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Xenotransplantation Policy and Participatory Technology Assessment in Switzerland

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Founded in 1963 by two prominent Austrians living in exile – the sociologist Paul F. Lazarsfeld and the economist Oskar Morgenstern – with the financial support from the Ford Foundation, the Austrian Federal Ministry of Education, and the City of Vienna, the Institute for Advanced Studies (IHS) is the first institution for postgraduate education and research in economics and the social sciences in Austria. The **Sociological Series** presents research done at the Department of Sociology and aims to share "work in progress" in a timely way before formal publication. As usual, authors bear full responsibility for the content of their contributions.

Das Institut für Höhere Studien (IHS) wurde im Jahr 1963 von zwei prominenten Exilösterreichern – dem Soziologen Paul F. Lazarsfeld und dem Ökonomen Oskar Morgenstern – mit Hilfe der Ford-Stiftung, des Österreichischen Bundesministeriums für Unterricht und der Stadt Wien gegründet und ist somit die erste nachuniversitäre Lehr- und Forschungsstätte für die Sozial- und Wirtschafts-wissenschaften in Österreich. Die **Reihe Soziologie** bietet Einblick in die Forschungsarbeit der Abteilung für Soziologie und verfolgt das Ziel, abteilungsinterne Diskussionsbeiträge einer breiteren fachinternen Öffentlichkeit zugänglich zu machen. Die inhaltliche Verantwortung für die veröffentlichten Beiträge liegt bei den Autoren und Autorinnen.

Contents

1 Introduction

Citizens, policy makers and social scientists often call for citizen participation for reasons of democratic legitimacy and effectiveness. An important field in which this has been claimed vigorously is science and technology policy. Thus, many countries witnessed the introduction of Participatory Technology Assessment (PTA). The "litmus test" of PTA, and of citizen participation, is their impact on policy-making.

- But can PTA keep its promises and increase the influence of citizens' voices on decision-making?
- What in actual fact is the impact of PTA on decision-making?
- How can we increase it?

In order to answer these questions the project "Impact of Citizen Participation on Decision Making in a Knowledge Intensive Policy Field" (CIT-PART) studies comparatively the impact of PTA and TA on policy-making in Austria, Canada, Denmark, Italy, Latvia, The Netherlands, Sweden, Switzerland, United Kingdom, the European Commission, the OECD and the Holy See. From that the project draws conclusions about the potential impact of institutionalised citizen participation on EU level.

This project exemplifies its questions through the reactions of various political systems to the challenge of Xenotransplantation (XTP), which stands for the transplantation of animal organs, tissues or cells into humans. XTP is highly controversial: Its advocates perceive it as promising since it could help to remedy the shortage of human transplants. Its opponents insist that it involves too many risks - most prominently infection risks - and ethical questions.

Adopting a theoretical approach of “social practices” it is assumed in the project that the impact of citizen participation on decision-making is not only dependent on the quality of the PTA process itself but on practices of policy makers in which PTA is embedded in. Following from our theoretical approach the project applies qualitative methods of empirical research. The CIT-PART research team involves researchers from anthropology, communication studies, political science, public law, social psychology and sociology.

1.1 Case selection

Switzerland is an interesting case for the CIT-PART project for several reasons. Firstly, one of the companies that invested most heavily in xenotransplantation in the 1990s was the Swiss based firm Novartis (then Sandoz), which in April 1996 acquired the UK firm Imutran. The close association of the leading industrial investor in xenotransplantation with

Switzerland's research and business location was one reason why this technology became a matter of debate in the Swiss political system and the general public. After a heated parliamentary debate in 1999 on whether to ban xenotransplantation in general, only allowing for a few well defined exceptions (as proposed by the Swiss government, the Federal Council, Bundesrat), the majority of the Swiss Parliament finally decided for an in principle permissive policy approach. In two subsequent laws, which came into effect in 2001 and 2004, the Parliament stipulated strict requirements for research and rules of liability prior to authorization of clinical trials (Eidgenössisches Department des Innern 2001).

Secondly, Switzerland is interesting because there was some xenotransplantation research taking place. Novartis and several research groups at university hospitals were active in this field. Research at university hospitals, however, did not focus on solid organ, but on cellular xenotransplantation (Bellucci et al. 1998: 157).

Thirdly, and most importantly, in the late 1990s the parliamentary Swiss Technology Assessment Programme (later renamed TA-Swiss) commissioned two TA studies on solid organ as well as cellular xenotransplantation (Hüsing et al. 1998 and 2001) and in 2000 a participative technology assessment exercise (PTA), called PubliForum Transplantationsmedizin (ZTA 2001).[1] In the PubliForum 28 citizens discussed problems of transplantation policy in general and in one working group specifically focused on the problems of xenotransplantation. Thus, Switzerland, besides Canada and the Netherlands, is one of the few countries in which PTA on xenotransplantation was carried out.

Finally, Switzerland is also interesting for our sample due to its political system. Its strong elements of direct democracy provide an opportunity to investigate the institutional match between PTA and direct democracy.

1.2 Methods

For this case study I interviewed eleven experts from TA-organizations (3 TA-Swiss, 1 Fraunhofer Institute for Systems and Innovation Research (FhG-ISI)), xenotransplantation research (3), public administration (2), politics and bioethics (1 interviewee each; see list of interviews). The interview partners were either involved in xenotransplantation research, TA and PTA on xenotransplantation and/or the respective policy making process.

The interviews were carried out from May to September 2010 in Switzerland and Austria. They were taped, fully transcribed and analysed using ATLAS.ti, a software package for qualitative content analysis. Data analysis followed Meusser and Nagel's (2002) suggestions

[1] The names used by TA Swiss on its publications changed over the years. Names used are Schweizerischer Wissenschafts- und Technologierat, TA Programm Schweiz, Technikfolgenabschätzung, Technology Assessment, Zentrum für Technikfolgen-Abschätzung. In this paper I indicate the name which was used in the respective document.

for analyzing expert interviews and focussed entirely on the manifest content. In the text interviews are for the most part paraphrased, sometimes they are also quoted verbatim. In both cases the number of the interview (see Annex) and the line numbers of the transcripts are indicated in the text.

Besides these interviews the case study includes an analysis of material from the Fraunhofer Institute for Systems and Innovation Research (FhG-ISI), generated during their TA studies on xenotransplantation in the late 1990s, which I collected at a research stay in Karlsruhe in November 2010. Moreover analysis covers documents and publications provided by TA-Swiss on the TA and PTA on xenotransplantation, materials produced during the lawmaking process (e.g., draft bills, reports, records) and newspaper articles provided either by interview partners or retrieved from the Internet. While the interviews provided the backbone for this case study the documents were used as additional factual information on the policy process and public discussion of xenotransplantation in Switzerland as well as a means to corroborate and check information gained in the interviews. The latter was crucial because more than 10 years passed since the regulation of xenotransplantation and since the TA and PTA on this topic. The documents therefore provide material which is not affected by the later reinterpretation of interviewees.

All translations of interviews and documents are by the author.

1.3 Acknowledgements

I want to express my deep gratitude to all interview partners from various Swiss organizations for their unhesitating and welcoming readiness to participate in the project. Without their friendly and open support this research would have been impossible. I particularly want to thank Dr. Bärbel Hüsing who patiently answered my numerous questions and generously provided her time, knowledge and archive material. I also want to thank Claudia Jandrisic and Karina Weitzer for transcribing the interviews.

1.4 Layout of the paper

In the interviews several basic narratives can be distinguished which are connected to different institutions, i.e. the narrative of TA-researchers, civil servants, politicians and xenotransplantation researchers. I will analyze the history of TA and PTA on xenotransplantation in Switzerland mainly by following these narratives. I will try to work out how these different streams of narration met in TA and PTA and find out their different experiences thereof. By following these narratives I will answer the main research questions of the CIT-PART project. The paper starts with a table providing an overview on the development of xenotransplantation policy in Switzerland. Thereafter I turn to the question whether xenotransplantation was an issue of public debate, a controversy, what the positions therein were? The next section turns to the actual xenotransplantation policy and sketches

two regulatory fields, in which this technology was regulated, i.e. the Federal Decree on the Control of Blood, Blood Products and Transplants of 1996 (amended 1999) and the transplantation law of 2004. This is followed by an analysis of the main actors (research, industry, critical NGOs, Parliament, Federal Office of Public Health, TA Swiss), positions and activities. I will then turn to TA and PTA activities in the context of xenotransplantation and its impact. The next chapter deals with political practices and PTA. In the final section I will summarize my findings and draw main conclusions.

