan’ and for a public information campaign. These phases were to be completed in the beginning of next year and should provide information about xenotransplantation, including the ethical aspects of it, in a way ‘that is specific and understandable, also for citizens. This is the start for a broader – societal and political – discussion. The results of the discussions will’ – as the Minister put it – ‘obviously be able to be one of the influences on the future Dutch policy regarding xenotransplantation’ (Second Chamber, 1998–1999, 26 335, no. 3).

On December 1, 1999, a new Law on medical-scientific research involving humans became effective, and the CCMO was established. According to the Minister, this amounted to a *de facto* moratorium on xenotransplantation, as the CCMO was made the sole committee with discretionary power on matters of xenotransplantation, and this committee was to decide against any research activity that would bring along ‘unacceptable risk of infection’ with zoonotic viruses (Second Chamber, 2001-2002, 28 2843, no. 3). However, parliament was not necessarily convinced of this. For instance, PvdA MP Swildens-Roozendaal states:

‘There should be not a single misunderstanding that the PvdA is very critical and cautious with regard to xenotransplantation. (...) We still have to have the societal debate. We therefore assume – I hope the Minister will confirm this – that for the central committee, which is allowed to judge proposals as of tomorrow, there will be not a single misunderstanding: no research is allowed until we have finished the debate and given the green light. Finishing the debate is not enough’ (Second Chamber, 1999, 28-2101).

The Minister promised to honor this request of the Chamber, but a few days later, it turned out that she could not: ‘the General Administrative Law and the factual circumstances together make it difficult for me to require this from the chairman of the CCMO’ (Second Chamber, 1999–2000, 22 588, no. 30).

In the US, January 2000 was declared the ‘national biotechnology month’, and the American embassy in The Hague organised a biotechnology conference. Minister Borst, with Ministers Jorritsma (Economic Affairs) and Brinkhorst (Agriculture) were present – a clear indication of the importance of biotechnology as a policy theme in the Netherlands. During the conference, Jorritsma argued that the Netherlands is to become a forerunner in biotechnology. Borst criticized hypocrisy in the Dutch attitude: at first, there are strict rules for transgenic animals which make it impossible for companies such as Pharming to conduct their experiments in the Netherlands, but afterwards, the Netherlands does want to use the medicines resulting from these experiments. This statement later led to a small parliamentary discussion, in which the Minister was questioned about wanting to abandon the “no, unless”- principle. In response, the Minister emphasized that the “no, unless” –

principle is, should be, and will probably remain government policy. She posited, however, that

‘nevertheless, the advantages, or should one say, blessings of [biotechnology] are big enough for the three of us [i.e. Ministers of Health, of Economic Affairs and of Agriculture respectively] to take a positive attitude. This attitude is shared with all colleagues in the Cabinet’ (Second Chamber, Minister answering MP-questions, 25 januari 2000).

On February 2, 2000 Minister Borst and the Second Chamber organised a general meeting to discuss xenotransplantation. At that time, two permit requests were waiting for CCMO approval. The 661D article of the Health- and Welfare act for Animals had still not been effectuated; the Minister of Agriculture was waiting for the parliamentary discussion about the policy paper Biotechnology, and the evaluation of the Decision Biotechnology and Animals, in order to decide whether or not to effectuate 661D. Important topics of debate were the appropriate role of politics vis-à-vis expert committees in regulation of xenotransplantation, and whether or not science should be allowed to proceed while the public debate had not yet been finished.

In a reaction to the parliamentary debate of February 2, research agency NIPO published a report (n=1280) about the public attitude regarding xenotransplantation. Fieldwork for the report had been done between the 4<sup>th</sup> and the 7<sup>th</sup> of February. NIPO concluded that 55% of the Dutch population thinks xenotransplantation is acceptable; 68% sees no principal disadvantages to the purgation of human blood via pig cells (73% of men, 63% of women). The elderly see more disadvantages to the technique than young people do; the least supportive of xenotransplantation are the adherents of the conservative Christian parties (SGP, RPF, GPV) (NIPO 2000). The Minister notified the Second Chamber of the report.

On February 8, 2000, Minister Borst met with the Second Chamber for a plenary debate about xenotransplantation. The primacy of politics became again the subject of debate [see under 6]. During the debate, several motions for different versions of a moratorium were put forward. One of these, the motion Terpstra/Swildens-Rozendaal got support from members of the VVD, SP, PvdA and GroenLinks, and was therefore accepted. The motion explicitly stated that it does not want to inhibit pre-clinical research into xenotransplantation under strict circumstances and based on the “no, unless-principle”, but argues that the risks of clinical research and application of xenotransplantation are too big to be acceptable. It furthermore excluded the two (clinical) studies for which permits were requested from the moratorium, which should be legally confirmed first by a temporary change in the Law on Exceptional Medical Procedures, and then by law. The moratorium amounted to a ban on clinical research and applications of xenotransplantation. The motions proposing more radical versions of a moratorium – e.g. including pre-clinical research during the societal debate – were rejected.



In July 2000, a first version of the report of the Workgroup Xenotransplantation of the Council of Europe was made public. In August 2000, newspapers reported that Geron – part of the Roslin Institute – had stopped research into xenotransplantation, which led to questions in parliament. In September 2000, the white paper biotechnology was sent to parliament. In October 2000, Member of Parliament Poppe voted to make the meetings of the Committee on Animal Biotechnology open to the public, because: *‘there are no fundamental reasons for the deliberation and decision making process of the advisory commission to take place behind closed doors, and the desired public debate will be served by openness and transparency in this regard’* (Second Chamber, motion Poppe). The proposal was rejected.

In September 2000, the Ministries of OCW (Education, Culture, Science), VWS (Health, Welfare, Sports), VROM (Traffic, Spatial Planning, Environment), LNV (Nature and Fisheries) and EZ (Economic Affairs) published a White Paper on Biotechnology. The paper mentioned the moratorium on xenotransplantation, commenting that *‘It were not so much the principal-ethical reasons that prompted a moratorium on xenotransplantation; more important was the opinion that xenotransplantation is currently still connected to too many unknown risks’* (Cabinet 2001: 44).

The public debate about xenotransplantation was held in the winter season of 2000-2001. The preceding information campaign had officially started in December 1999 and had been organized by the aforementioned small consumer organization Foundation Consumer & Biotechnology (C&B). The same organization would also instigate and oversee the various activities of the public debate.

In July 2001, the Minister informed Parliament that the Council of State had warned her that the proposed temporary moratorium – by means of a General Order in Council [in Dutch: amvb] – is only appropriate when the circumstances ask for emergency regulation. As no further clinical xenotransplantation research was at the time prepared or implemented, this emergency regulation was not necessary. The Minister therefore prepared a law proposal amounting to a legal ban on xenotransplantation as was proposed by Terpstra/Swildens-Rozendaal.

In October 2001, the Minister informed parliament about the results of the public debate, about which a report was published in August. The Minister concluded that

‘the hope that I have expressed earlier, namely that the public debate would result in a wide range of opinions, questions and preferences from the Dutch society, seems to me to have been fulfilled to a considerable extent. Regarding the opinions of the participants about xenotransplantation, I observe that, according to the report, thinking about xenotransplantation is nevertheless very nuanced and diverse. (...) I am pleased that the participants are aware of the many aspects connected to

xenotransplantation. Whereas the (new) use of animals and the consequences thereof form a reason for part of these people to be against xenotransplantation, others find the goal more important and see no principal difference with the use of animals for other goals. Also, in general, the goal is regarded important enough to not principally reject xenotransplantation. This is, as you know, in agreement with my ideas regarding the subject' (Second Chamber, 2001-2002, szw0000895).

The proposal for the adjustment of the Law on Exceptional Medical Procedures was published in March 2002. The adjusted law still provides possibilities to adapt to possible future developments. Awaiting these, clinical xenotransplantation was legally banned when the First Chamber ratified the proposal, and the Law was officially published in July 2002.

Thus, whereas MPs referred frequently to the public, and to the importance of the societal debate, political decision making about xenotransplantation developed entirely separate from the public discussion. Moreover, the ban was prompted more by a concern about the possibly uncontrollable risks of xenotransplantation, than on the basis of an ethical discussion.

**Table 3 A short chronology of the Dutch xenotransplantation debate**

<b>1996</b>	Minister of Health formally asks Health Council for an advice regarding xenotransplantation.
<b>1.1998</b>	Health Council presents its advice on xenotransplantation saying that it is too early for any conclusion regarding the future viability of xenotransplantation as a clinical technique. However, the Council deems it important to consider ethical questions while the technique is still at an early stage of development, and therefore recommends that information should be made available and public debate encouraged. (Gezondheidsraad, 1998). In a letter to parliament, the cabinet agrees in important respects with the Health Council's perspective regarding xenotransplantation. The letter is in favor of stimulating and developing xenotransplantation, notably as a resolution for dealing with the shortage of donor organs that is considered too high.
<b>3.1999</b>	Minister meets with First Chamber, and argues, among other things, that trust should be placed in expert committees such as the Central Committee for Research involving Humans (CCMO), rather than in a legal moratorium
<b>5.1999</b>	The Minister announces that she has given a subsidy to Foundation Consumer & Biotechnology ( <i>Stichting Consument en Biotechnologie</i> ) for the public information campaign on xenotransplantation and medical biotechnology.

<b>12.1999- 2.2000</b>	Public information campaign
<b>2. 2000</b>	The Minister meets two times with Parliament to discuss xenotransplantation. During a debate on February 8, several motions for different versions of a moratorium are put forward. One of these, the motion Terpstra/Swildens-Rozendaal gets support from members of the right-wing liberal party VVD, socialist party SP, labour PvdA and left-wing greens GroenLinks, and is therefore accepted. The motion states that it does not want to inhibit pre-clinical research on xenotransplantation under strict circumstances and based on the “no, unless-principle”, but argues that the risks of clinical research and application of xenotransplantation are too big to be acceptable. Motions proposing more radical versions of a moratorium – e.g. those calling for a ban that would include pre-clinical research, at least during the societal debate – are rejected.
<b>2.11.2000- 20.4. 2001</b>	Public debate
<b>7.2001</b>	Minister proposes the moratorium to be changed into a legal ban, for technical judicial reasons
<b>8.2001</b>	Final report of public debate is published, and presented to the minister
<b>7.2002</b>	The adjustment of the Law on Exceptional Medical Procedures is published and made official, legally banning clinical research and applications of xenotransplantation.

## 5 The xenotransplantation –related developments in view of social fields and practices

In this chapter we locate the process of regulating xenotransplantation within its wider context of social fields and social practices as described in chapter 3.

### 5.1 Social field of policy making

Within the Ministry of Health, xenotransplantation became the responsibility of the division Ethics. This was, for one, because the topic potentially involved several ministries: not only the Ministry of Health, but also that of the Ministry of Agriculture, the Ministry of Economic Affairs and the Ministry of Spatial Planning (then VROM). A second reason for this was that (pers. comm. interview 14):

‘All things of which you could expect that there are different ideas about it in society, and/or in politics I should say, at the left and at the right or at the top and at the bottom to put it like that, yes, those [topics] end up with us’.

Despite this potential for controversy, xenotransplantation was to a large extent dealt with by routine policy making practices. This applies, for instance, to the fact that the Ministry’s consulted the Health Council, which can be considered as a first ‘stepping stone’ in the development of health policy. Likewise, the involvement of expert committees such as the CBD who develop policy step by step by their judgment of individual cases or permit requests is an important characteristic of Dutch biotechnology policy.

But apart from the routine practices of policy making, the xenotransplantation discussion also gave rise to reflections in parliament about the appropriate role of politicians vis-a-vis scientists – more in particular, expert committees – and the public. The xenotransplantation case also touches on the decision-making rights of institutions. Who should decide about this controversial topic? The experts? The public? Or the politicians?

This is a sensitive topic, as xenotransplantation research would be the responsibility of the newly established CCMO. The Ministry of Health had – awaiting the new Law on Exceptional Medical Procedures – first asked some hospitals to have potential xenotransplantation permit requests judged on a voluntary basis. As soon as the Central Committee for Research involving Human Subjects was established, xenotransplantation would become the responsibility of the committee. The Ministry of Health assumed that (pers. comm. interview 14):

‘It won’t be a regular procedure in the near future, so we thought, this [xenotransplantation] as a CCMO responsibility is sufficient for now. But the

Chamber wanted *coûte que coûte* to create a legal ban, so that was the reason that I've written that ban at a given moment'.