Table 1: Overview of landmark developments and timeline

	1993	1994	1996	1997	1998	1999	2000	2001	2004	2007
			consultation	governmental bill	governmental Bill for interim regulation		Organizes and participates in PubliForum	implements authorization as passed by Parliament		
Parliament: Amendment of the Federal Decree on the Control of Blood, Blood Products and Transplants			Initiative for moratorium Government declines moratorium	Commission declines moratorium and asks for a regulation that requires authorization of clinical trials	Government. Bill for interim regulation	National Council accepts bill Council of States declines ban Council of States accepts Council of States' proposal				
Parliament: Trans-plantation (TP) law	Motion demands a ban on trade with human organs	Motion demands constitutional and legal basis to regulate TP	Parliament decides on consultation for a federal regulation of TP	Report on consultation		Referendum passes with more than 88%		Government. bill on TP	Federal law on the TP of organs, tissues and cells passed	TP law in effect
TA-Swiss			Open call for tender for TA. Deadline: 7.11.	TA study finished	Press release and public presentation	Steering Committee discusses impact of TA. OECD conference	PubliForum TA cellular XTP Press release Lunch for MPs			
XTP-Research					TA (advisory group)	Research conference OECD conference	Statement of Academy of Medical Sciences PubliForum (expert)			
Basel Appeal			Public campaign		TA (advisory group)		PubliForum (expert)			

2 The Swiss Xenotransplantation Debate

2.1 Public debate

This section addresses the question of whether there was a public discussion on xenotransplantation in Switzerland at all; if so, whether this can be described as controversial and what the basic positions taken by different actors were.

Xenotransplantation definitely became an issue of public debate in Switzerland in the 1990s in Parliament, parliamentary commissions and the media (Interview 1: 30-38), although the debate was neither extensive nor continuous. Several parliamentary institutions and activities dealt with the question of whether a moratorium or even a ban on xenotransplantation would be an appropriate policy measure (see below). Newspapers also repeatedly contained reports concerning the issue of xenotransplantation. According to a TA-researcher, stories on xenotransplantation were covered by the mass media following reports of scientific breakthroughs with an undercurrent of discomfort, futurism and horror (Interview 5: 116-120; 251-260). An interviewed scientist shared this view and recalled a small, discontinuous and marginal debate, which reached its peak two or three times when circling around scientific breakthroughs and political developments such as the parliamentary debate. However, eventually public interest faded when xenotransplantation research did not advance as rapidly as predicted (Interview 6: 098-106). An interviewed politician also assessed public as well as parliamentary debates on xenotransplantation as marginal (Interview 3: 138; 220-221). Bringing xenotransplantation on the parliamentary agenda, however, contributed to turning the topic into an issue of some public attention. In her view, on the political level xenotransplantation was linked to discussions about gene therapy, stem cell research and other spectacular biomedical processes because there was a general lack of regulation of these issues at that point (Interview 3: 12-18). Thus, in summary, public debate on xenotransplantation can be described as small and of concern to only a small group of informed actors.

The Swiss xenotransplantation debate was also controversial and the positions taken therein ranged “from clear approval to strict rejection” (Bellucci et al. 1998: 157). According to an interviewed scientist who summarized the opposing views, there were people interested in this new and innovative development while others were in principle opposed. In his opinion, they considered xenotransplantation as condemnable and dangerous, without providing the respective data, because of their fear of the new and unpredictable (Interview 8: 130-142).

Several interview partners pointed out a kind of xenotransplantation hype in the 1990s, which was characterized by exaggerated forecasts, promises and hopes triggered by a market study which forecasted a huge increase of xenotransplantation in the coming years. (Laing 1996). During this hype, which eventually faded, supporters argued that

xenotransplantation could alleviate organ shortage, contribute to saving patients' lives and increase their quality of life.[1] The advocates' main argument was to help patients and, from the perspective of an interviewed scientist, there are in principle no immunological and physiological arguments today, which could absolutely obstruct this technology (Interview 8: 119-125). In this line of argument xenotransplantation was framed by organ shortage and its alleviation (Interview 1: 45-47; 57-58; Interview 4: 58-61). Advocates responded to the argument that xenotransplantation would exploit animals by emphasizing the fact that millions of pigs would be slaughtered each year for food in Switzerland anyway (Interview 8: 273-287) and that using animals for a cure would be a far higher goal than eating them (Interview 4: 71-81).

In contrast to this assessment an interviewed TA-researcher recalled that actors opposing xenotransplantation argued along various lines. They came from a tradition critical of biotechnology and also brought new aspects into the debate. In her opinion, their arguments are not to be considered as naïve and emotional, in the sense of being primarily based on pitying suffering animals. Rather, challengers of xenotransplantation raised concerns over the keeping and raising conditions of source animals (Interview 2: 116-137). They introduced aspects of animal welfare into the debate and raised concerns about potential infection risks, which were brought up by virologists. The opponents questioned patients' survival rates, the quality of life of recipients and raised possible problems of identity as well as of psychological states (Interview 2: 155-164).

The biotechnology critical NGO "Basler Appell gegen Gentechnologie"[2] repeatedly argued that advocates of xenotransplantation would consider this approach a medical quantum jump[3] while, in their view, it would basically just result in spectacular profits for the pharmaceutical industry. From their perspective, xenotransplantation would involve a threat for entire mankind because pathogens and viruses might cross the animal/human barrier. Moreover, they questioned whether it would be ethically acceptable to genetically modify animals.

Questions of animal welfare, however, were not central in the arguments of a critical politician who was very active in bringing xenotransplantation on the political agenda. She emphasized the importance of regarding the choice of research areas as power politics and described transplantation medicine as an ideology of organ storage and replacement

[1] Today the interviewed TA researchers and civil servants considered xenotransplantation as rather unlikely to be realized, particularly in the case of solid organs. Also xenotransplantation researchers criticized the hype of the 1990s in the interviews. However, they were more optimistic about the general prospects of xenotransplantation. They emphasized the slow and incremental progress of research which might eventually lead to cellular as well as even solid xenotransplantation. Moreover, in their opinion, xenotransplantation research would also benefit allotransplantation.

[2] I will use in the following a rough English translation of their name, i.e. Basel Appeal against Genetic Engineering, or short Basel Appeal.

[3] This phrase turns up frequently, e.g. in a brochure of Basel Appeal to press reports and Parliamentary speeches (NZZ 1999a: 16).

(Interview 3: 90-108). Moreover, she criticized the fact that in health debates individual human life would be considered of paramount importance while the question of ethical limits to medical procedures, e.g., because of unpredictable risks, consequences for public health and the transgression of an animal/human barrier, would not be raised (Interview 3: 248-312).

According to a qualitative survey on the various positions which different Swiss organizations took on xenotransplantation Hüsing at al. (1998: 172 ff.) came to the conclusion that advocates promoted xenotransplantation because of its promises to alleviate human suffering and because this technology was regarded as the logical consequence of allotransplantation. The use of animals would also be justified, in this perspective, if unnecessary harm to animals could be avoided. In principal the keeping and breeding of animals for human use would not be a new practice. However, xenotransplantation would be subject to the fulfillment of certain requirements such as research to minimize risk of infection; solutions to hyper acute and later rejection mechanisms; guarantees of human dignity, identity and health; guarantees of animal welfare; definition of an organizational, legal, ethical and societal framework of conditions under which xenotransplantation can be carried out.

Critics of xenotransplantation in contrast reasoned with a plethora of wide ranging arguments:

- New pathogens might be created by transgressing the species boundary.
- The problem of hyper acute rejection and subsequent rejection mechanisms might not be resolvable or only with a high use of resources. Alternatives, on the other hand, may be realized faster, more cost effectively and might be more socially and ethically acceptable.
- This approach of spare part medicine might cause long-term changes in the relationship of humans to their own body, the relationship between animals and humans, as well as towards sickness and death.
- The creation of chimeras through xenotransplantation might result in changes of identity in recipients.
- Xenotransplantation might only be achieved by means of unacceptable experiments on humans.
- The breeding and keeping of animals for xenotransplantation would require species-inappropriate conditions.
- Xenotransplantation would increase the use of animals quantitatively.
- The approach would involve the cloning of animals, which has to be rejected.
- The production of animals through genetic modification would not be in accordance with the constitutional “dignity of creatures”.
- Xenotransplantation does not fit with a human and fair health care system.
- Xenotransplantation would act against efforts to strengthen prevention.

- It would increase costs for the health care system and decrease the readiness for organ donation.
- As long as there is no basic health care in developing countries xenotransplantation as expensive top medicine has to be refused for reasons of global inequality.
- Society would not accept xenotransplantation and there would be less controversial alternatives.
- Society should discuss the issue before definite decisions are made; big enterprises, particularly Novartis, would create a monopoly and gain profits without competition.
- Finally, financial interests might suppress a democratic public debate (Hüsing et al. 1998: 174 ff.).

These conflicting standpoints became obvious during the year 1999 when in both chambers of the Swiss Parliament the option of a temporary ban was controversially discussed (see below).

Virologists were positioned somewhere in between these two camps. Although the (according to an interviewed TA-researcher's analysis) "euphoric" (Interview 2: 130) transplantation surgeons considered virologists as peers because these were also scientists, they also regarded them as "spoilsports" because of their raising questions regarding risks, which again were picked up by critical NGOs (Interview 2: 116-137). A xenotransplantation researcher considered the discovery of a potential risk of infection as a catastrophe, which almost killed the research area entirely. Today, however, he assessed the risk of infection as less serious than it was considered in the late 1990s (Interview 8: 86-117).

In Parliament, xenotransplantation was primarily discussed in the context of research and economic policy. In repeated debates in the National Council and the Council of States in 1999, members of Parliament from conservative and liberal parties emphasized the importance of the pharmaceutical industry and its interest in xenotransplantation research for Swiss research and Switzerland as a business location. They opposed a ban or moratorium because they argued that Switzerland could not stand alone with such a political measure. Pointing out the promises of xenotransplantation, they advocated research into xenotransplantation with prior authorization (see below).

The responsible ministry, the Federal Office for Public Health (FOPH, Bundesamt für Gesundheit) also identified xenotransplantation as a hot issue in 2001 by stating that "xenotransplantation is being controversially debated in the public for technical, political, ethical and emotional reasons". Drawing from the consultation procedure on their proposed transplantation law, which included a regulation of xenotransplantation and which most respondents criticized or rejected, the FOPH provided several arguments why xenotransplantation was refused by Swiss civil society, i.e. risk of infection, animal welfare, uncertain medical and economic benefits and ethical concerns (Eidgenössisches Department des Innern 2001).

In contrast to the majority in Parliament the FOPH, took a restrictive and cautious approach towards xenotransplantation because of the potential risks of creating new viruses, which would be hard to control and could create epidemics. Though they also discussed ethical issues, the risk of infection was their main focus of criticism of xenotransplantation (Interview 4: 318-324) while animal welfare was less of an issue (Interview 4: 367).

Thus, as one interviewed TA-researcher summarized, the framing of the Swiss xenotransplantation debate was not much different from other countries. However, a distinguishing dimension of the Swiss case was that actors critical of biotechnology and animal welfare activists were well organised and positioned because of their previous activities (Interview 2: 116-137).

2.2 Xenotransplantation regulation

Before relevant regulation came into effect, provisionally in 2001 and finally in 2007 (see below), it was permissible in Switzerland to carry out xenotransplantation without prior authorization by authorities. The Federal Decree on the Control of Blood, Blood Products and Transplants regulated the protection against infection (Nationalrat 1997a: 3). This decreed that tests had to be carried out and that state of the art measures had to be taken to exclude zoonoses and diseases from prions, which might cause infections in humans (Nationalrat 1996a: 3, Hüsing et al. 1998: 127). No prior authorization but only a notification of authorities was required.

This permissive environment changed in 2001 when the FOPH, following a motion from the parliamentary Commission of Science, Education and Culture in 1997 decided to make clinical research on xenotransplantation subject to prior authorization (see below). This became necessary because the Commission did not want to wait until a transplantation law, which would also regulate xenotransplantation and was then being debated, finally came into effect. Because of what it assessed as a high risk of infection, the Commission decided that speedy action was necessary (Interview 263-269) and asked the government to work out a bill stipulating prior obligatory authorization for clinical trials of xenotransplantation (Interview 2: 272-273).

The FOPH, who was in charge of the issue within government wanted to take a strict approach in its draft bill by creating a high threshold for clinical trials. This was to be accomplished by a general ban of xenotransplantation trials with authorized exceptions (Interview 4: 287-293). However, this proposed article became the center of controversy in both chambers of Parliament between conservative and liberals on the one side and social democrats and the green party on the other side and did not pass (see below). Parliament decided to reject a moratorium and instead require prior authorization of xenotransplantation by the FOPH. Liability regulations for xenotransplantation research were formulated according to the Swiss model for genetically modified organisms (Interview 4: 377-383).

In Chapter 3, Article 43 the transplantation law of 2004 which adopted the previous regulations formulated in the amendment of the Federal Decree on the Control of Blood, Blood Products and Transplants stipulates that xenotransplantation of organs, tissues and cells is subject to prior authorization by the FOPH (Bundesversammlung der Schweizerischen Eidgenossenschaft 2007) and determines under which conditions such an authorization has to be issued. Permission for *clinical trials* has to be granted:

(a) if the risk of infection for the population can be ruled out with a high probability;

(b) therapeutic benefit is expected,

(c) necessary technical and operational requirements are met;

(d) quality insurance systems are in place.

Authorization for xenotransplantation as *standard procedures* is to be granted if the risk of infection for the population can be ruled out and therapeutic benefit has been established as well as the previously mentioned conditions described by (c) and (d) are met.

According to Article 44 the holder of a permit has to examine the recipients regularly over a long period of time for pathogens or indications thereof, to carry out a post mortem of a recipient for infections; document relevant information and incidents; document in a way that source animal and recipient as well as biological probes can be traced; to store these documents and probes and to provide them to authorities on demand so these can take immediate and necessary steps to protect the health of the population and to inform authorities if required.

Moreover, according to Article 45 organs, cells and tissues of animals have to be tested for pathogens or indications thereof.

In order to cover potential liability claims Article 46 stipulates that the holder of a permit can be required to take liability insurance. According to Article 47 the liable party has to bear the costs for measures that authorities have to take to hold or reduce the risk of infection for the population and to determine and repair the damages caused by infection.

In addition the government will decree a directive on the handling of organs, tissues and cells of animal origin regarding the (a) dealing with source animals, (b) the quality of animal organs, tissues and cells, (c) requirements for the tests carried out to monitor health of recipients and source animals, (d) preconditions for the authorization and authorization procedure, (e) duration and kind of storage of documentation and biological probes, (f) requirements on which pathogens or indications thereof must be tested; (g) in which cases organs, tissues and cells can be transplanted despite reactive test results; (h) identification

of organs, tissues and cells, which have been harvested from genetically modified animals as well as (i) requirements for (1.) informed consent, (2.) information and approval of medical personnel, (3.) information of contact persons and recipients.

An interviewed researcher regarded the law as positive in principle but also considered the regulation as too restrictive. If clinical trials become promising in the future these (as he perceived them) administrative and bureaucratic hurdles might prove prohibitive (Interview 8: 306-316).

2.3 Actors

After having sketched out the Swiss xenotransplantation debate and policy, in the following section, I will introduce the most important actors of the debate as well as their involvement in the policy development.

2.3.1 Research

According to an interviewed scientist there was not much xenotransplantation research in Switzerland (Interview 8: 66-84). Several research groups participated in EU funded research projects and were trained by and/or collaborated with US researchers (Interview 8, Interview 10). There was no research in solid organ but rather in cellular xenotransplantation (Schweizerischer Bundesrat 2001: 51).

In its answer to a parliamentary interpellation in 1996 the government stated that in Switzerland no xenotransplantation on humans has been carried out but that animal cells were used as vector cells in gene therapy. At four hospitals in Zurich, Lausanne, Bern and Geneva animal cells were used for clinical trials. At the university hospitals in Geneva and Lausanne animals were kept and raised for research in the area of xenotransplantation. Sandoz/Novartis also did research in the area of xenotransplantation and kept and raised animals for that purpose. These experiments were restricted to animal-to-animal transplantation (Nationalrat 1996a: 1 ff.).

Researchers played an active part in the xenotransplantation debate. They participated in the TA study on xenotransplantation as interviewees as well as members of the advisory group (see below). They also contributed to the PubliForum: again, as members of the advisory group, as informants of the lay panel in the preparatory weekends and in the public event as well (see below). Experts also participated in the public debate by giving interviews and writing articles in newspapers (Interview 8: 41-44, e.g., Seebach 2001).

2.3.2 Industry

Industry, namely Novartis, played an important role in the Swiss xenotransplantation debate. Several interview partners agreed that one reason why xenotransplantation became topical in Switzerland was that Novartis, which was heavily investing in this technology, had its headquarters in this country (Interview 1: 005-007, Interview 8: 66-84, Interview 2: 49-57). The fact that Novartis was one of the "global players" (Bastian: 1997) and main potential profiteers of xenotransplantation was repeatedly reported and discussed in the press (NZZ 1996: 23, SonntagsZeitung 1996b) as well as criticized by biotechnology critical NGOs (see below). Though Novartis did not do much xenotransplantation research in Switzerland itself, it owned the UK based firm Imutran and also supported research in the U.S. with money and patents (Interview 6: 63-76).

Several interview partners emphasized Novartis' financial interest in xenotransplantation (Interview 1: 042-044, 053-056, NZZ 1999b: 16) and the fact that xenotransplantation might turn transplantation medicine, which mainly relies on donations and where the main market is for immunosuppressive drugs, into a lucrative business. If industry could provide animal organs, much money would be involved (Interview 2: 061-068).

Novartis opposed a Swiss ban or moratorium on xenotransplantation. In an interview carried out by members of the press, head researcher Paul Herrling considered the probability of infections as rather small. His firm would not be happy with a moratorium as advocated by Fritz Bach, a leading US xenotransplantation researcher, because "a moratorium of undefined duration would be of use to nobody because it would block research" (Basler Zeitung 1998).