The fact that the Second Chamber wanted to regulate xenotransplantation whereas this would normally be the responsibility of an expert committee (the CCMO) could in the worst case be considered as a motion of distrust. This was all the more important because the CCMO is a non-departmental agency, a more or less autonomous administrative authority. Although the committee does, of course, abide by a legal framework, it is a committee at arm's length of the Ministry of Health. As the Minister put it succinctly in a debate with the Second Chamber on February 2, 2000:

'The main question in the debate about xenotransplantation was for the Minister who decides, the CCMO or politics. Politics has already spoken. (...) The Minister thought it would be superfluous to have a legal moratorium besides the CCMO. Although a moratorium should not be seen as a motion of no-confidence regarding the CCMO, it resembles it. Why should politics draw limits for xenotransplantation in the broad sense of the term, besides the CCMO, and not for other cases?'

The default decision-making authority for permit-requests concerning clinical xenotransplantation would have been the CCMO. By the parliamentarians' insistence on a ban, the parliamentary debate was not only about xenotransplantation itself, but also about the relevant political unit: the abstract principle of the primacy of politics, and the practical interpretation of it. MP's had to demarcate or carve out their own position, both with respect to the expert committee and to the voice of the public as exemplified by the PTA. This becomes clear when xenotransplantation is discussed in the Second Chamber, on February 2, respectively 8, 2000. Whereas the MP's try to emphasize the ethical question of 'how far one should go', they also have to be careful not to hinder or disrespect the CCMO. The following quotes are illustrative (Debate February 2, Second Chamber, 26335 no 13):

Mrs Terpstra (VVD): 'Is the conclusion now that politics does not play a role of importance anymore? Should we leave the question, how far one should go, to the CCMO, as the Minister proposes?' Mrs Terpstra emphasizes that she places a lot of trust in the very careful judgment of the CCMO. However, she thinks that politics has its own responsibility'. (...)

Mrs Swildens-Rozendaal (PvdA): 'The request for a moratorium should not be understood as a motion of no-confidence with regard to the CCMO, on the contrary. She certainly did not doubt the integrity and expertise of the CCMO. The request for a moratorium means clarity from politics'.

The role of the MP's vis-à-vis the CCMO is again discussed in the debate on February 8. The Minister then goes as far as to condemn the MP's involvement as a motion of distrust (Second Chamber, 46-3429):

Mr van der Vlies (SGP [small, conservative Christian party]): 'Of course, the judgment of the CCMO is of great importance. There is the expertise and we should not want to imitate, let alone equal that. That judgment can of course partly lead the debate, but the primacy of politics applies to this as well. That in itself seems undisputed.' (...)

Minister Borst-Eilers (D66): (...) 'Given the regulation and in particular given the implementing agency thereof, the CCMO, I can only conclude that this vote amounts to a lack of trust. I know that this is not the intention and that they only want to give a crystal clear, political signal that exceeds the existing moratorium. I therefore do not want to spend many words on the issue of trust, but for the Government, this aspect is certainly of importance'.

The MPs also try to determine how the primacy of politics relates to the societal debate. How should the MPs interpret their role as representing the voice of the people, in respect to that 'unrepresented' or at least more immediate voice?

Mr van der Vlies (SGP [small, conservative Christian party]): '[Xenotransplantation] is a loaded ethical problem that is rightly judged to be of great importance. That debate still has several loose ends and must absolutely have a thorough continuation. The Minister takes that position as well and initiates a societal debate about that. The results are of course meaningful, but I have argued last week that they are – for the SGP – in itself never decisive, as the societal debate can never substitute the judicial responsibility of a party in this House. No, we have to weigh our own judgments. That is the primacy of politics.' (...)

Mr Rouvoet (RPF [small, conservative Christian party]): (...) 'To respect the societal debate, it is not prudent to let the research continue as if the citizens are not thinking about this subject. I also think about the debate about cloning in this respect. We therefore think a moratorium is important. (...) You are not going to allow research with risks when you still want to hear from the population how it thinks about this, when the result could be a no against xenotransplantation, are you?' (...)

Mrs Swildens-Rozendaal (PvdA [social democratic party]): (...) 'we have what is called the "primacy of politics" in common language, that is, politics as representative of society. (...) I am wondering whether the Minister

sufficiently understands that politics should take its responsibility (...) That responsibility implies in this case that a signal must be given. That is of all the more importance, because the societal debate still has to be conducted. The Minister argues that her message is clear and that xenotransplantation should, in principle, be possible. That message can, according to her, also be seen as the start of the societal discussion. In answer to my questions she has said that we can retrace our steps when it becomes apparent from the societal discussion that there are other ideas about this. We take the opposite attitude. We think that we should wait now, and that we should legally confirm this. This is also important for the societal debate. The one thing cannot be seen without the other’.

What becomes clear from the extracts of these two debates, is that the appropriate distribution of decision-making rights is by no means a settled case at the time of the xenotransplantation debate: ‘[t]he main question in the debate about xenotransplantation was for the Minister who decides: the CCMO or politics’ (Second Chamber, 26335 no 13). Politicians from all parties were, on the one hand, searching for their own role, while conspicuously careful not to intrude or damage the respected field of expert committee decision-making - possibly because this resonates with crucial Dutch values. On the other hand, the MPs seemed hesitant vis-à-vis the societal debate: should they give a clear message, weigh their own judgment, or should research be halted altogether awaiting the results of the debate?

An important principle influencing these and similar questions was the above-mentioned so called ‘no, unless’-principle. At the time of the PTA, various issue movements were concerned that the ‘no, unless’-principle was in practice interpreted as ‘yes, provided that’. The reason was the amount of leeway expert committees have in the Netherlands, as was the impression that such ‘committee[s were] on the side of the researchers’ (pers. comm. interview 2), if only because members of such committees are recruited from within the – often limited – circle of researchers in the field (see 5.2.1 and onward). In order to understand this better, we will now focus on the social field of TA.

## 5.2 Social field of TA

As will become clear below, the social fields of TA and that of PTA were at certain points interwoven. The Rathenau Institute, originally a TA institute, used the xenotransplantation debate to test a new method of public participation – a play – and the chairman of the Committee Biotechnology involving Animals was also involved in the public debate. In this chapter, we will explain more about the workings of the most important expert committees and organizations responsible for xenotransplantation TA.

### 5.2.1 The Health Council

The Health Council is the most important national advisory council regarding issues of health and health policy. It was established in 1987 to advise about health research, medical technology and research infrastructure. The Health Council convenes in several autonomous, multidisciplinary committees, which often consist not only of medical doctors and researchers, but also of jurists and ethicists.

Two of the nineteen contributors to the Council's xenotransplantation report had connections with Imutran, a Cambridge based pharmaceutical company with major interests in xenotransplantation; dr. Ab Osterhaus and dr. Frank Grosveld were members of, respectively, Imutran's Safety Board and Scientific Board. In a general policy statement, the Council explains that:

‘For committees of the Health Council, the general requirement is that one does not have or does not represent a direct interest in a particular result of the advice; this applies for instance to a member of a commercial or patient interest group, or to an employee of a company that makes a product which is subject of the advice. In the case of exceptional medical procedures that might be a source of revenues for the own centers of the few experts on the specific field, it will be seen to that other experts ensure a balance. (...) If someone has essential expertise, but his research is so close to the advisory subject that he should not have a say in the matter, an appointment as advisor is a possibility (Knottnerus, n.d.: 3).

Both Grosveld and Osterhaus participated as members, not advisors, but the potential intertwining of policy and innovation networks is seldom mentioned in the xenotransplantation discussion. Interestingly, Mrs. Borst, the Minister of Health who requested the Council's advice on xenotransplantation herself was a former member of the Health Council, as was Prof. Schrotten, chair of the committee on biotechnology involving animals as well as member of the advisory board for the xenotransplantation public debate (approached for the job by Minister Borst, a former colleague at the Academic Hospital Utrecht). This mechanism is commonly referred to as the ‘revolving door’, and illustrates how often policy advisers and politicians shift places in the Netherlands, a phenomenon that in general doesn't stir much public concern.

### 5.2.2 CCMO: Central Committee on Research Involving Human Subjects

The CCMO was created on April 6, 1999. It reviews research involving human subjects on the basis of statutory provisions. The CCMO is a non-departmental agency and thus not directly responsible to the Ministry of Health. The committee had no role in the decision to start a public debate on the topic, nor did it advise the ministry in that context. Responsible



within the CCMO for issues related to xenotransplantation was one of the leading researchers in the field of xenotransplantation in the Netherlands. Never, however, has the CCMO been approached with a request for permission of research in this field, as the stage of involving human subjects has never been reached (pers. comm., interview 11). Because of that, members of the CCMO, i.e. the ethical committee regarding research on humans, never were put in the position to have to consult with members of the CBD, i.e. the ethical committee regarding research on animals.

### 5.2.3 CBD: The Committee on Biotechnology involving Animals

The Committee on biotechnology involving animals (CBD) was established, as of April 1997, on the basis of the Animal Health and Welfare Act (*Gezondheids- en welzijnswet voor dieren*, GWWD). This Act implies a ban of biotechnological acts involving animals without prior permission. The permission can be granted by the Ministry of Agriculture, who will decide only upon hearing the CBD. The CBD consists of nine members, among them (in varying configurations) social scientists, veterinarians and animal and human medical doctors, (bio)technologists and ethicists. For some time, also juridical expertise was included, in the person of the committee's chair. Given the complex issues to be decided upon, and the (economic) interests at stake, the issue of animal biotechnology in general, and the committee in particular, were served well with having the committee's advises cast in juridical sound terms (pers. comm., Interview 2).

The Committee developed its set of criteria by which to assess an application for research on a case by case basis. A first step was made by soliciting advice from a number of ethicists and philosophers. Their input was reworked, and gradually revised on the basis of cases, into a framework for assessing the ethical aspects of research permit applications that was operational in practice. Among the criteria formulated was, in addition to aspects involving the health and welfare of animals, a criterion regarding the integrity of the animal.

Judging requests for research permits on the basis of possible impingements of the integrity of animals was a uniquely Dutch approach (pers. comm. Interview 2). This ethical issue became a key issue in the deliberations of the committee. It was formulated first on the basis of the (prior US-based) case of the 'blind chicken', i.e. the idea of genetically modifying hens in such a way that they would be blind, so as to keep them from picking each other. While this would actually benefit the health of chicken, the committee argues, it still should be decided against as it would interfere with the animal's physical integrity. A comparable case was made in regard to so called switch-gene modifications. This implies the production of animals with genes of which the expression can be switched on or off according to some trigger (e.g. food) provided. While some would argue that this is not in contradiction to criteria regarding the health of animals, especially if the genes remain 'switched off', it is still an infringement on the animal's integrity, the CBD argued, if only because of the animal's increased cancer risks.

In order to make a case in a convincing manner, the committee sought to ‘always be fact-regarding. Also in debates on norms and values, in particular in such debates, the facts must be taken into account first’, in the words of the committee’s chair (pers. comm., interview 2). Furthermore, to keep a neutral position, the committee restricted its communications with other interested parties and the public at large as far as possible to ‘written communications and telephone.’ In addition, all its outputs were openly available for public scrutiny, with the exception of the committee’s meetings’ minutes. The idea behind this restriction on transparency was that the individual members of the committee had to be enabled to speak freely, without being concerned about comments from (often fellow-) researchers and colleagues. The reason why the committee was keen on keeping a neutral profile was a concrete experience from the days of its predecessor (the temporary committee on animal biotechnology), which performed a similar role in the early days of biotechnological research, including in view of bull Herman. In the light of that development members of the temporary committee had met with employees of GenePharming to discuss matters on a couple of occasions, as a result of which they were accused by organizations with a focus on animal rights to form a ‘pact’ (*congsi*) with the biotechnological industry. Since then, members of the committee were on their guard not to give reason for such accusations. However, it was their impression that they never succeeded in casting away the shadow of doubt among animal activists.

Nevertheless, the committee restricted itself to advise on ethical grounds, omitting economic arguments from its considerations. This was a deliberate yet deplored choice, which followed from the decision by the Minister of Agriculture to explicitly charge the committee with duties regarding ethical advice only, and to keep the right to formulate and include economic considerations in the eventual decision. Thus, also in this context, the relative power of an expert committee – here the CBD – is seen to be considerable yet ambiguous. The anecdote below is illustrative in this respect:

The example concerned the question of importing transgenic animals. This topic surfaced in May 1998 when members of the conservative Christian party RPF questioned the minister of agriculture (Aartsen, VVD) about the controversial Bio Primates Research Centre in Rijswijk (BPRC), where kidney tissue from two transgenic pigs has been transplanted into two macaques. The Society for the Protection of Animals wrote a letter of complaint about the experiment. According to a gentlemen’s agreement between the Society for the Protection of Animals and the KNAW, the Royal Dutch Academy of Sciences, the experiment should have been announced to the CBD, even though this was not legally required. The reactions to the experiment show the drawbacks of this very Dutch system: the amount of regulatory space and the resulting insecurity of the expert committee involved. The following press comments are illustrative. CBD chairman Schroten argues that:

‘According to the simplest formulation of the gentleman’s agreement, the experiment should indeed have been reported to us, but it is not that simple.

(...) Anyhow, we can actually say nothing about experiments concerning xenotransplantation, because there is not yet an official government perspective. And such a perspective is not to be expected before the new government is formed. At the moment, we are in a vacuum. The current situation is satisfying for nobody. Formally, the BPRC is allowed to conduct these experiments' (Anon. 1998).

Molecular cell-biologist Frank Grosveld comments:

I would have thought it more prudent if they [Bio Primates Research Centre] had done that [report to the CBD]. On the other hand, they probably would have received no reaction, because requests for xenotransplantation are not responded to, as long as the government has not yet made a directive regarding xenotransplantation. And that won't be any time soon. I have been waiting for a year for a reaction to my request to make transgenic mouse for xenotransplantation. There is now an advice from the Health Council, but the ethical committee does not want to commit itself to that, because the minister can still reject the advice. As long as there is no government perspective, experiments can go on. I admit all this is not very clear (Aan de Brugh, 1998).

#### 5.2.4 The Rathenau Institute

Another TA institution that should be mentioned here is the Rathenau Institute. The Rathenau Institute was founded in 1986 as an independent advisory institute to the Dutch Parliament. At the time, it was called the Netherlands Organization for Technology Assessment (NOTA) and its establishment was in line with a White Paper seeking to enhance the integration of science and technology in society, and propagating technology assessment (TA) as a practical instrument to do so. In spite of its conceptual background, the organization in its early years did not systematically explore possibilities for public participation in opinion forming and decision-making. Rather, in the practice of translating societal concerns into policy advice, an emphasis was put on the consultation of experts on particular technological and societal issues. When in 1993, in an evaluative study after its first five-year period the organization was seen to fail to live up to the original expectations (Van Eijndhoven, 2000: 154-155), its mission was re-defined as contributing to social debate and political opinion forming on issues that are the result of, or are connected with, scientific or technological developments, including the ethical aspects of these developments (cf. Rathenau Institute, 1994: 9). A change of name – the organization now was called the Rathenau Institute – accentuated its changed (or rather, re-stated) mission. With the emphasis now clearly put on public debate, positioning research in a more supportive role, the acronym NOTA – of which the final two letters represent the Dutch translation of 'technology assessment' featuring the word 'research' (*technologisch aspectenonderzoek*) –

was considered to bear the wrong connotation. Hence the change of name, the new institute being named after Professor Rathenau, who had been one of the pioneers in promoting analysis-supported debate on science and technology.

As the Rathenau Institute was the most important (P)TA institute of the Netherlands, it was to some extent surprising that it was not the Rathenau Institute itself that got commissioned to set up the xenotransplantation debate but rather a relatively small organization. This is explained in different ways by the various interviewees. One explanation is the fact that parliament was wary of turning to one particular party at all times to mediate between them and society. In spite of the Rathenau Institute's efforts to develop a profile of neutrality and mediation, it was conceived of as being an advocacy actor in its own right (pers. comm., interview 13). The topic of xenotransplantation offered a suitable occasion for further experimentation with forms of public deliberation as organized input into the policy process, and the involvement of a relatively small actor as its organizing party promised a new way to explore the road of public engagement. For the Ministry of Health, it was wise to keep the different channels separated. As the Rathenau is a formal advisory institution for parliament, direct requests from the ministry were considered to be 'sensitive' at the time (pers. comm., interview 15). A different explanation was that the Ministry of Health was not satisfied with the public outreach of a previous debate organized by the Rathenau, and was - presumably therefore - looking for a different organizer. Moreover, the Rathenau Institute did not agree with xenotransplantation as a new technology as the topic of the debate, focusing rather on the problem of organ shortage.

Thus, the Rathenau Institute started a two year program under the title '*Het tekort voorbij? De toekomst van orgaanvervanging (Beyond the shortage? The future of organ replacement)*' which ran partly in parallel to the xenotransplantation campaign. Two elements of the Rathenau campaign of relevance for our purpose here are a survey and the play *Dierbaar Leven* (Precious Life; a translation of an originally British play – see paragraph 5.3 – that features the word *dier*, animal in it) – as both of these employed PTA methods and were considered as part of the public debate.

### 5.3 Social field of PTA: the organized public debate

Our different interviewees give various explanations as to why xenotransplantation became the topic of a PTA. A policy maker from the Ministry of Health argued that xenotransplantation was an especially suitable topic, because of the risks it involved and its subsequent relevance for a large part of the population: xenotransplantation 'touches fundamental values' (pers. comm. interview 14):

'With a lot of things you don't have to try that [performing a play about it], because, it remains a bit cold, even if your actors are very skilled, but the people looking at it will still think, OK, what does that have to do with me?

But precisely because, a lot of people have a certain (...) antipathy against bio industry, so they will feel a bit committed. On the other hand, you know as well that lots of people are waiting for an organ, so that influences your opinion as well’.

Other respondents assume that xenotransplantation was chosen more or less co-incidentally: it was part of a series of increasingly large public debates. A third reason mentioned by our interviewees was that the unexpectedly cloned sheep Dolly had influenced the xenotransplantation debate:

‘Everyone was shocked, the Second Chamber was shocked, the Ministry of Health was shocked, all of a sudden there were all kinds of questions and no one knew what was going on and were we doing this in the Netherlands as well? And then they sat together because that could not happen to us again, that would be stupid. And then they saw this new technology and said, let’s be in time this time’.

The organization Consumer & Biotechnology (*Consument and Biotechnologie*, hereafter C&B) that organized the official public debate about xenotransplantation held in the winter season of 2000-2001, was established in 1991, in cooperation between the Dutch consumer foundation and the Ministry of Agriculture, Nature and Fisheries. At the time, this Ministry structurally financed the organization, which consisted of no more than three core employees (another employee was hired especially for the xenotransplantation project). The goal of C&B was to help consumer organizations to come to a weighed judgment about biotechnology.

C&B started by organizing an information campaign from December 1999 to February 2000. Although this campaign included some possibilities for people to voice an opinion, it was primarily aimed at informing the public, rather than asking for its view. Between the information campaign and the official public debate, was a gap of almost half a year. The Ministry of Health had opted for this structure in order to be able to see whether the public had been sufficiently and objectively informed, and whether the public was interested at all. However, the separation of the information campaign and the public debate did have its drawbacks, as one of the organizers explains (pers. comm., interview 1):

‘We very much regretted that there was no immediate public debate [following the information campaign], because we had huge media attention with our website. But that website was purely informative (...), to make people aware of their ideas and by means of questions to allow them to think through and hence articulate what was the context of their opinion, that was of course impossible, you couldn’t do that with a website. So we had

gathered a lot of momentum at the time, but we actually couldn't do anything'.

In the debate with the Second Chamber on February 2, 2000, Minister Borst outlined the intended debate as follows (Second Chamber, 26335 no 13):

'A lot of people should be able to actively take part in the societal debate. Consumer and Biotechnology is detailing the proposal on the request of the ministry. We are thinking about groups of the population. A group of laypeople would then debate during an afternoon, using one or two specific examples. Another idea are afternoons or evenings for the public, like the Rathenau Institute has organized previously, or debates for students. The website will have to be made more interactive as well. Furthermore, a printed news letter will be published'.

C&B set itself a threefold goal for the public debate:

- information transfer
- opinion formation
- inventory of opinions

These three goals were strongly intertwined. The public would have to be informed prior to opinion formation and inventory, so that irrational fears could be removed from the debate. Various actors assume that if the public only knew better, it would think differently. Knowledge dissemination was an important point for the Ministry of Health, as one of our interviewees underlined (pers. comm., interview 14):

'It is only possible to conduct a debate if you provide the information about the topic that you want to debate. And for me, that was an important aspect of C&B, that they took care that [information] was there. And that is of course something else than having some hearings in rooms in the country, where, I may put it, organization X comes to tell a story about this and when you do not give any more information about the topic, then people will come, because there are always people attracted to this kind of things, and as soon as there is a certain term in it they will always come, but then you would not attract people of whom you would say, I really want to know their opinion about this topic'.

Providing the public with the right information is thus connected to attracting the 'right' kind of public. But availability of 'objective' information is also seen as an opportunity to enable people to experience the dilemmas of policy makers. The PTA has a deliberative aspect in

that it is intended as a possibility for individuals not only to practice their civil skills, but also to change their minds. But this change is primarily spoken about in terms of a transformation from an irrational, initial negative reaction, towards a more rational, positive reaction. This quotation from C&B project leader Margreet Bloemers, in an interview conducted in September 2000, is illustrative:

'You have to take emotions seriously, but we want to conduct the debate only after people have been informed and have thought carefully about xenotransplantation. Informing and debating, that is the core. The goal is a serious deliberation among the public. That can lead to a clearer image of how the public thinks about xenotransplantation. The difficulty is that the discussion has so many sides. As I said: people are generally afraid of new technology, and this applies all the more to xenotransplantation. The primary reaction is usually negative. But when you press for their choice in the case they themselves would be seriously ill, and there would be no human organ available to save their life, most reactions are a lot more nuanced (Anon., 2000).

On the basis of this so called knowledge deficit model (Bodmer, 1985; Layton et al., 1993), C&B started with an information campaign, which was considered as a first step towards the debate. This leads to a somewhat paradoxical approach: on the one hand, the campaign is designed to gather public opinions regarding xenotransplantation; on the other hand, only the educated views seem to count. Several students of public knowledge have convincingly argued that this deficit model with its focus on the educated opinion is a simplification of 'the' public's attitude towards science (e.g. Wynne 2006, Irwin and Wynne 1996, Jasanoff 2005).

On the basis of findings from the information campaign, and from a pilot debate conducted among focus groups, C&B defined five themes for the debate:

- 1) dealing with shortages in the health care sector (organs, budget, capacity)
- 2) dealing with the makeability of the body
- 3) use of animals
- 4) dealing with risks
- 5) who decides? (role of government, politicians, science, business)

The debate received the title: *Xenotransplantatie, kán dat?, Xenotransplantation, is and should it be possible?* It consisted of the following activities (some of which, such as the public survey, were initiated or sponsored by other parties):

- debates via the websites [www.xenotransplantatie.nl](http://www.xenotransplantatie.nl), with a total of 27.000 visitors of whom 400 reacted, and via [www.biodebat.nl](http://www.biodebat.nl) (aimed at Dutch students of schools for higher education), in which approximately 1000-1200 students participated;
- national debates at the opening and closing of the campaign, for which experts and interest groups were invited;
- smaller public discussions, conducted by a moderator with the help of an interactive information DVD, involving approximately 700 participants. For this, C&B essentially offered xenotransplantation as a topic for discussion for those groups that were interested, among which were, for instance, associations of rural women. Here, the above listed concerns were put on the agenda by the organizing actor C&B, and were – at least in the meetings videotaped – discussed one by one in an orderly fashion.
- C&B adverts in media, and C&B participation in interviews;
- free postcards from pubs, clubs, etc.;
- a public survey, conducted by Rathenau/SWOKA among 600 respondents
- the theatre performance '*Dierbaar Leven*' (Precious Life) (the latter two activities were organized by the TA institute Rathenau)

For the SWOKA/Rathenau report *Het tekort voorbij* (Beyond the shortage), fifteen citizens from different backgrounds were interviewed. Among them were four heart of kidney patients and two members of the Society for Animal Protection. The interviews focused on the spontaneously mentioned criteria used by respondents for judging solutions to the problem of organ shortage. On the basis of these interviews, questions have been formulated for a survey among 18+citizens. Of the 966 citizens who had promised their cooperation, 574 returned a completed form. After two weeks, non-respondents were prompted by means of a phone call, which included some questions to compare the attitudes of respondents and non-respondents. Apart from this, the questionnaire was handed out to 400 kidney patients, of whom 46 returned a completed form. Lacking an address or other contact information of the patients, prompting was impossible. Respondents were asked to rank the acceptability of different solutions; whether or not they would like to receive an organ acquired by the solution; whether the government should or should not stimulate and subsidize the solution.