Dietrich W. Scholer, by then head of Novartis pharma policy, could also not follow the TA study's cautious approach towards xenotransplantation. Novartis would take questions of risk rather seriously and more research was needed exactly for that reason. A moratorium, in his view, would be counterproductive. He criticized the government for its plan to ban xenotransplantation, which, from an international perspective, would be an exception (NZZ on/line 1998).

Repeatedly members of the National Council and Council of States critical of xenotransplantation criticized the influence of the pharmaceutical industry on politics in their contributions to debates (NZZ 1999a: 16). Paul Herrling, head of research at Novartis, was also invited as an expert in a meeting of the parliamentary Commission of Social Security and Health on 14.2.1999, which discussed Swiss xenotransplantation policy (Parlamentsdienste 1998). Novartis representatives also participated in the advisory group of the TA study (see below) and watched its progress with close scrutiny (Interview 2: 363-370).

2.3.3 Critical NGOs

Though a number of different NGOs gave their opinion in the formal consultation process on the transplantation law (Eidgenössisches Department des Innern 1997a), the most significant, influential and active NGO in the xenotransplantation debate was Basel Appeal.[4]

Basel Appeal essentially contributed to the public debate on xenotransplantation in Switzerland by putting the issue on the agenda and 'creating a public'. The NGO was founded in 1988 by a group of people critical of biotechnology who had previously been active in the anti-nuclear movement. Having learned their lesson from the conflict about nuclear energy, they formed the organization after a conference on reproductive medicine and biotechnology with the intention of raising a technological issue early on so as to be politically successful (Interview 3: 61-66). Areas of activity were campaigns against "GMO food, patenting of life, deliberate release of a vaccine against rabies from the biotechnology lab, enzymes for washing powder from biotechnological production" (Basel Appell 1996a: 44). Though Basel Appeal was active throughout Switzerland, it was based and mainly active in Basel (Interview 3: 69).

The issue of xenotransplantation was brought into the group by one of its board members, Florianne Koechlin, a biologist and chemist by training. The NGO started its campaign against xenotransplantation in 1996. This involved a number of activities:

- In 1996 Basel Appeal published an informed and extensive brochure (Basler Appell 1996a). This booklet of 44 pages, mostly authored by Florianne Koechlin, deals in several short articles and in a detailed way with issues relevant to xenotransplantation such as the behaviour and keeping conditions of pigs, hyper acute rejection, post-transplantation-chimaeras, risk of infection and xenozoonosis, problems of genetic modifications of animals, the business of transplantation and xenotransplantation (particularly emphasising the role of Novartis) and potential consequences of xenotransplantation for the identity of recipients. It also provides an overview on possible applications (Basler Appell 1996a).
- Basel Appeal petitioned for a moratorium until 2020 and collected a total of about 6,500 signatures (Tages Anzeiger 1996).
- They contributed to the formal and informal consultation procedure on the transplantation law and the Federal Decree on the Control of Blood, Blood Products and Transplants respectively.
- Florianne Koechlin gave a number of interviews to the press (SonntagsZeitung 1996a, Die Ostschweiz 1997).

[4] www.baslerappell.ch/ (download: 30.12.2010).

- She was informant on xenotransplantation in the PubliForum and discussed the results of the TA study xenotransplantation on occasion of its public presentation on 7.9.1998 at a Roundtable (Technology Assessment 1998).
- Members of the group were in both the advisory group of the TA as well as the PubliForum (see below).

2.3.4 Parliament

Since one of Basel Appeal's board members, Margrith von Felten, was also a member of the National Council for the Social Democratic Party (SPS), the NGO had connections to the federal legislative. On 5.6.1996 Mrs. von Felten brought xenotransplantation on the parliamentary agenda by turning Basel Appeal's call for a moratorium into an interpellation to the Federal Council (Nationalrat 1996a) and on the same day, almost verbatim, into a parliamentary initiative addressed at the Committee for Science, Education and Culture (Nationalrat 1996b).

2.3.4.1 Interpellation von Felten (96.3223)

In her Interpellation Mrs. von Felten asked nine questions about xenotransplantation research in Switzerland, its risks and ethical problems, the political measures the federal government was considering and its readiness to decree a moratorium (Nationalrat 1996a). The government replied several months later on 14.8.1996 by writing that the question of under what circumstances xenotransplantation should be permitted would be considered during the development of a transplantation law (see below). The government did not see at this time a cause to take measures in the form of a moratorium in the case of xenotransplantation (Nationalrat 1996a: 3).

2.3.4.2 Parliamentary Initiative von Felten (96.419)

In her second parliamentary activity, the parliamentary initiative, Mrs. von Felten stated that, "because of the completely open ecological, medical, ethical and sociopolitical questions a moratorium for experiments with xenotransplantation on humans is urgently necessary; an according bill is to be prepared" (Nationalrat 1996b: 1). In her explanatory statement she quoted Basel Appeal's brochure and argued against xenotransplantation, mentioning the examples of Ebola, BSA and AIDS because of the risks of infection they pose. She also raised ethical questions about genetic modification of animals, using animals as "organ storage" for humans and the transgression of the boundary between animals and humans (Nationalrat 1996b: 2).

The Committee for Science, Education and Culture dealt with this initiative almost one year later on 22.5.1997 (Nationalrat 1997a). It declined a moratorium with a majority of 15 to 9 votes. According to its report, the majority and minority agreed that xenotransplantation

posed several questions and problems, which would need reflection. However, the majority believed that this technology was getting increasingly important, independently of the question whether it was responsible from an ethical and health perspective; research was therefore not stopped. In practice a moratorium would not mean a pause and time for reflection but a complete prohibition and end for research. In the majority's opinion, Switzerland could not stand apart from international developments and regulations therefore had to be made parallel to the development of research (ibid.). In a nutshell, these were already the arguments that would be used by opponents of a prohibitive approach to xenotransplantation in the coming parliamentary battle over a ban or moratorium.

In contrast, the minority thought that a moratorium would not entirely stop research but would provide time for discussion and reflection, e.g. in a consensus conference. A moratorium would not prevent research because risk research with cell cultures could continue.

2.3.4.3 Motion Commission Science, Education and Culture (97.3251)

Despite the rejection of a moratorium, the commission's majority of 11 votes, with 5 contra and 7 abstentions, recognized that there was need for speedy action because of the risk of infection. They therefore asked the Federal Council to regulate xenotransplantation provisionally by making it subject to prior authorization. The commission asked government to prepare this provisional regulation because it regarded the period until xenotransplantation would be definitely regulated by a comprehensive transplantation law as too long. The minority declined this motion because, in their view, it would in principle permit xenotransplantation (Nationalrat 1997b: 3).

Although both the interpellation and parliamentary initiative were actually declined, they were still quite consequential and, by putting the issue on the parliamentary agenda, significant steps towards an interim regulation of xenotransplantation in 2001.[5]

2.3.4.4 Amendment of the Federal Decree on the Control of Blood, Blood Products and Transplants (98.035)

On 13.8.1997 the government declared its readiness to accept the parliamentary motion and pointed out the fact that an amendment of the Federal Decree on the Control of Blood, Blood Products and Transplants (SR 818.111) from 22.3.1996 would be necessary to make xenotransplantation subject to prior authorization. This law, not mentioning it explicitly, already allowed xenotransplantation implicitly and in principle; however in article 18 only stipulated a reporting obligation and in Article 19 specified a testing obligation to ensure protection from infection (Bundesrat 1998: 10 ff.).

[5] Also the Parliamentary Commission on Social Security and Health passed a motion on 7.11.1997 asking for a moratorium for xenotransplantation.

On 3.6.1998 the governmental bill was sent to Parliament and, in contrast to the position taken by government in the reply to the Interpellation von Felten, in principle proposed a temporary ban of xenotransplantation of organs tissues and cells of animal origin into humans (Art. 18a Abs 1) and only allow for two exceptions.

- Firstly, xenotransplantation of cells, tissues and organs might be allowed if they are carried out within clinical trials and are authorized by the FOPH.
- Secondly, xenotransplantation of certain cells and tissues of animal origin might be allowed if the risk of infection for the population can be excluded according to the state of the art. Moreover, authorization depends on a therapeutic benefit of the intervention having been proven (Bundesrat 1998: 3; 27 ff.).

This theoretical ban on xenotransplantation was proposed as a temporary solution, for about three years, until a comprehensive federal transplantation law would definitely regulate the issue of xenotransplantation. It was anticipated that the latter would be implemented by 2002 at the earliest (Bundesrat 1998: 3, NZZ 1998).

The Ministry did not carry out a full-fledged formal consultation for this draft bill but, since the amendment was only temporary and its content already laid down by the National Council, only an informal one.[6] Animal welfare organizations, NGOs critical of biotechnology and the Swiss Science Council welcomed the ban. Representatives of industry, medicine and science, on the other hand generally welcomed the obligation for authorization but were either rigorously against or more hesitant regarding a temporary ban. Particularly the Swiss Association for the Chemical Industry declined a temporary ban and pointed out that such a regulation would be disproportionate and unjustified, since concrete indications would be missing that xenotransplantation either caused concrete dangers and damages already or that these might be impending according to recent scientific findings (Bundesrat 1998: 18ff.).