The consistent message of the SWOKA/Rathenau report was that respondents considered xenotransplantation the least acceptable solution to the problem of organ shortage; most respondents did not think that this method should be stimulated or subsidized by the government. These results were published in April 2001, shortly after the public debate.

The Rathenau Institute did also consider the xenotransplantation debate as an opportunity to test a new method of public participation in particular, to approach young people: discussion helped by a theatre play – *Dierbaar Leven* (Precious life). The science theatre group Pandemonia performed the play. This element of the debate was financially supported by the Rathenau Institute, the Ministry of Health and Stichting WeTen (Foundation Knowledge;



Science and Technique). According to our respondents, this cooperation occurred more or less coincidental. The Ministry of Health was looking for public participation, whereas the Rathenau was trying to reinvent itself with new forms of TA, and the play *Dierbaar Leven* provided an opportunity to combine these wishes (pers. comm. interview 9).

*Dierbaar Leven* was originally an English play by Judy Upton, published in 1999 under the title *Pig in the middle*. The play tells the story of two young kidney patients with very different characters: the boy Remco loves burgers, enjoys clubbing and sports, the girl Gemma is a vegetarian and animal activist. Their young doctor wants the best for her patients, but is also on the pay roll of a pharmaceutical company. When Remco is offered a pig kidney, Gemma vehemently protests. The play ends with no conclusion; Remco gets an infection, which makes him at least temporarily unsuitable for xenotransplantation.

The first performance of *Dierbaar Leven*, on November 10, 2000, was attended by the Minister of Health. It preceded a discussion between several interest groups and organizations and was the opening event of the national public debate. The play was performed on schools between December 2000 and June 2001. Many schools were interested in having *Dierbaar Leven* performed; there were approximately 400 requests for the play, but there was budget for no more than 100 school performances. The final reach of the play was 95 schools, 9875 students, 300 teachers, 300 other adults.

After the performance, the actors - staying in the respective roles they performed on stage prior to the discussion! – embarked on a discussion with the students, helped by a moderator who initiated the session with words such as “*Don't be ashamed, raise your voice. (...) We have to decide in the Netherlands whether we are pro or contra xenotransplantation. Your opinion is part of the debate.*” (Van Beek 2000). Pandemonia director Witmond was, when interviewed in the radical left-wing magazine *Ravage*, positive about the play and accompanying leaflet, but – as she confirmed in our interview - critical about the questions asked to the students: “*Some of these questions are very suggestive. For instance, students are asked if they want to jeopardize the health of the entire population for the health of 1500 sick Dutch people.*” (Van Veen 2001).

Of the 100 performances, 55 were to be evaluated with questionnaires. Of the student response forms, 1,932 (approximately 50 percent) were sent back. Of the teacher response forms, 46 (38 percent) were returned. Both students and teachers think that the play enlarges students' knowledge about xenotransplantation. The number of students without an opinion regarding xenotransplantation decreased drastically; the number of students with a negative attitude radically increased, as can be seen in table 4.

*Dierbaar Leven* was frequently mentioned in the media; three national newspapers and two regional papers published an article about the play. Our interviewees were still unanimously enthusiastic about this element of the debate.

**Table 4 Students' opinion regarding xenotransplantation**

	Before the play/discussion	After the play/discussion
No opinion	464	94
Positive	907	865
Negative	381	793

Source: Walre de Bordes (2001).

The PTA was never designed to be a formal or proportional representation of the population. According to C&B, the debate's target group was 'the general public'. As there were only limited resources available, it was not possible to target a large part of the population. C&B therefore decided to approach 'as diverse a part of society as possible.' This was done via public organizations, interest organizations and professional organizations, experts, politicians, and policy makers. Individuals could participate via the website, local debates and surveys; youths were approached via the schools.

C&B tried to involve cultural minority groups in the debate, but did not succeed in this. The main reason for this was the lack of resources of the organization. The small public discussions were organized on the request of the societal organizations involved. As minority organizations were either not interested or hard to reach, no discussions were organized with them.

C&B also states that a relatively large number of women and people aged 50+ participate in the public discussions, but it does not quantify this observation in its report. Meetings predominantly attended by women did not seem to deviate from meetings during which the men formed a majority, and meetings attended by a majority of elderly were 'mirrored' by meetings attended by large numbers of young adults. Due to the Dierbaar Leven theatre performance, a relatively large number of young people actively participated.

C&B acknowledged the different nature of the responses to the survey, respectively in the public debate: arguments in the debate are offered spontaneously, whereas the survey necessarily works with closed questions so that opinions are dependent on the phrasing of the questions.

In the processing of the results into a report, the opinions expressed in the small-scale public discussions were key. These formed the basis for a qualitative analysis, which was then compared with the results from other activities. According to C&B, the public discussions provided a better possibility for in depth discussions than other activities (2001: p 16): *'the image of the opinions and preferences held by the public has, to a great extent, been based*

*on activities involving adults. During the public discussions, in particular, it was possible to go into the arguments in more depth than was the case during other activities.'*

The final report was, in line with the above statement, written by the organizers on the basis of the public discussions and other activities. It contained a palette of opinions, but no clear message to policy makers. Although politicians showed their commitment to the debate – for instance, the end report was presented to the Minister in person - a clear political message did not seem to be a major goal of the debate, as becomes clear by this remark of one of the organizers (pers. comm., interview 1):

'What I realize now, when I was retrieving all this in relation to your interview, is that, when we presented the final report [to the Minister], we have not asked her at all, what will you do with this moratorium?'

Likewise, a policy-maker from the Ministry of Health emphasizes about the final report (pers. comm., interview 14):

'It is no document for decision-making. No one should see it like that, I think, for then it would be useful for no one, because there is always only a part of the population that actually participates, so there are people whom you will absolutely, never reach in whichever way, so that's an opinion you will never have'

With regard to the themes of the debate, C&B concluded in its final report that, within the public discussions, the 'makeability' (amenability) of the body was an issue of particular concern to participants. Younger people tended to argue that all possibilities to prolong life must be used, whereas adults more frequently indicated that there was a limit to this. The animal theme was also frequently raised during discussions. Risks and shortages were not often mentioned; it seems 'as if people regard these themes as more of a given fact' (C&B 2001: 17). The reluctance to debate these more formal 'expert' themes might also stem from a sense of insecurity, since reactions on the response forms were different; respondents selected risks as the most important theme, followed by shortages and makeability of the body.

In the conclusion to the final report, C&B (2001: 33) observed that a 'sufficient number of people has participated interactively in the public debate for it to be possible to draw conclusions about the opinions held by citizens in respect of the desirability of xenotransplantation.' These opinions are summarized in the following points. First of all, 'the reason for xenotransplantation is important' and this reason is 'to resolve the shortage of donor organs and, by doing so, to save people's lives'. This being said, 'The Netherlands is divided about xenotransplantation'. Approximately half of the respondents did not have an outspoken opinion about xenotransplantation; the precise number of supporters and

opponents is not quantified in the report. The conclusions also testify of a basic trust in government since, although they regard the risk of infection as a central consideration, they 'do not expect that xenotransplantation will be used if uncertainty exists in respects of the risks it involves'. This being said, a majority did not want the government to encourage research into xenotransplantation and '[m]any see the development of xenotransplantation as a confirmation of the idea that the progress being made by science is transcending the boundaries of what people find ethically acceptable.'

## 5.4 Social field of (spontaneous) citizen-participation

When xenotransplantation became a policy theme, various issue and interest groups tried to influence policy-making and public opinion concerning xenotransplantation. The groups that were both very active and vocal or conspicuously absent from the debate are mentioned below. Although some single issue groups such as the Working group Xenotransplantation Questions (*Werkgroep xenotransplantatievraagstukken*, hereafter WXV) tried to alter the dominant framing of xenotransplantation as a scientific innovation and as a possible solution to the problem of organ shortage, the dominant discourse remained unchanged.

### 5.4.1 Animal rights and welfare organizations:

The best-known Dutch organization for the protection of animal rights, the *Dierenbescherming*, was principally against xenotransplantation, and took Gene Pharming to court in 1993 and 1994. The organization attended CBD meetings and actively tried to influence public opinion formation.

Two smaller organizations, the foundation against vivisection (*Anti-Vivisectie Stichting*) and the Dutch Society for Replacement of Animal Testing (*Vereniging Proefdiervrij*) also joined the debate.

The animal organizations were not only against the killing of animals for human spare parts, and the practice of keeping pigs in specific pathogen free circumstances but also tried to promote the more abstract notion of the intrinsic value of the animal.

The organization for the protection of animals *Dierenbescherming* organized a conference about xenotransplantation in December 1997, a month before the advice of the Health Council was published. The *Dierenbescherming* was one of the organizations consulted by C&B and it included pages about xenotransplantation on its own website, on January 27, 2000 - a few days before the debate in Parliament. Visitors were asked to give their opinion. A leaflet was published under the title *Inhuman for animals; developments surrounding xenotransplantation*. Furthermore, while arguing for a moratorium on both clinical and preclinical research into xenotransplantation, the *Dierenbescherming* also urged its members to register as donors.

The foundation against vivisection and the Dutch Society for Replacement of Animal Testing organized a ludic action in December 1999: by presenting a marzipan pig to members of parliament, they aimed to ask attention for the experimental animals, and argued for a ban on research into xenotransplantation. This was part of the campaign '*Xeno, say no!*', which also consists of leaflets and a website.

The animal rights organizations were an active voice in the debate. The view of the *Dierenbescherming* - as expressed in *Inhuman for animals* - was included in the educational leaflet of *Dierbaar Leven*. One of the characters in that play was also an animal activist. Three of the six cartoons in the final C&B report portrayed animals as organ plants.

#### 5.4.2 Working group Xenotransplantation Questions (WXV)

The WXV was probably the most dissonant voice within the xenotransplantation debate: the group explicitly wanted to propose an alternative discourse. The WXV had been established in September 1999 by three people with a background in anti biotechnology campaigning, to participate in the information campaign and the public debate. The WXV members approached xenotransplantation from an economic angle, speaking, for instance, about a transplantation industry and emphasizing that transplant organs create a lifelong market for pharmaceutical companies selling immunosuppressant medicines. The WXV also questioned the desirability of expensive, life prolonging measures such as organ transplants, arguing that this might damage the availability of basic care.

The approach of the WXV did not only differ from the mainstream debate in terms of content, but also in form. At first, the working group tried to have its views incorporated in the C&B information. This attempt was unsuccessful. When C&B failed to place the link to the WXV's website in time for the opening of the xenotransplantation information website, the WXV decided to show up with banners at the official opening (pers. comm. Interview 5):

'We were used to standing with banners, but we noticed that it was exciting [to the rest of the audience]. I believe that the Minister was there as well; in this setting it was not normal at all, we went to that kind of debates very often and I've never seen that there was some kind of overt protest'.

The setting in which this occurred was *Nieuwspoort*, the Dutch parliamentary media center and thus a symbolic site for traditional politics: a room in which press conferences are given about decisions that have been taken. Interaction in *Nieuwspoort* between politics and media takes place under implicit rules of conduct and the banners of the WXV brought a different, more antagonistic kind of politics to the established *Nieuwspoort*.

At the start of the information campaign, the WXV also disseminated its view on xenotransplantation via free leaflets for all public libraries. It established a website, which

was copied to a CD-rom for use on schools. Furthermore, the WXV provided lectures for interested groups, was available for interviews, attended meetings of the public debate and contributed articles to news papers. It thus copied the methods of the official debate in order to reach the public, while simultaneously questioning the position of C&B (pers. comm., Interview 5):

‘... for they position themselves as the middle ground, as the neutral, actually, they are assumed to have the neutral vision, whereas what they did, we did not find that neutral’.

As C&B decided not to let any outsider experts or interest groups speak at the public discussions, the WXV had to make its point in indirect way, by asking questions while sitting in the audience.

The antagonist stance of the WXV was not without its costs. Because of its stance, the WXV was unable to find any discourse coalition partners. It could not find an ally in the animal rights organizations, as these had decided for a strategy against xenotransplantation, but explicitly in favor of organ donation. Some organization that opposed transplantation because of its holistic view on the body could not be regarded as a real ally, because the WXV considered its line of reasoning insufficiently scientific. The Working Group thus found itself isolated in the debate, because of its explicit focus on who decides, and who wins from technological developments such as xenotransplantation. This turned out to be a very difficult perspective. The critical voice came either too early (and was then accused of scaremongering) or too late. As our interviewee explained (pers. comm., interview 5):

‘In the past, in the first years of biotechnology, some people said, yes, then we will improve people, and then you were ignored in the debate, yes, you scare people, that is not true at all and that will not happen at all, and then for a very specific group (...) and every technology was for a specific group (...) And now it is accepted that, yes, but you have already accepted this and you have accepted that and then it is not a big step to take the following steps as well’.

The members of the WXV came to be perceived as the ‘perennial antagonists’. As one of the organisers of the debate put it (pers. comm., interview 1):

*‘My colleagues from C&B knew them, for they always came with this ‘huh, stupid, ridiculous and bad, bah’ [remarks] and they also came with banners. Well, fine, but it was not as if we forbade them to speak or anything’.*

The WXV was critical about the invited xenotransplantation debate in general. Comparing the xenotransplantation debate to the 1980’s Broad Societal Discussion about nuclear

energy, the working group concludes that xenotransplantation debate is lukewarm: xenotransplantation is not a vital concern. Although media interest in the topic grew because of the public debate, most journalists worked on the basis of an already fixed problem definition, according to WXV.

The WXV was also very negative about the possibilities to access the organized public debate. There was no financial support for issue groups such as the WXV; the printing of leaflets had to be financed by the groups themselves. The WXV complained about repeated exclusion from meetings. It also claimed that C&B failed to put the information provided by the WXV on its website in time for the official opening of the debate. By the time the information was placed on the site, press attention had already vanished. The WXV observed that:

‘Within the public debate as it was organized by C&B, there was no support to promote new visions. No money has been made available, nor has there been made space within the official program. Moreover, there was almost no publicity for organizations such as WXV that tried to defend a new vision. These organizations were not invited on the stage during the debates and other meetings. They had to try touch on an alternative discourse while sitting in the audience by asking single questions (Werkgroep (Xeno-)transplantatievraagstukken, n.d.).

The WXV concludes that no real debate has taken place, and that there was no space for an alternative discourse, involving questions such as *‘how do we deal with illness and death and who decides about the structuring of health care?’* (Werkgroep (Xeno-)transplantatievraagstukken (nd).

Despite these criticisms, the opinion of the WXV is mentioned in the C&B report: *‘not everyone is convinced that the donor shortage problem is one that must be resolved’*. C&B compares the views of the WXV with those of the respondents, and observes that *‘6% of the respondents in the public survey did not regard the shortage of donors as a problem. Of this group, 19% believe that we must accept that we will die. The ‘accept that we will die’ argument was also frequently heard during the public discussions, but not so much in relation to the question of whether the shortage is a problem. Rather, as a reaction to xenotransplantation in general’* (C&B 2001: 20).

The opinion of the WXV also receives half a page in the educational leaflet handed out to students to accompany the play *Dierbaar Leven*.

### 5.4.3 Patients' organizations

One of the most important patients' organizations for the xenotransplantation debate was the Dutch kidney foundation (*Nierstichting*). Although the Kidney Foundation valued the knowledge about rejection processes that would potentially result from xenotransplantation research, it did not regard xenotransplantation as the preferred solution for the problem of organ shortage. The reason for this was, in part, that the risks of xenotransplantation were unforeseeable, but also that xenotransplantation was 'morally sensitive' (pers. comm. interview 15). The Kidney Foundation therefore chose to focus on other measures, such as education about the importance of organ donation, extra human resources for donation procedures within hospitals, stimulating non-heart beating donation and supporting living donors. The Kidney Foundation was not actively involved in the xenotransplantation debate, neither in the public debate, nor via the Ministry of Health.



## 6 The PTA's impact

The way in which a PTA's impact can be assessed is debated. Some fifteen years after experimentation with PTAs began the assessment of their impacts is considered a key concern of PTA research (Abels, 2007). The overall conclusion from impact assessment literature is not optimistic. Most analyses of PTAs are cautious if not sceptical about a PTA's potential to influence the processes of political judgement and decision-making it seeks to address (e.g. Renn et al. 1993, Mayer 1997, Rowe and Frewer 2000). The general assessment is that "only few participatory procedures actually have some empirical impact on political decision-making" (Abels, 2007: 110, cf. Bütschi and Nentwich 2002, Joss 1998). Among the issues discussed is attribution: to which extent are developments observed arguably the result of public engagement arrangements? Furthermore, a topic of discussion is the focus of impact assessment studies: should one limit one's view to the decision-making process as such, or should one take into consideration the wider policy field in which such a process takes place?

In this report we endorse the second perspective. After all, political will formation and policy preparation are seen to take place in flexible networks of (state and non-state) actors. An impact assessment should do justice to this networked reality. Below, we will first discuss the impact of the PTA and characterize it according to the template developed for the comparison of (P)TA exercises on xenotransplantation within the CIT-PART project (Griessler and Biegelbauer, 2010). We will then elaborate our impact assessment using notions from McAdam, Tilly and Tarrow's (2001) 'dynamics of contention' (DOC) theory (cf. Loeber, Griessler, Versteeg, 2011).

In terms of the reach of the debate, C&B concludes that *'sufficient numbers of people participated interactively in the public debate for it to be possible to draw conclusions in respect of citizens' opinions about the desirability of xenotransplantation'* (C&B 2001: 5). If these conclusions were taken seriously and were inserted into the policy process, input and throughput legitimacy would have been improved. Even though the final report of C&B did not convey a clear political message, this does not necessarily mean that policy makers were not – or could not have been – influenced by it. As one of the organizers of C&B put this (pers. comm., interview 6):

'The Minister does not decide on her own, and she is always advised by civil servants who attend the events and who are in touch with us on a regular basis. We also organized a kick-off debate and a final debate, at which all who were active in the field of xenotransplantation were present, including xenotransplantation scientists, politicians and representatives from NGO's and industry'.

The loosely organized interaction between the Ministry of Health and C&B as a public 'channel' might thus be more important than a clear political message in the final report. This tally with the observations of a Member of Parliament we interviewed. Rather than focusing on a final report – *'well, you know, so many reports are written, so much research is done'* – the organized debate was *'only one of [his] sources of information'* within the cacophony of societal voices, albeit a concisely summarized one, and hence efficient and useful.

Although, in the case of xenotransplantation parliament had already decided for a moratorium before the start of the actual public debate, there would still have been room after the debate had been finished to challenge or change government policy had this been deemed necessary. But given the fact that the results of the debate did not strongly deviate from the policy decided for, it is impossible to test this hypothesis in the case of the xenotransplantation debate. On the other hand, a process can also have an impact by reinforcing existing actor positions or dominant images, for instance about the knowledge deficit of the public.

Within the Dutch public debate, the technical options of xenotransplantation have – to a certain extent – been assessed and made visible. The various interest groups have helped to provide an overview on a range of possible consequences, such as the risks of unknown, hidden viruses; the living conditions for a person with a xenotransplant; the changing moral status of the animal; distribution issues within the health care system; the makeability of the body etc. It is clear, however, that it was difficult to discuss the desirability of organ transplantation, or possible connections between xenotransplantation and economic interests, as the remarks of the WXV show. The (opinions about) various policy objectives have been explored, albeit not systematically. Existing policies have hardly been assessed within the xenotransplantation debate: this applies both to the existing system of donor registration, and to the regulation of xenotransplantation research. **The PTA did not set the agenda in the political debate, but it did stimulate public debate; several interest groups joined the deliberative space created by the PTA, and media reporting about xenotransplantation increased.** One could argue therefore that the PTA has intensified the public debate. By means of the play *Dierbaar Leven*, a scenario regarding future applications of the new technology has been introduced. Actor positions were relatively fixed: interest groups did not change their stance. As much as the deliberative ideal might focus on this possibility of changing perspectives, this flexibility turned out to be difficult to realize in the 'Realpolitik' of everyday life. As one of our respondents remarked:

'I talk to these people [of the interest groups] and then I ask 'Do you really think so? (...) Do you really think that animals are more important than humans?' 'No, of course not, but we have to air that opinion', otherwise you'd get, these are interest groups, you'd get in conflict with your supporters. So they are just bound to that opinion, so they really won't,

under the influence of good reasons, suddenly change their opinion, of course not, they can't'.

Table 5 Types of 'Impact' of PTA in Different Actors/Areas

Type of Impact (impact on)	Knowledge/Information	Attitude/opinion	Actor's behaviour/initiatives
<b>Policy-making</b>	<p><b>On actors involved</b> About attitude of lay people/stakeholders</p> <p><b>On issues at stake</b> Concepts/Scenarios for problem solving</p>	<p><b>Towards issue</b> New perspectives on problem</p>	<p><b>With regard to issues at stake</b> Further investigation Change in the political agenda</p> <p><b>With regard to pTA</b> Willingness to take results of PTA into account to "go on with PTA"</p>
<b>Scientific Community</b>		<p><b>Towards actors involved</b> Attitude towards 'public understanding of science'</p> <p><b>Towards PTA</b> Scientific debate on PTA</p>	
<b>Public Debate</b>		<p><b>Towards PTA</b> Comments on the procedures by interest groups</p>	<p><b>With regards to actors</b> New climate of communication and co-operation</p> <p><b>With regard to issues</b> Stimulate debate on new issue</p>
<b>Media</b>	<p><b>On PTA</b> Reports with main focus on the procedure in cases where PTA is newly introduced. Reports on results when PTA is a well established procedure</p>	<p><b>Towards PTA</b> In some cases comments on procedure</p>	
<b>Industry</b>	<p><b>On actors involved</b> Consumers' preferences</p>		<p><b>With regard to issue</b> Change in research and development programme</p>

(cf. Hennen 2002: 263, simplified by the authors)

Given this fixed position in the debate, it is perhaps no wonder that interest groups such as the organization for the protection of animals *Dierenbescherming* have – more or less behind the scenes - also focused on other solutions, such as cooperation with pharmaceutical actors, helping them to solve problems in order to diminish the number of laboratory animals used for research: a perfect example of unexpected network governance (pers. comm. interview 7).

On the individual level, the debate might have helped to foster self-reflection, as could be evidenced by the changing of student's attitudes after having watched *Dierbaar Leven*. There was little or no blockade running or antagonistic action – only the actions of the WXV could perhaps be qualified as such. The comprehensiveness in policies did not increase as a result of the debate, nor were the policies actively evaluated through it. There was no new initiative to further scrutinize the problem at stake, nor was a new orientation in politics established. No new ways of governance were introduced. Policy alternatives were not systematically filtered, no innovations were implemented and although new legislation was passed, this occurred not as a result of the PTA.