The results of the already mentioned discussion in the Commission for Science, Education and Culture and the rather oppositional statements in the informal consultation leads one to suspect that the governmental bill had a history of controversy in the two chambers. Actually it was finally not adopted as proposed by the government. The question of a temporary ban or, in other words, whether Switzerland should take a restrictive position and say “no” to xenotransplantation “unless” certain requirements were met, as proposed by the government, or whether to take a permissive “yes, but”-position and to allow xenotransplantation in principle with strict requirements, lay at the center of the controversy.

[6] Organisations invited were: Gesellschaft für Chemische Industrie, Interpharma, Swisstransplant, der Schweizerische Wissenschaftsrat, das Institut de droit de la santé de l’Univeristé de Neuchatel, der Basler Appell gegen Gentechnologie, die Schweizerische Arbeitsgruppe Gentechnologie, die Schweizerische Akademie der Medizinischen Wissenschaften, die Verbindung der Schweizer Ärzte, der Schweizer Tierschutz und der Schweizerische Nationalfonds zur Förderung der wissenschaftlichen Forschung.

In the first debate on the bill on 4.3.1999 that took place in the National Council, the first and bigger chamber of Swiss legislative, this conflict was already played out (Amtliches Bulletin 1999a, NZZ 1999a, 1999b).[7]

Neither the restrictive faction, consisting of the Green Party and Social Democratic Party (SPS), who wanted a total ban without exception (see e.g. Berner Tagwacht 1997, Tages-Anzeiger 1997), nor the permissive faction of Christian Democratic People's Party (CVP), Free Democratic Party (FDP) and Swiss People's Party (SVP), who did not want to take a prohibitive approach but only wanted to stipulate strict requirements, could yield a majority. Finally, the National Council adopted the governmental draft with 88 to 79 votes (Vanoni 1999).

Because of the majority's concerns about transplantation patients and the Swiss research location, the Council of States, the smaller second chamber, decided on 10.6.1999 against the governmental draft of a ban with 26 to 7 votes. It voted for permitting xenotransplantation of organs, cells and tissues after prior authorization and under certain requirements (Amtliches Bulletin 1999b, Vanoni 1999).

In order to settle the difference between the two equal chambers the plenum of the National Council, out of concern for the research location, followed the very close vote of its commission and permitted xenotransplantation of organs, cells and tissues with certain requirements on 8.10.1999 (Amtliches Bulletin 1999c, Vanoni 1999).[8] This temporary regulation should have been effective for about three years, when a new transplantation law was to be implemented.

Supporters of a ban mainly argued with the risk of infection and pointed out the big influence of pharmaceutical enterprises on Parliament, explicitly Novartis.[9] Opponents of the ban, on the other hand, mainly argued in terms of securing the Swiss research location, that the general electorate already declined total bans in the preceding biotechnology referendum

[7] The responsible Committee Social Security and Health had an expert hearing on 14.2.1999. As experts invited were Bärbel Hüsing (presentation of results of the study xenotransplantation of TA Swiss), Prof. Dr. Andrea Arz de Falco (Xenotransplantation from ethical perspective), Prof. Dr. Karin Mölling (Xenotransplantation and virology), Prof. Dr. Paul Herrling (Research in the area of xenotransplantation).

[8] A compromise, which tried to accommodate the council of state by keeping the ban and alleviating the requirements, was declined by 77 to 72 votes (Curia Vista 1999).

[9] For instance, the social democrat Franco Cavalli said in the plenary debate: "The Parliamentary history of this federal decree resembles a cheap tragic comedy. This decree shall be effective for three years. During this time factually there is a global moratorium for xenotransplantation of tissues and organs. Whether there is a ban with possible exceptions or a strict process of authorization with strict requirements, practically this is all the same. Nevertheless the right in this House and particularly the lobby of pharmaceutical enterprises wanted to show once again who the master of the house is. The way in which this final version of the federal decree was forced is in my opinion an insult to reason. One has argued with the research location of Switzerland, which is ridiculous. One has argued against a seemingly solo of Switzerland, which is even more ridiculous" (Amtliches Bulletin 1999d)

and that no other country would have banned xenotransplantation by then.[10] The economic argumentation played an outstanding and extraordinary role in the parliamentary debate and finally turned the governmental bill from an initial ban to permission in principle. The parliamentary debate on the issue can be characterized as severe, adversarial, raising fundamental issues, and, at times emotional. Thus, the result of the provisional regulation in 1999 was that the Swiss regulator at least in principle took a permissive position with an obligation for authorization so long as certain requirements were met.

The law was implemented by government on 23.5.2001 and came into effect on 1.7.2001 (Eidgenössisches Department des Innern 2001). If xenotransplantation of organs, tissues or cells from animals are transplanted into humans, prior authorization is needed from the FOPH. This requirement involves a free and informed consent of the recipient about the relevant measures and the necessary rules of behavior (ibid, Eidgenössisches Department des Innern 2007).

2.3.4.5 Transplantation Law

As already shown, the regulation of xenotransplantation was closely connected to the development of a comprehensive federal Swiss transplantation law.

Initially the discussions about transplantation and xenotransplantation were independent. In international comparison Switzerland regulated transplantation very late. This can be explained by the distinct distribution of competencies between cantons and the federation. The regulation of health relevant topics falls under the competence of the cantons. Cases where the federation has the competence according to the Swiss constitution are the exception to this. Transplantation did not pose such an exception and for a long time it was within cantonal competence, which meant that each canton had its own regulation or no specific legal regulation at all (Schweizerischer Bundesrat 2001).

Attempts to develop a federal legislation date back to the mid 1980s but these were always pushed back. Finally, in 1993 and 1995 the Swiss Parliament accepted two motions which asked the government to prepare the constitutional bases for a federal transplantation law (Interview 4: 96-113). Motion Onken (7.12.1993) demanded the ban of commercial trade with human organs in Switzerland. Motion Huber (28.2.1994) demanded the creation of a constitutional and legal basis to cope with the manifold legal and organizational problems posed by transplantation medicine (Nationalrat 1996a: 2).

[10] For example Christine Egerszegi-Obrist in the plenary debate: “Whereas the governmental draft provides an unnecessary prohibition and would cause negative consequences for patients and the research location Switzerland, the motion of the minority provides a reasonable authorization solution according to the proven principle ‘No bans, but yes to strict and responsible regulation’” (Amtliches Bulletin 1999a).

These advances towards a federal transplantation law happened at around the same time as xenotransplantation became topical. Although it was coincidental that a transplantation law was being developed, it nevertheless put xenotransplantation on the political agenda (Interview 2: 49-57). Initially, the FOPH intended to regulate both issues in a comprehensive transplantation law. In the end this plan was not realized because of a motion from the National Council asking for a temporary regulation of xenotransplantation. As previously mentioned, the Federal Decree on the Control of Blood, Blood Products and Transplants was therefore amended with regards to xenotransplantation.

A constitutional base was necessary in order to comprehensively regulate transplantation medicine on the federal level. The development of a transplantation law took several years, one reason being that the procedures to pass a federal law are extremely time-consuming. Before a law could be passed cantonal responsibilities had to be transferred to the federation. This implied a change of the constitution and a need for a referendum. For this to take place the FOPH had to draft a constitutional amendment; this went into consultation in autumn 1996 and, according to plans made in 1997, should have been sent to Parliament as a bill in the spring of 1997. It was also intended that this draft should include a final regulation of xenotransplantation (Eidgenössisches Department des Innern 1997b). In fact, the work on the actual transplantation law ran parallel to and was coordinated with the work on the constitutional bases for the transplantation law (Nationalrat 1996a: 2).

In the consultation of the constitutional amendment, the Green Party and the Schweizer Tierschutz (Swiss Animal Protection) demanded a constitutional ban of xenotransplantation. The Basel Appeal demanded a moratorium until 2020 and supported its claim with a petition of 6,500 signees. The Social Democratic Party also demanded a moratorium (Schweizerischer Bundesrat n. d.: 20, Eidgenössisches Department des Innern 1997a: 19 ff.).

On 7.2.1999 a vast majority of the electorate was in principle in favor of regulating transplantation on a federal level (Monnier/Weber 2005, Schweizerischer Bundesrat 2001: 67).[11] Parliament was therefore able to regulate xenotransplantation on a federal level.

The formal consultation process was carried out between 1.12.1999 and 29.2.2000 (Schweizerischer Bundesrat 2001: 69). As already mentioned, the regulation of xenotransplantation, as adopted by the National Council in 1999, was criticized during the consultation by the majority of respondents. Many statements demanded a ban or a moratorium of xenotransplantation and argued with points about the risk of infection, animal

[11] Article 24 decies Fededral Constitution: I. Die Bundesverfassung wird wie folgt geändert: 1. Der Bund erlässt Vorschriften auf dem Gebiet der Transplantation von Organen, Geweben und Zellen. Er sorgt dabei für den Schutz der Menschenwürde, der Persönlichkeit und der Gesundheit. 2. Er sieht insbesondere die Unentgeltlichkeit der Spende vor und sorgt für eine gerechte Zuteilung von Organen. II. Dieser Beschluss untersteht der Abstimmung des Volkes und der Stände (Schweizerischer Bundesrat n. d.: 45).

protection, the violation of the dignity of the animal, uncertain medical and economical benefits as well as ethical concerns (Schweizerischer Bundesrat 2001: 73, 127). The governmental bill also refers to the results of the PubliForum and mentioned that there were concerns regarding the medical and psychological consequences of xenotransplantation. Though the PubliForum did not demand a moratorium by majority, it emphasized alternatives to alleviate organ shortage, e.g. by prevention of diseases which might lead to organ failure (Schweizerischer Bundesrat 2001: 127). Despite this critical assessment the bill proposed to maintain the regulation of 1999, which stipulated no ban or moratorium but rather an obligatory prior authorization. It did so without providing reasons for this decision (Schweizer Bundesrat 2001: 127, 164 ff.). The federal transplantation law was passed on 8.10.2004 and came into effect in 2007. After the provisional regulation in 2001 xenotransplantation was thereby finally regulated within the transplantation law.

2.3.5 Federal Office for Public Health (FOPH)

The Swiss FOPH is responsible for xenotransplantation since it concerns itself with human health (Interview 4: 4-9). It was also the competent authority to develop a federal transplantation law in the late 1990s and early 2000s. Xenotransplantation became an issue for the FOPH because of the general hype surrounding this technology (Interview 4: 23), the research results, the hopes to help patients with transplantation of tissues, cells and organs of animal origin and because of early regulations in the US and the UK (Interview 4: 021-030).

As already shown, the regulation of xenotransplantation was embedded in a longer and broader history of the FOPH's activities in the early 1990s in regulating blood safety and preservation as well as the transplantation of organs and tissues. However, at that point xenotransplantation was not an issue yet.

This changed in the late 1990s when the question of which regulation would be applicable in the case of xenotransplantation in Switzerland arose. At that time it would have been legally sufficient to notify authorities if xenotransplantation experiments were conducted. The Swiss Parliament, as already mentioned, considered this situation unsatisfactory. In a motion it required that the government regulate xenotransplantation and make clinical trials subject to prior authorization. Reacting to this parliamentary motion, the FOPH initially planned to prohibit clinical research on xenotransplantation in general and to only allow a few thoroughly specified exceptions. This proposal, however, was not accepted by Parliament. After negotiations, a more permissive regulation was adopted that made xenotransplantation subject to governmental authorization.

As already mentioned, the FOPH had to work out a comprehensive transplantation law, which also included xenotransplantation at about the same time (Interview 4: 37-61).

2.3.6 TA-Swiss

On proposal of the government, TA-Swiss was established by the Swiss Parliament in 1992 as then temporary Program for Technology Assessment (TA-Programm Switzerland, later TA-Swiss) so as to establish a system of TA tailored to Switzerland. TA-Programm should investigate the positive and negative consequences of new technologies, taking into account different aspects such as ecology, economy, the political system, culture and others. Moreover it should integrate already existing TA efforts in science and industry and create a bridge between experts in science, technology and the general public. It should also provide as much as possible objective and methodologically correct TA analysis (Technology Assessment n. d., Pfersdorf 2008: 54).

TA-Swiss is mandated and financed by the Swiss Parliament for the purpose of carrying out independent TA on debated and controversial technologies, to work out recommendations and to organize discussions; these involve experts, different interest groups but also citizens (Interview 1: 65-71). In order to reach these goals, it monitors technologies rather broadly (Interview 5: 7-8). TA-Swiss regards itself very strongly as political consulting organization to Parliament and government (Interview 1: 134-135, 144-145, 158-162) and tries to take into account issues, which are topical on the political agenda. In comparison to other TA organizations, such as the Dutch Rathenau Institute or the Danish Board of Technology, they focus less on organizing public debates. Instead their focus is more on informing politicians about expert and citizen opinions on sensitive questions, with regards to technology, early on for their political work (Interview 1: 348-351). TA-Swiss perceives itself as a group of counselors, which must not replace but should instead advise, supplement and counsel Parliament. At times, TA-Swiss tries to do this by carrying out expert studies, at other times by organizing citizen conferences (Interview 1: 407-415).

TA-Swiss is free and independent in the selection of technologies to investigate, a fact that is strongly emphasized in interviews (Interview 1: 154-171, Pfersdorf 2008: 54 ff.). After monitoring controversial technologies and deciding which of them would be of interest, the office of TA-Swiss, formulates project proposals to its steering committee (Leitungsausschuss). This governing body has to approve project proposals as well as budgets and the release of reports (Interview 1: 77-85, 126-128, Schweizerischer Wissenschaftsrat n. d., Pfersdorf 2008: 55).

In the past a few politicians were amongst the 15 to 16 members of the steering committee. However, this practice stopped in 2007 when TA-Swiss was separated from the Schweizerischer Wissenschafts- und Technologierat, an advisory body to Parliament, and incorporated into the Akademien der Wissenschaften Schweiz, a research organization (Interview 1: 173-177). This transfer was aimed at strengthening TA-Swiss's independence. It was thereby detached from its direct connection to Swiss politicians and put at arm's length to government. Although Parliament retained some rights to propose topics, it is

basically the steering committee that has the final say on the selection of which technologies to investigate. In general, members of Parliament only raise a few new topics because they are too removed from technological developments (Interview 1: 180-182). It is the office and its steering committee and not public administration and politics that decide whether to investigate a topic (Interview 1: 209-215).

Due to financial restrictions TA-Swiss has to look for additional funding to carry out its work but would only accept public money and no funds from private industry since that might jeopardize their trustworthiness (Interview 1: 200-206).

3 Technology Assessment

TA-Swiss did not receive a political order to carry out its TA on xenotransplantation. It was the office of TA-Swiss itself that proposed this activity to its steering committee. It took this initiative because it perceived xenotransplantation as an up and coming biomedical development the social and ethical impact of which would need closer scrutiny. One of the events triggering TA-Swiss's interest were reports of British based Imutran's activities in this field (Interview 1: 91-92) and Sandoz's market study (Laing 1996) predicting a huge increase in xenotransplantation within the next decade. Although in hindsight TA-Swiss did not take Sandoz's predictions at face value already by that time, they regarded xenotransplantation as an up and coming topic that would potentially require TA so long as there was still space for political action and maneuver (Interview 5: 8-16).

In one interview partner's recollection, Sandoz's brochure was quickly followed by reactions from Swiss NGOs such as the Basel Appeal, studies by the US-American Institute of Medicine, the British Nuffield Council and the German European Academy. The WHO also started to deal with the topic. In hindsight, one main impetus for investigating xenotransplantation was TA-Swiss's observation that the actors opposing xenotransplantation started to mobilize; these argued that it would be unethical, risky and only for the profit of industry (Interview 2: 25-34). The steering committee agreed with the office's plan rather quickly (Interview 5: 106-113).

In a one-page background paper, the call for tenders for a TA study on xenotransplantation argued for TA: They mentioned the societal and ethical aspects of this technology, the Basel Appeal's call for a moratorium and quoted Florianne Koechlin's concerns of xenozoonosis (Schweizerischer Wissenschaftsrat 1996b). They also quoted ethical concerns about using animals as spare part warehouses for humans and referred to the public controversy about the use of primates for research. Moreover, the call for tender under the heading of economical aspects quoted Salomon Brother's study which predicted a huge increase of revenues because of xenotransplantation and also referenced Sandoz/Novartis activities in this area. Finally, the paper quoted the parliamentary initiative and interpellation of Margrith von Felten in which she put xenotransplantation on the agenda of Parliament (see above; see also Bellucci et al. 1998: 156).

TA-Swiss is a small organization, staffed with six to seven people (Interview 5: 123-124 Schweizerischer Wissenschaftsrat n. d.). Therefore in general it contracted out its TA studies to competent research organizations. Moreover, it does not have the necessary and specific expertise in each and every technology field (Interview 126-132, Schweizerischer Wissenschaftsrat n. d.).

After an open and international call for tender, TA-Swiss contracted FhG-ISI, a German research institute based in Karlsruhe, to carry out a TA study on solid organ xenotransplantation (Hüsing et al. 1998). The TA study was to provide an overview on the international state of the art of xenotransplantation and its positive and negative consequences from societal, ethical-anthropological, economic and clinical perspectives. In particular, it should emphasise the Swiss situation with regards to acceptance of xenotransplantation and regulatory questions (Schweizerischer Wissenschaftsrat 1996a).