We will elaborate this impact assessment building on notions from McAdam, Tilly and Tarrow's (2001) 'dynamics of contention' theory (see for a full argument Loeber et al, 2011). McAdam et al (2001) developed the dynamics of contention theory in an ambitious attempt to dissolve the boundaries between research agendas such as nationalism, social movements and democratization. Our agenda is quite different from theirs. For our purpose, we will forego the wider implications of their work, however appreciated, to merely 'borrow' a number of their analytical notions. Notions from DOC seem well-suited to develop an analytical framework for assessing the impact of PTA, as they speak of a more fluid, networked understanding of the relation between the citizen and the polis. To that end, we adopt their concepts of *diffusion*, *brokerage*, *category formation*, *boundary activation*, *object shift* and *certification or decertification*.

To understand an arrangement's potential impact, our first contention is that it should not be taken for granted that a (policy) issue has a given audience of interested citizens. In the case of newly developing technologies, for instance, an issue may be taking shape well beyond the gaze of potentially interested or otherwise affected citizens. More fundamentally, as various authors have pointed out (Dewey, 1991 [1927], Marres, 2006), issues do not form in splendid isolation, nor do their publics: issues and publics presuppose one another. Rather than as a pre-given entity, a public of individuals comes into being when a phenomenon (and its potential assets and faults) catches their eye. In order to become active as citizens, individuals need information from one side or another on a (new) issue being framed. A PTA may well serve as a (first) source of information, and may present the very reason for citizens to become involved (rather than being a means to express their prior engagement). For assessing the potential impact of PTA in this sense it is a relevant question to which extent a PTA enables *diffusion*: does the PTA provide an opportunity for state and non-state

actors to make (aspects of) the issue known to a broader audience that previously wasn't aware of it?

A second issue of attention is tied up with the extent to which a PTA is complementary to existing platforms for citizens and others (state-actors, experts, civil society organizations and so on) to meet and engage in an exchange of thoughts and views on some issue. If indeed the idea of the state as a uniform, bounded political unit is let go off in favor of an understanding of a multitude of venues for participation in public conversations and political judgement, the question is not only which venues are more decisive in terms of formal political power (the issue addressed above, from the perspective of the bipolar model). The question is equally one of effective accumulation or *brokerage*, contributing to the “intelligence of democracy” (Lindblom, 1965; Lindblom and Woodhouse, 1993): is an active connection made between two (or more) previously unconnected social sites or actors and actor groups?

A third question of interest is when, under which conditions and at what stage of its development, an issue stirs the attention of citizens who are ‘on standby’ (cf. Hajer 2003). Will that happen spontaneously as Marres in her work (2006) seems to suggest? A relevant question for assessing the impact of PTA is to which extent it has enabled an issue public of interested citizens or actor groups to emerge. This is a question about the emergence of meaning or *category formation*: is an identity or shared boundary created between a set of sites or actors?

This in turn leads to a fourth question for impact assessment, namely that of *boundary activation*: are identities of actors or interest groups (re-)asserted in the light of the issue at stake? A PTA might cause politicians to re-assert the importance of their own role, or scientists to emphasize the importance of expertise in decision-making.

A fifth issue is the possibility of an *object shift*: is there an alteration in relations between claimants and objects of claims in either the short or the long run? A PTA might give rise to new, unexpected coalitions between different interest groups, or between interest groups and third parties.

A sixth and final issue is that of *certification* or *decertification*. The question here is whether and to which extent actors and their performances or claims are considered valid by external actors, and are validated through their (speech) acts. The PTA might, for instance, be publicly declared important, representative or legitimate by members of the formal representative democratic system, but can on the contrary also be used to legitimize the formal representative system.

Although this list is by no means exhaustive, it provides a starting point to explore the various ways in which a PTA could have an impact on the policy field in which political will

formation and judgment on a (newly developing) technology are playing out. In the following, we will use this framework to study the impact of PTA's. We will show that, although the impact of PTA is limited in traditional terms, the DOC-based framework helps us to see changes that occurred due to a PTA.

**In terms of *diffusion*, the PTA could be called a success:** it provided an opportunity to make (aspects of) xenotransplantation known to a broader audience that previously wasn't aware of it. This was the case also for state actors such as civil servants at the Ministry of Health. For some people previously active in anti-biotechnology campaigns, the PTA formed a reason to establish the so-called Working Group (Xeno-)transplantation Questions. Although this interest group experienced difficulties to make its message known, it acknowledges that the PTA provided a platform for voicing its views, in the slipstream of which other actors could make their point of view.

**The PTA also had an impact in terms of *brokerage*.** For instance, an unexpected coalition emerged between the main Dutch animal welfare organization (*Dierenbescherming*) and patients' organizations that considered the issue of xenotransplantation in the light of donor organ shortage. Patients' organizations were not too pleased with the PTA, arguing that it addressed 'the wrong issue' (they would rather see a discussion about a different donor registration system) and that talking about xenotransplantation would discourage potential donors. On the other hand, the animal welfare organization – which vehemently opposed xenotransplantation – could not afford to look self-centred, caring for animals rather than assisting humans dying for lack of donor organs. Thus, animal welfare organizations found themselves encouraging their members to become human donors. One might describe this particular process as alteration in relations between claimants and objects of claims, in other words, as an example of object shift in terms of the DOC-based framework. Our respondent from the *Dierenbescherming* described the newly established contacts with patient organizations as 'unique' (pers. comm., interview 7):

'As if we as *Dierenbescherming*, by opposed against experiments involving animals (...) would hinder scientific development, and now it turned out that these organizations weren't that much in favor of xenotransplantation either. So they suddenly became a kind of partners'.

**The PTA also stimulated processes of *category formation and boundary activation*.** In terms of category formation, an ambiguous process occurred. On the one hand, a common identity was created between a diverse set of actors, namely, patients and vegetarians, who were considered to hold a privileged speaking position within the debate – 'you might be against this, but you would say something different if you yourself were dying waiting for a new kidney', or 'you might be against this, but only if you do not eat meat'. On the other hand, this identity was to a large extent fictive, as the real patient organizations were wary of the risky, new technology. Thus, a discursive identity was created from above, while the

'real' patients and vegetarians did not claim this identity. In terms of boundary activation, we see in other words, how the PTA gave rise to reflections about the primacy of politics, and the appropriate role of parliament vis-à-vis the public and the expertise of scientists, but that the topic 'faded away', as one of our respondents put it.

**There were attempts at decertification of the PTA, as well as at its certification:** the PTA was considered valid to different extents. Some actors doubted the PTAs relevance (biotechnologists; pers. comm.), or its timing. Government actors questioned the representativeness of the PTA. The above mentioned Working Group (Xeno-)transplantation Questions wrote its own, critical evaluation of the debate. Yet the debate was certified and considered legitimizing by the Minister when she wrote in a letter to parliament that the results of the debate corresponded with her own views on the subject.

It is of course impossible to be certain whether or not these effects would also have taken place without the PTA. This applies particularly to **boundary activation**: on the one hand, the debate gave rise to meta-reflections in parliamentary politics e.g. on the relevance of initiating public debates). On the other hand, the PTA would not have been organised if these doubts had been there already. Furthermore, xenotransplantation did not present a major societal controversy. Attention for the issue was generated via this PTA, so it seems justifiable to state that **diffusion, brokerage, category formation, object shift and (de)certification were stimulated by the PTA.**

**Table 6: Public debate on xenotransplantation in the Netherlands 2000-2001**

Diffusion	Yes: the campaign itself employed activities to diffuse information, such as a website and free cards, and generated free publicity in various national media, such as news papers, radio and television.
Brokerage	Yes: an unexpected, temporary coalition emerged between animal welfare organizations and patient interest groups (however, this coalition dissolved when other issues than xenotransplantation challenged the coalition parties' co-operation).
Category formation	Yes: a new discursive category was formed, consisting of patients in need of a donor organ grouped with vegetarians with a legitimate claim against using animal donors. Yet 'no': actual patients and vegetarians dismissed the correctness of this discursive category.
Boundary activation	Yes: the PTA gave rise to reflections in parliament about the primacy of politics, and of the role of politicians in comparison to scientists and the public.



Object shift	Yes: animal welfare organizations encouraged their members to become donors.
Certification or decertification	Yes: various actors doubt the relevance or legitimacy of the debate; government actors question the representativeness of the PTA. At the same time, the process is certified through the Minister's statement in defence of her policy-decision to ban xenotransplantation by stating that the results correspond with her own ideas.

(cf. Loeber, Griessler, Versteeg, 2011).

## 7 The Dutch public and its right to speak

During the public debate about xenotransplantation, several actors tried to define who is and who is not allowed to speak. In this paragraph, we will focus on the image of the general public in an attempt to draw the connections between the various social fields mentioned above. First, we will focus on the discursive dichotomies dividing the public in different groups with supposedly different rights to speak. We will then move on to the image of public opinion during the xenotransplantation policy process.

One of the mentioned dichotomies is that between *vegetarians and non-vegetarians*. For instance, when Minister Borst meets with the First Chamber in March 1999, she remarked that:

‘I always wonder about how many people who eat pork meat as if it was natural, start a voluminous disquisition about the instrumental use of the pig as an organ donor and regard this as a big ethical problem. I find it more legitimate that a vegetarian such as Mrs Tuinstra speaks this way than all those Dutch people who are no vegetarians and still say: you cannot breed an animal to then use it as a donor. Apparently you can if you eat them. I approve of a societal debate. I will be glad to promote that. Maybe the Rathenau Institute can fulfill a role in this. Then this aspect will certainly be discussed as well and might be clarified for me’. (First Chamber, 30 March 1999).

Likewise, in the play *Dierbaar Leven*, the dichotomy is between burger eating, ‘normal’ boy Remco who thinks about accepting an animal kidney, and the activist vegetarian Gemma who is vehemently against it. Research has indeed shown that a higher proportion of the non-vegetarians than of the vegetarians accept xenotransplantation (Hagelin et al., 2000). Nevertheless, the image of the vegetarian seems to act as a kind of figurehead within the debate, excluding everyone who does eat meat.

Another division is made between *donors and non-donors*. As we have seen, organizations for the protection of animal rights encouraged their members to become donor. This might, of course, have helped to legitimize their own position as antagonists of xenotransplantation as a new technology, and counter claims such as ‘Face it, humans are more important than pigs’ (Van Dijk 1998).

A third division is made between *patients and non-patients*. A typical statement is that one is now opposed to xenotransplantation, but recognizes that this might be different when one falls ill. We have seen, however, that at least some of ‘the real patients’ do not approve of

the debate, as they are afraid that a debate about the possibilities of xenotransplantation will further diminish the availability of human organs.

Thus, whereas the divisions between *vegetarians and non-vegetarians*, or *patients and non-patients* might seem to be self-evident or logical given the topic of the debate, we see how the discursive patient, the donor and the vegetarian are raised to the status of moral touchstones, thus diminishing the right to speak of healthy people who are no donors and eat meat. That this is not self-evident, becomes clear when we remember that xenotransplantation can also be framed as an issue of *weighing collective risks and individual health benefits*, that is, possibly influencing healthy, meat eating people as much as those in need of transplants. This latter framing was a major reason for organizing the public debate in the first place, and is ultimately adopted in the ban (*“to avoid that medical xenotransplantation procedures are conducted with humans, without reasonably excluding unacceptable risks for the health of humans. This applies not only to risks for the experimental subject/patient. At least as important is to reasonably exclude unacceptable risks for his environment, and therewith for the public health”*) (First Chamber, 30 March 1999).

The image of public opinion is a malleable one, as becomes clear from the statements of various actors in the xenotransplantation debate. On the one hand, the organization has to be a mediating and more or less neutral channel, transmitting public ideas and images concerning xenotransplantation to the government, and therefore tries to be ‘as objective as possible’. On the other hand, despite the statement by WeTen that the government wanted to know the ‘raw opinion of the people’ (*ongezouten mening van het volk*), it seems as if the public debate was designed to find not the raw but the ‘real’ public opinion, that is, an opinion undistorted by irrational fears.

When Minister Borst discussed xenotransplantation with the Second Chamber on February 2, 2000, she outlined the elements of the intended debate, one of which is an opinion poll. It seems as if the debate is designed at least in part to collect opinions of those in favor of xenotransplantation:

*‘We also intend to have a public opinion poll during or at the end of this year. According to a press statement, two third of the people is against xenotransplantation. However, that is no opinion poll. When one is against something, one is more inclined to voice his opinion than when thinks it’s OK.* (Second Chamber, Minutes of the General debate, 2 February 2000, 26335 no 13.)