FhG-ISI did a typical TA study. They analyzed literature and did interviews with stakeholders, ranging from animal welfare activist organisations, concerned patients and physicians to associations, both for and against xenotransplantation. However, the study also included several elements of invited participation (Hüsing et al. 1998: 9 ff.; 231):

First, as already mentioned, 18 in-depth interviews were carried out with Swiss experts from the fields of industry, medicine (surgery, transplantation, veterinary medicine, virology, preventive medicine, and professional organizations), law, patient associations, and social/critical organizations (Bellucci et al. 1998: 157).

Secondly, organized stakeholders were also asked to answer seven questions about their position on this technology in writing which, so as to allow for framing of xenotransplantation by the respondents, were deliberately formulated rather openly and qualitatively (Hüsing et al. 1998: 232).

The following questions were asked: (1) Is xenotransplantation an issue of relevance for your organisation? Why? How important is it for your organisation? (2) To which extent have you been occupied as organisation with xenotransplantation? (3) What are the most important aspects from your perspective? (4) What are the results of your considerations? Why? Which aspects did your organisation not evaluate conclusively? (5) In which way do you want to deal with xenotransplantation in future? (6) What measures are needed? (7) Which measures are necessary and suitable to lead to a public discussion of xenotransplantation (Hüsing et. al. 1998: 11)?

The stakeholders included a very broad range of organisations including political parties, research funding organisations, obligatory health insurances, interest organisations of health care professionals, scientific associations, animal welfare activists, NGOs critical of biotechnology and churches (Hüsing et al. 1998: 234).

A total of 145 organizations had been addressed. 77 (53%) did not reply and 68 institutions replied (47%). From organizations which replied, 14 stated that xenotransplantation was not relevant for them, 19 wrote that the issue was not relevant but forwarded the letter to concerned organizations. Finally, 34 organizations gave a statement, i.e. 23% of those initially addressed (Hüsing et al. 1998: 12).

An interviewed TA-researcher argued that it was unavoidable in TA on new and emerging fields to ask experts and stakeholders their opinion because otherwise it would be impossible to get the necessary information. Moreover stakeholders can provide a basis for feasible recommendations, which, in contrast to ivory tower philosophy, are imperative for TA (Interview 2: 96-102). In other words in order to produce useable recommendations the involvement of stakeholders was necessary.

The report was published in August 1998 and took a cautious approach towards xenotransplantation. A cautious call for a moratorium was also debated in the aftermath of the TA study. Opponents of a moratorium argued that such a ban, which would also prohibit basic research, would make it impossible to study the problems associated with xenotransplantation. Advocates argued that only a moratorium without loopholes could ensure that a really open dialogue took place in public (Newsletter TA-Programm Schweiz 1998: 3).

This study was followed by a TA on cellular xenotransplantation (Hüsing et al. 2001).

4 PubliForum

After TA-Swiss had finished its TA on solid organ xenotransplantation and had disseminated its results to politicians, administration and the public[12] by publishing a long and short version of the report (Hüsing et al. 1998, TA Programm Schweiz 1998) and presenting it to the public (Technologiefolgenabschätzung 1998, Technology Assessment 1998), they thought about how to proceed with the topic of xenotransplantation (Interview 9: 005-007).[13] As an interview partner stated, because TA-Swiss believes that it is important to inform politicians and citizens about what experts think as well, they go beyond classical expert TA in cases they consider important (Interview 1: 131-135, ZTA et al. 2001: 4). TA-Swiss decided that a PubliForum might be a sensible way to proceed with the topic and to thereby re-use the results of the TA (Interview 5: 270). But there were also other organizations, which considered a PTA valuable:

- From the TA study it emerged that it was unlikely that public discourse on xenotransplantation might yield consensus given the incompatible positions on xenotransplantation. In the opinion of the authors of the TA study, much could be gained if escalation was avoided. To achieve a rational debate, the discourse was to be initiated and furthered rather than left to its own resources, e.g. by measures tailored to specific target groups using brochures, media reports, presentations and discussions for professionals, multipliers and interested citizens. The TA study already argued for a citizen panel or consensus conference, which might be carried out in the context of the pending regulation of transplantation medicine. The results of such an event should be appropriately considered in the political decision making process (Hüsing et al. 1998: 178, Bellucci et al. 1998: 165).
- The FOPH considered transplantation medicine a well-suited topic for trying out the Danish consensus conference model in Switzerland, an idea, which was also supported by the responsible minister. In a documentation the FOPH department of law refers to the TA study by stating that the authors recommend a societal opinion formation process with regards to xenotransplantation and transplantation medicine ("Verfassungsbestimmung über die Transplantationsmedizin" Chapter 5.9) TA-Swiss organized the PubliForum together with FOPH and the Swiss National Fund (SNF), who at that time had a funding program on transplantation medicine, (Interview 4: 185-202).
- In 2000 the Swiss Academy of Medical Sciences claimed that "the organization of a 'public forum' could be useful to open the debate" on the "aims of allogeneic and xenogeneic transplantations and on other potential solutions for the problem of the

[12] In its newsletter TA Swiss reports in September 1998 that it presented the TA Study on 7.9.1998 in an event which was attended by more than 100 people. They also mentioned that print media and the radio programmes DRS and RSR reported this event (Newsletter TA-Programm Schweiz 1998: 3).

[13] TA Swiss monitored the impact of the TA and reported to its Steering Committee (Technology Assessment 1999). The impact mentioned in this paper is a press release by the Federal Office for Public Health, a reference in the German TAB and an OECD document which reports about the TA study on xenotransplantation (Interview 467-474).

> shortage of donor organs". In this discussion "the costs and the benefit for the patient and for society (…) as well as the ideological differences existing within the general population" (SAMW 2000: 392) should be debated.

The PubliForum on transplantation medicine was not to the first to be organized by TA-Swiss; the PTA was preceded by two PubliForums on energy policy and genetically modified organisms. TA-Swiss learned two lessons from these exercises as well as from international comparative research on PTA. Firstly, that strong expertise in the topic addressed was needed and, secondly, that the PubliForum should be connected with an actual political decision. Recognizing these two lessons, TA Swiss reused the knowledge and expertise gained in the TA. It placed the topic of xenotransplantation in the wider context of transplantation medicine, which was at that time discussed in the context of the imminent transplantation law. The PubliForum therefore became connected to an ongoing regulative initiative (Interview 1: 225-33) and xenotransplantation became one among six areas which were discussed in the PubliForum (Interview 5: 285-291). By creating this connection and involving the FOPH[14] as well as the Swiss National Science Foundation[15] as co-organizers, TA-Swiss not only strengthened the PubliForum's link to the policy making process and research but also to its financial bases for the PTA.

4.1 Aim

The TA-experts interviewed stressed that it is not the goal of a PubliForum to make a binding decision on a technology but rather to inform politicians about citizens' opinion early on. A PTA deals with complex issues, which pose challenges to both politicians and the electorate. It is an early process in which citizens are informed about the issue at stake. PTA provides a means for an organized and informed debate and a possibility to uncover certain aspects important for the citizens but which legislators may overlook. This may happen not because legislators are stupid or evil but because experts, jurists and university graduates were dealing with these issues from a specific level and angle (Interview 5: 398-403).

Several TA-experts stressed the term *qualitative* when they described the PubiForum. It is not the goal of a PubliForum to provide a representative picture of what the Swiss population thinks about a topic but it is a *qualitative* process, which results in a report about what 30 Swiss citizens think. These did not know each other before and were informed by experts with whom they spoke in the PTA. After a total of eight days people are quite informed about a topic and the resulting reports are of good quality. A PubliForum is a *qualitative* process, which can become one element in the larger mosaic of the political process; this may result in a law or referendum (Interview 1: 377-398). Another TA-researcher emphasised that it

[14] One civil servant was member of the Advisory Committee, two in the organisation group (ZTA et al. 2001: 86) and one as informant in the PubliForum (ZTA et al. 2001: 65 ff.).

[15] The SNF at that time had a national research program on transplantation research called "Implantate und Explantate" (NFP 46) (ZTA 2001: 4ff.).

was interesting for TA-Swiss not to hear a "yes or no" but to *qualitatively* learn what people think about certain issues and to hear their arguments (Interview 2: 394-396).

One TA-researcher pointed out the difference between a referendum and a PubliForum. The popular referendum is organized at the very end of the process; it is about "yes" or "no" and results in a "yes" or "no". A PubliForum, on the other hand, is not about being for or against xenotransplantation but about investigating the opinions on xenotransplantation. It is a *qualitative* process in which new ideas might also develop (Interview 9: 387-393, see also ZTA et al. 2001: 4).

As one scientist explained, the goal of the PubliForum was to make the public aware of the topic and to get a non-expert opinion from a kind of lay jury that listened to and questioned experts. Moreover, in the context of a xenotransplantation regulation, one aim was to get a feeling for what the public thought of xenotransplantation after being informed (Interview 6: 056-068).