Because the knowledge of the public was expected to influence the opinion formation, it was a central concern to the organizers of the public debate. The WXV even claimed that C&B tried to demarcate what would be appropriate knowledge, by making exclusive contracts with the public organizations that participated in the debate. According to the WXV, they had

received a letter from the secretary of the NVVH (Dutch Organization for Housewives), which stated that:

'It is the very idea of C&B that people should not know too much about it (...). De NVVH has, in coordination with C&B, chosen for a design which will allow the members of the NVVH to discuss the subject without pre-existing knowledge about the advantages and disadvantages, that is, no more knowledge than the average Dutch person' (Werkgroep (Xeno-)transplantatievraagstukken (nd).

When confronted with this statement, C&B project leader Margreet Bloemers explained that the intention of C&B was to conduct the small public discussions only with the organization involved. In this way, C&B was better able to control the information with which the public was provided – including interest groups such as the W(X)V might lead to a one-sided emphasis on the negative perspective (pers. comm. Interview 1). C&B regards itself as a more or less neutral channel via which the opinion of society as a whole can be conveyed:

'In February, when the moratorium regarding the clinical use of xenotransplantation and the clinical research into that was published, the politicians have said: society as a whole must have the opportunity to inform itself about this subject, and to have a say in it. The government has to provide a channel via which everyone can utter his opinions, images and emotions. There is a trend to take this increasingly into account in the decision making process'. (Anon. 2000).

When Bloemers is asked whether the debate should not be seen as merely window dressing, and whether the gathered opinions will really be used:

'The Minister has promised to weigh the results of the public debate in decision-making. When the final policy would be different from the public opinion, she will explicitly clarify her choice' (Anon. 2000).

Thus, at this point in the policy process, the moratorium is presented as merely a halt, which will allow public opinion to feed final decision-making. This perception was crucial for the public debate, as another organizer of the debate explains (pers. comm. interview 6):

'We were happy with the temporary moratorium, because otherwise, it would have seemed as if the minister or the CCMO had just pushed through and had already decided about xenotransplantation in the Netherlands. So it was very prudent that they decided for a temporary moratorium of two years'.

However, exactly *how* the public opinion will be taken into account remains an open question. In April 2001, the government answers – when asked about the role of the societal debates about cloning, xenotransplantation and genetically modified food in decision making:

‘The problem of these debates is that the results can almost certainly not be seen as a correct representation of the opinions of the population as a whole. From the public debates, it can become apparent which aspects of a certain area of application are not regarded problematic by part of the population, which applications are acceptable under conditions and which applications are unacceptable. Knowledge about these opinions can then be weighed in the administrative and political decision making’. (Second Chamber, 27 428 en 27 543, no. 4)

The preface of the C&B report - written by Egbert Schroten, professor in Christian ethics, Director of the University Centre for Bioethics and Health Law, and Chairman of the Dutch National Committee on Biotechnology involving Animal – qualifies this statement:

‘public debates are intended to involve the public (more) in a certain issue. But, following on from this, they are also about generating support for policy and trust in policy makers, matters that are of fundamental importance in a democracy. When introducing new technologies with radical consequences for society, such as biotechnology and information technology, support and trust are even crucial’. (C&B 2001: 4)

Rather than being a space in which the opinion of ‘the’ public can be voiced, the public debate is here described as a vehicle to create trust in existing policy and decision-making structures. Rather than drawing clear boundaries by political decisions, public debates and depoliticized expert committees such as the CBD help to establish a framework within which the sector can develop.<sup>5</sup>

This twofold goal might – together with the emancipatory intentions of the debate - explain the search for an ‘authentic’ public, unspoiled by the polarized opinions of the interest groups, and the focus on a palette of opinions rather than on a clear message to politics. But all our interviewees acknowledged the struggle to get in contact with the ‘right’ public. A former Rathenau employee, who was critical about the meetings as organized by C&B, also remarked that the citizen panels as organized by the Rathenau were problematic in a different way. Respondents would start uninformed, their opinions being similar to those

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<sup>5</sup> Illustrative is the following quote from the preface of the C&B report (C&B 2001: 4): public debates are intended to involve the public (more) in a certain issue. But, following on from this, they are also about generating support for policy and trust in policy makers, matters that are of fundamental importance in a democracy. When introducing new technologies with radical consequences for society, such as biotechnology and information technology, support and trust are even crucial. A public debate can form a modest contribution to this.

obtained by street surveys. However, once they were informed, they would become experts and air expert opinions, losing their value as a 'sample' of the public (pers. comm., interview 9).

In short, the role of the public in the Dutch xenotransplantation debate can be summarized as insignificant in terms of its influence on political decision-making. Compared to the other Dutch societal discussions about biotechnology, the xenotransplantation debate was by no means exceptional in its mixture of one-way and two-way communication, and its emphasis on knowledge and trust (see Dijkstra, 2008: 142).

## 8 Conclusions and discussion

While ten years after the debates took place most respondents declare to remember very little of the events, and the word ‘xenotransplantation’ is virtually absent in policy texts and media, at the time the topic generated quite some heat, notably in policy circles. In the Netherlands, there was no widespread public concern in regard to it, which – looking back – is in line with the absence, by and large, of social turmoil or protest in the light of such issues as BSE (‘mad cow disease’) or GMOs, as was the case in other European countries (Loeber et al. 2007). Reasons for this relative complacency may be argued to root in the trust put by the Dutch population in the technical approach to risk governance in the Netherlands (cf. Paul, forthcoming) and in the positive appreciation of biotechnological developments in general (cf. Gutteling 2002). Yet, apparently there was sufficient reason to stage a large-scale public debate on the topic.

By way of conclusions, first, the reasons will be summarized why such an elaborate PTA on the topic was initiated in the first place. Thereupon, conclusions will be drawn as to the (lack of) impact of the PTA on the formal policy-making process. Against this background, an answer will be formulated to the question to which extent xenotransplantation was considered an intractable policy issue in the Netherlands.

### 8.1 The ‘why’ of a Dutch PTA on xenotransplantation

From the above it can be concluded that the reasons why parliament, and with it, the Minister of Health, insisted on the organization of a public debate are threefold.

First of all, the topic appeared on the political agenda at a time when the political scenery of the Netherlands was changing to an extent not seen before. While confessional parties had been represented in all Dutch Cabinets since 1918, now a coalition between liberal and social democratic parties was crafted. Among the parties in office was a social-liberal party (D66) that was known for its liberal perspective on health care themes. It was this party’s former leader, dr. Borst-Eilers, who was the Minister of Health at the time the xenotransplantation policy process unfolded. In the context of this new political configuration and economic welfare, novel approaches to regulating controversial health issues (such as euthanasia) were deemed possible. As one of the organizers of the xenotransplantation debate put it (pers. comm. interview 6):

‘The time was ripe for larger debates; a lot of people had the feeling, that it was necessary to involve more citizens, more stakeholders in debates such as the one about xenotransplantation’.

Secondly, it was a time when high hopes were held as to the potentiality of improving the quality of democracy by organizing societal debates. It was the time of the re-formulation of the Dutch TA Institute's formal mission (cf. Rathenau Institute 1994) to contribute to societal debates and opinion forming on scientific or technological developments. Experimenting with methods and approaches to participatory forms of Technology Assessment, the Rathenau Institute, and with it, policy-makers in general were convinced that organizing public engagement in view of technological developments was a good thing as such. As expert bodies, politicians and organizers of the debate at the time reasoned on the basis of a deficit model, aiming at least as much to educate and thus emancipate the public as to gather its view, it is not surprising that this 'good thing' did not result in clear policy recommendations.

That it was not the Rathenau Institute itself that got commissioned to set up the xenotransplantation debate but rather a relatively small organization is explained in different ways by the various interviewees. One explanation is the fact that parliament was wary of turning to one particular party at all times to mediate between them and society. In spite of the Rathenau Institute's efforts to develop a profile of neutrality and mediation, it was conceived of as being an advocacy actor in its own right (pers. comm. interview 13). The topic of xenotransplantation offered a suitable occasion for further experimentation with forms of public deliberation as organized input into the policy process, and the involvement of a relatively small actor as its organizing party promised a new way to explore the road of public engagement. For the Ministry of Health, it was wise to keep the different channels separated. As the Rathenau is a formal advisory institution for parliament, direct requests from the ministry were considered to be 'sensitive' at the time (pers. comm. interview 15). A different explanation was that the Ministry of Health was not satisfied with the public outreach of a previous debate organized by the Rathenau, and was - presumably therefore - looking for a different organizer. Moreover, the Rathenau Institute did not agree with xenotransplantation as a new technology as the topic of the debate, focusing rather on the problem of organ shortage; a smaller and more dependent organization such as C&B would be less capable to determine its own agenda (pers. comm. interview 9).

What was known at the time was that the application promises implied by immunosuppressive medical research were challenged seriously by strong societal protest against the manipulation and breeding of potential donor animals in the UK, notably by militant animal activists.<sup>6</sup> In the Netherlands, as is clear from the above, these protests were mirrored to a minor extent only, whereby British concerns over the wellbeing of animals were complemented with a broader range of issues, including the potential risks to the human population, ethical objections against genetic modification in general and the illusive power of the multi-nationally organized pharmaceutical industry.<sup>7</sup> The Dutch public information campaign described in chapters 4 and 5 may be viewed as a way to get the Dutch public

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<sup>6</sup> See <http://www.xenodiaries.org/chronology.htm>, accessed September 26, 2011

<sup>7</sup> See: Groeiende weerstand tegen xenotransplantatie, *Ravage* 11, September 1, 2000, <http://www.ravagedigitaal.org/archief2000/0011a15.htm>, accessed September 26, 2011



informed on the topic. To build on and elaborate that campaign with a formally organized public debate may be understood as a response to the fact that, because of the information campaign, the promises of the pharmaceutical research prompted people to form an opinion on the possible applications of newly developing technology. In turn, the promise of potential benefits of such research in the form of concrete solutions to an existing problem – the shortage of donor organs – could help justify the financing of further research on the topic. Such a cyclical, and mutually influencing development between technological progress and public opinion making as described by Mampuy and Brom (2010) for the case of synthetic biology (who base their argument on Gartner's technology hype cycle; cf. Fenn, 1995) seems to offer suitable explanatory ground to explain the felt need to set up such a large-scale public deliberation arrangement even in spite of any public unrest regarding the issue of xenotransplantation in the Netherlands.

## 8.2 The PTA's (lack of) impact

These reasons for the initiation of a large-scale public debate in the Netherlands may also help to explain the dominant framing of the issue in the debate, namely in terms of *xenotransplantation as a potential solution to the problem of donor organ shortage*. While the Dutch cabinet, witness its initial letter to Parliament about stimulating and developing xenotransplantation, as well as the debate as organized by C&B considered xenotransplantation as a resolution for the shortage of donor organs, the main actors in the transplantation domain, either involved in its logistical organization of representing organ requiring patients, did not necessarily share that perspective. As discussed in chapter 5, they were *not* in favor of xenotransplantation as a solution to the problem of organ shortage, and were not at all keen on initiating such a debate. Notably the researchers, as was discussed above, felt it was a waste of time and money, and merely stalling technological progress. It is noteworthy to observe that within the public debate, or in the discussions in parliament and the media, this perspective was seldom voiced. In the public debate, xenotransplantation was rarely connected to the economic importance of the Dutch biotechnological sector, which, in other policy circles and plans was an important topic of concern and investments.

Yet, as said, the urge to arrange a PTA on the topic came both from the Health Council and parliament, and was shared by some in the Ministry of Health. At the same time, in the absence of social turmoil or academic activism, the Health Ministry had no reason whatsoever to doubt suitability of the regular regulatory practice for dealing with biotechnological research issues, which was based on an expert handling and case by case admission by expert committees.

It is perhaps not surprising then that in answer to the question *to which extent did the PTA have an impact on judgment and decision-making practices in the policy field at issue* it is observed from the data presented in this report, that the PTA remained an 'add-on' to the regular process of regulation and decision-making. The moratorium and the ban were the

result of a Second Chamber motion, not of the PTA itself. The policy process was characterized by the regular dynamics of Dutch policy-making on biotechnological issues – expert advice to the Ministry of Health, presentation of this advice by the Minister to parliament, its discussion in parliament in – usually – two rounds, formulation of policy measures for regulation, an assessment of the measures proposed by highest judicial council in the Netherlands – which at no time ever got challenged or distracted by the decisions taken in regard of the PTA, its staging or its outcomes. This being said, it must be added that the results of the PTA did not necessitate to a drastic revision of the policy already decided form, which complicates the question whether or not the PTA (could have) had an impact. There was, in any case, still the possibility to change policy had this been deemed necessary. But at least as much and maybe more than on the actual results – which would not amount to a correct representation of the population's views – the debate focused on the enlightenment of the public.

A major goal of the debate was to help enlighten the public about the potentiality of xenotransplantation as a solution to donor organ shortage issues. The public was, in order to be able to voice its concerns, considered to be in need of education on the topic. Only after having been provided with adequate information the 'real' voice of the people could be heard, and this real voice was assumed to be more rational and more positive than the initial public reactions, or the more radical voices of interest groups on both sides of the spectrum. Although one of our interviewees argued that there were no proponents within the debate – due to the lack of knowledge about the actual risks - it also seemed to be hard to voice objections against xenotransplantation. These could easily be dismissed by the referral to an "authentic, affected public" (Braun and Schultz, 2010): the construction of virtual stakeholders, such as 'the patient' and 'a vegetarian'. These perceived authentic stakeholders came in view in the discussions among parliamentarians and in the statements by the minister of Health on the topic. In several speech acts, they served as moral touchstones in the debate: anyone against xenotransplantation was, such was the connotation, acting explicitly against the interests of patients in need of a donor organ or transgressing one's moral right to speak on animal-related issues.

In this light, it is not surprising that the PTA was seen to have little impact in terms of actually influencing the formal decision-making process. For one, the results from the debate were presented to the Minister only after the formal, final decision to put a ban on xenotransplantation research and application in the Netherlands had been taken. This idea was proposed by the Minister of Health in July 2001, inspired by the technical judicial advice of the highest judicial council, while the final results of the public debate were presented to her in August 2001.

However, as is discussed in chapter 6, a PTA's impact may be assessed from a wider, more sophisticated understanding of how political judgment and decision-making takes place. Given the information featured in chapters 3 and 4, the Dutch policy domain in which this

process evolved comprised of the policy fields of biotechnology as well as organ transplantation, as well as of animal-related medical concerns and of human medical ethics. Within this broader field, the PTA can be argued to have had an impact in all terms identified above as relevant: in terms of *diffusion* - the PTA provided a clear opportunity for state and, to a lesser extent, for non-state actors to make aspects of the xenotransplantation issue, and their views on these, known to a broader public; in terms of *brokerage* – because of the PTA, an unexpected, temporary coalition emerged between animal welfare organizations and patient interest groups; in terms of *category formation*: a new discursive category was formed, consisting of virtual patients in need of a donor organ grouped with vegetarians with a legitimate claim against using animal donors; in terms of *boundary activation* - the PTA gave rise to reflections in parliament about the primacy of politics, and of the role of politicians in comparison to scientists and the public; in terms of *object shift* - animal welfare organizations encouraged their members to become organ donors, and, finally, in terms of *decertification* - various actors came to doubt the relevance or legitimacy of the debate.

On the basis of the above, it may be concluded that at the time the PTA provided an additional deliberative space, where interest groups and members of the public could join – even though in by and large separate trajectories – the ‘usual suspects’ involved in biotechnological policy formation to discuss xenotransplantation as a technology, but also related issues such as the appropriate registration system for organ donors. This happened both in face-to-face contacts, such as during the public meetings, and in a more indirect way, via websites and news paper articles. Various methodologies were used; quantitative and qualitative research, adverts, websites and forums, public discussions at various places. The media attention generated by the debate was helpful for some of the smaller interest groups. However, the PTA was finally perceived as mainly an echo of the concerns of decision-makers (Versteeg and Loeber 2010).

In terms of gender, no impact is observed. Gender was seldom explicitly mentioned in the xenotransplantation debate. The only group to mention it was the action group against xenotransplantation, WXV that argued that the increased attention for transplantation surgery was associated strongly with the medical branch, with a very low percentage of women present. In contrast, in the public debate and wider PTA events women were the dominant group of attendants. According to C&B, a relatively large number of women participated in the public discussions, although their perspective did not seem to deviate much from what was expressed in meetings attended predominantly by men. Had there been a deviation, the view of women would then be represented better rather than worse, given the fact that C&B has based its report mainly on the public discussions. However, it is difficult to draw conclusions regarding the number of women and men, as these have not been quantified in the PTA’s final report. Of the organizations consulted prior to the public debate, there were five female and six male spokespersons; of the four moderators, one was female; two of the four C&B people responsible for the debate were female, as were two of

the four deputy members. Although women were underrepresented in the monitoring committees and the consulted technical experts, it seems as if the role division within the organization of the debate was fairly equal.

### 8.3 Xenotransplantation: an intractable policy issue?

In conclusion, on the basis of the above, and in discussion with new literature on the topic of intractable policy issues, the question may be answered *to which extent and how the Dutch handling of the xenotransplantation issue presents an example of dealing with intractable policy issues.*

As said, the intractability of policy issues, as defined by Hisschemöller and Hoppe (1996), and Schön and Rein (1994) is implied in the combination of factual uncertainty and normative dissent about which aspects of an issue are relevant, and by which criteria these should be judged. A new perspective on intractability has been developed in view of newly developing technological issues of late. Developments such as synthetic biology, the development of human enhancement technologies and genetic engineering all imply the potentiality of insecurity as to the 'symbolic order' by which to make sense of these developments and their products. As Swierstra et al. (2009) convincingly argue on the basis of work by Douglas (1966 [2002]) and Smits (2002), characteristic of the symbolic order is that it offers way to draw boundaries by which to make sense of reality as it presents itself to the human observer. Boundaries such as in the dichotomies between man/woman, life/death, natural/artificial, and human/animal present an implicit grammar by which we order our thoughts and arguments. New technological developments such the ones mentioned hold in common that they challenge the self-evidence of these boundaries. Synthetic biology for instance does not fit easily with the basic dichotomy, so fundamental to our understanding of the world, between nature and artifactual reality. Swierstra and his colleagues coin the phrase 'ultra-intractable' (*ultraontembaar*) to refer to issues that potentially bring along, in addition to the factual uncertainty and normative dissent, uncertainty or at least confusion with regard to the symbolic order in which it is embedded.

Xenotransplantation potentially entails all three aspects of (ultra-)intractability: there was uncertainty about technical and factual aspects, e.g. in regard to retroviruses that might spread from porcine organs to the human host or population. While all other technical issues however complex, seemed solvable, this issue presented – at the time – a controversy between scientists that was left unresolved. That was the result, in turn, of a dissensus in regard to the proportionality of costs involved in developing suppressing mechanisms for such viruses. This controversy was only one among the many topics in the public debate. Some controversies over the relative relevance of some aspect of the issue over another, or over some assessment criterion over another, were reported. The foremost were controversies emerging from the way the issue was framed as a solution to a pre-existing problem. As said, xenotransplantation was primarily framed in the Netherlands as a solution

to the problem of organ shortage. Whereas some groups perceived xenotransplantation as a possibility which might enhance the options of patients in need of a transplant, others feared that the problem of scarcity will be here to stay - either because of a growing wish to postpone death, or because the number of human donors might diminish when animal organs are available. In none of the discussions retrieved, either via video or in writing, were there manifestations of concern about 'symbolic uncertainty', a transgression of the symbolic order as possibly implied by trans-species grafting (animal/human).

The deliberative space created by the PTA presented an additional (set of) arena(s) to the many sites for contention and political judgment that characterizes Dutch regulatory practice. While formal decision-making was completed before the final report of the debate was made available, the straightforward conclusion that the PTA therefore could not have had any impact on the decision-making process is incorrect (see chapter 6). This observation draws attention to a more striking conclusion: the decision to organize a PTA did, in contrast to what may be expected, not necessarily mean that the issue of xenotransplantation was considered an 'intractable' policy issue in the Netherlands. Instead, organizing a PTA fitted well within the standing practices of regulation of that time; the PTA was a complement to parliamentary decision-making. Both the Health Council and parliament considered the issue a relevant topic for public consultation – a point of view shared by the Minister of Health, who came from a political party (D'66) with a strong emphasis on direct democracy. Although the PTA was acknowledged as an instrument of legitimation, it was equally intended to educate or 'emancipate' the public with regard to its attitudes concerning biotechnology. Negative attitudes concerning new technologies were implicitly or explicitly regarded as emotional or irrational. It is perhaps not surprising then that the public's debate end-report was not intended to convey a one-off, one-dimensional political statement. Rather, the C&B organizers meant it to be rich in perspectives and thus informative to the Minister and her civil servants, whose position to have a final say in this matter was not challenged, at least not by the debate's organizers. In contrast to this, the advice from expert committees and regulatory agencies such as the (at the time newly established) CCMO, the Health Council and the Council of State was explicitly taken into account in the policy process. Even though in parliament the issue of the public's right to speak was discussed in terms of the 'primacy or politics' debate, the PTA was not intended or viewed as a radical breach with standing regulatory practice, merely as an innovative complement to it.

## 9 Annex

### 9.1 References

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## 9.2 List of interviewees

1. Margreet Bloemers, projectleader C&B for the xenotransplantation debate, 3-6-2010
2. Egbert Schroten, CBD/advisory board xenotransplantation debate, 1-7-2010
3. Lea Witmond, manager Pandemonia, responsible for the theatre play *Dierbaar Leven*, 2-7-2010
4. Tony Maples, artistic leader Pandemonia, responsible for the theatre play *Dierbaar Leven*, 2-7-2010
5. Jeroen Breekveldt, Werkgroep (X)TV, 16-7-2010
6. Frans van Dam, C&B, now CSG, 24-8-2010
7. Marianne Kuil, Animal protection agency *Dierenbescherming*, 13-9-2010
8. Henk-Jan Ormel, Member of parliament, confessional party CDA 23-9-2010
9. Gert van Dijk, ethicist, formerly employed by the Rathenau Institute, 2-11-2010
10. Nande Kootker, policy maker at NTS Dutch Transplant Foundation, 4-11-2010
11. Frank Grosveld, biotechnologist and scientific advisor to the CCMO, 5-11-2010
12. Lydia Sterrenberg, former program manager at Rathenau Institute, 8-11-2010
13. Dirk Stemerding, TA researcher Twente University, and senior program manager at Rathenau Institute, 22-11- 2010
14. Gerrit-Jan Olthof, Ministry of Health, 9-12-2010
15. Jasper Boomker, Dutch Kidney Foundation *Nierstichting*, 14-12-2010

### 9.3 List of abbreviations

Amvb:	Order in council
C&B:	Consumer & Biotechnology
CBD:	Committee biotechnology involving animals
CCMO:	Central Committee Medical Research involving human subjects
CDA:	Christian-Democratic Appeal – christian-democratic political party
D'66:	Democrats (19)66 – liberal-democratic political party
EZ:	Ministry of Economic Affairs
GM:	genetically modified
GPV:	(then) Reformed Political League, now Christenunie
GWWD:	Law on Animal Health and Welfare
KNAW:	Royal Dutch Academy of Science
LNv:	(then) Ministry of Agriculture, Nature and Fisheries
NVBD:	Dutch Society for the Protection of Animals
NVDEC:	Dutch Society of Animal Experiment Committees
NWO:	Dutch Science Organization
OCW:	Ministry of Education, Culture and Science
OECD:	Organization for Economic Co-operation and Development
PTA:	Participatory Technology Assessment
PvdA:	Party of Labour
RDA:	Council for Animal Affairs

RPF:	(then) Reformatory Political Federation (now Christenunie)
SER:	Socio-economic Council
SGP:	Reformed Political Party
SP:	Socialist Party
SWOKA:	Institute for strategic consumer research
VROM:	(then) Ministry of Traffic, Spatial Planning and Environment
VVD:	People's Party for Freedom and Democracy
VWS:	Ministry of Health, Welfare and Sport
WXV:	Working Group (Xeno-)transplantation Questions



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