4.2 Process

The PubliForum was modeled on the Danish consensus conference (ZTA et al. 2001).[16] In April 2001 about 10,000 randomly selected Swiss residents were contacted, provided with information about the planned PubliForum and invited to participate. Interested citizens could apply by filling out a short biographical questionnaire. Out of 100 persons who registered, 28 were selected so as to obtain a heterogeneous sample of age, sex (50% male, 50% female), profession, and linguistic region (Bütschi n. d.).[17]

At the beginning of the PubliForum the lay panel studied fact sheets on transplantation medicine. These were produced by a science journalist and sent to the panel before the actual events. The citizens subsequently met on two weekends in September and October 2000. On the first weekend they were introduced to the concept of a PubliForum and, after input from experts, discussed medical, ethical and legal aspects of transplantation medicine. It was also considered which questions to address in the public event.

On the second weekend the lay panel decided on which issues they wanted to continue to discuss in the public hearing. These topics were that of a definition of death, perspective of those concerned, allocation of organs, regulation of organ donation, research and xenotransplantation (ZTA et al. 2001). The lay panel also selected which experts they wanted hear from on these questions. For that purpose TA-Swiss put together a list of about 90 experts, with backgrounds ranging from ethics to medicine, from which lay citizens had to

[16] "The TA-Programme developed a slightly modified form, which are adapted to Swiss multilingualism. To avoid the misunderstanding that the exercise's primary goal was be to reach consensus, it calls this approach PubliForum" (Schweizerischer Wissenschaftsrat n. d.).
[17] For a participant list see ZTA et al. 2001: 11 ff.

make their choice. The experts invited to cover the topic of xenotransplantation were Bärbel Hüsing (biologist, main author of the TA study on xenotransplantation, FhG-ISI), Richard Friedli (religious study, University Fribourg) and Florianne Koechlin, (biologist, Schweizer Arbeitsgruppe Gentechnologie).

The PubliForum took place from the 24. to the 27.11.2000 and was organized as a two-day public discussion with experts on the six selected topics. With respect to xenotransplantation the citizen panel posed several questions to their informants (ZTA et al. 2001: 78ff.):

- How do you evaluate the health risks, benefits and ethical consequences of xenotransplantation?
- How can these health risks be identified and prevented?
- Which alternatives to xenotransplantation exist and how do you evaluate them?

The public discussion with experts was followed by a day for citizens to produce their report in discussions closed to the public and a concluding day for the lay panel to present its report to the public (ZTA et al. 2001).

To write their recommendations the lay panel formed working groups which, to facilitate discussion, were homogenous concerning language. Each group had to produce recommendations on one topic. TA-Swiss provided a template of how to structure this report: first, a summary was needed of what the lay citizens had learned during the process in terms of content; second, the citizens should present their opinion and, third, recommendations. The recommendations should be as explicit as possible about to whom they are addressed and should be formulated as clearly as possible. Work in groups alternated with plenary discussions.

The PubliForum was facilitated by a trained moderator whose aim it was to achieve a consensus within the group (ZTA et al. 2001: 6). As a TA-researcher explained, the idea of the PubliForum was not to stimulate a vote with majority and minority positions as it is usually the case in political arenas (for instance a parliamentary commission), but to generate ideas and recommendations shared by the group. However, this was not always possible and if consensus was unattainable there was always the possibility of a vote (ZTA et al. 2001: 8). This happened in the case of xenotransplantation; while the majority considered the regulation proposed by the FOPH as sufficient, a minority favoured a total ban or moratorium (Interview 9: 174-201).

In a public presentation the citizen panel passed its report to the heads of the responsible parliamentary commissions of the National Council and the Council of States. These members of Parliament were “very interested in the results” and invited the lay citizens to meetings of their commissions. The responsible civil servant of the FOPH also thanked the

citizens and stated that their results would be taken into consideration in the development of the transplantation law (ZTA et al. 2001: 9).

4.3 Output

In their statement the citizen panel summarized the responses of the informants as follows:

If xenotransplants became an adequate alternative to human grafts their benefits would include: that there would be sufficient organs for transplantation, the allocation of organs would only be based on medical criteria; elective surgery with better prospects would be possible, recipients would no longer have to feel a sense of guilt towards their deceased human donors, the bases for organ trafficking would be weakened, even if xenotransplantation were only be used as bridging solution it would be possible to save human lives.

Health risks would include: a risk of infection with unknown diseases, stronger immunosuppressive drugs would be needed, knowledge about long term functioning of animal organs is lacking, known psychological problems for recipients might be aggravated and new problems might arise, the chance of psychological rejection due to cultural or religious reasons has to be investigated. Because of these risks a number of informants demanded a moratorium for xenotransplantation.

Ethical considerations involved: the question of whether we are allowed to degrade animals to spare part storages, the fact that in certain religions the pig is considered as impure and that a bridging solution would only further increase organ shortage. One informant also considered the spread of animal cells in the human body as problematic.

So as to minimize further risks, animals can be raised in sterile conditions and tested for known pathogens. Nevertheless, it cannot be excluded that unknown pathogens are present. Animals can also be modified genetically to suppress rejection.

Alternatives to xenotransplantation include prevention, increasing the readiness to donate and to promote living donation. Alternative technologies, which were promising in the long term, (requiring approximately the same time to develop) were: artificial organs, research into the causes of organ failure, tissue engineering, and stem cell technology.

The citizen panel came to the opinion that the risk of infection involved was not only a problem for the recipient but for the entire population and that retroviruses could cause diseases that might spread epidemically. Furthermore, the panel considered the transgression of the species boundary as problematic and concluded that psychological problems must on no account be underestimated and trivialized. The benefits, as reported by experts, would not outweigh the great risks of xenotransplantation by far. The lay jury

therefore especially emphasized alternatives named by experts. A significant majority of the panel supported the statement that the breeding conditions of “source animals” would not at all meet requirements of species-appropriate animal husbandry. Genetic modification on pigs, which would be necessary to reduce rejection, was considered ethically questionable. The panel also stated that it did not think that an animal might be degraded to a spare part stockroom.

5 citizens voted for a moratorium on all xenotransplantation research and another 5 opted for a moratorium on clinical research. However, a majority of 14 people were not in favor of any form of a moratorium because they considered the legal requirements as sufficient.

In its recommendations, the citizen panel stated that they would call attention to alternatives to xenotransplantation to alleviate organ shortage. In particular prevention should be intensified and legal regulations for living donation should not be formulated too restrictively. Additionally, research into artificial organs, organ failure and tissue engineering should be supported and intensified.

Finally, the regulations proposed in the government bill regarding xenotransplantation and clinical trials were considered sufficient; a majority was therefore not in favor of a moratorium. However, liability regulations should be formulated more strictly (limitation and insurance). A paragraph is also missing which requires the written consent of a xenotransplantation recipient (ZTA et al. 2001: 32 ff).

4.4 Advisory Group

TA-Swiss technology assessments are routinely accompanied by a so-called advisory group (Begleitgruppe) (Interview 9: 60-63) that brings together members of TA-Swiss’s steering group and independent experts (Technology Assessment n. d.). This covers topics rather broadly (Interview 5: 132-134) and has two intertwined goals: (1) to provide quality assurance; (2) to create legitimacy by involving stakeholders

As one interview partner explained, the advisory body legitimates the TA process and its output. It does so by the fact that a broad spectrum of institutions and people concerned with the issue at stake were involved in and consented to the study (Interview 2: 249-257). Furthermore, it increases the credibility of the TA by assembling the best competencies (Interview 4: 139-145). Another interviewee described the advisory group as a tool for tapping into the TA people’s scientific, political, regulatory and ethical expertise (Interview 8: 251-264). The advisory group was also a quality assurance tool since TA-Swiss’s staff cannot provide expertise on all topics.

Besides providing credibility in terms of content, the advisory group should also safeguard a TA’s political acceptability by avoiding one-sidedness (Interview 4: 505-523). By setting up

an advisory group and involving influential and concerned groups, TA-Swiss tries to embed the TA in the respective policy field.

The TA study on xenotransplantation and the PubliForum were both accompanied by an advisory group. The advisory group of the TA study included two ethicists, a jurist, a Member of Parliament (who was also on the board of Basel Appeal), a surgeon, a civil servant from the FOPH and representatives of compulsory health insurance, Novartis, a self help group of kidney patients and the steering group.[18]

Participation in the advisory group can also be understood as a matter of politics and as a strategic decision. One interview partner, for example, criticised the involvement of Novartis given their interest in xenotransplantation. To provide another example, Basel Appeal perceived its participation strategically. It provided valuable information, which Basel Appeal would not have been able to access had they refused participation (Interview 3: 374-175). The NGO planned to leave the advisory group with an uproar, if the TA were to be one-sided and characterized by interests; because their member felt that her political and critical opinions were taken seriously by the contractor of the TA study this never happened (Interview 3: 354-355). Actually, it seems that Basel Appeal was quite pleased with the TA results; a circular reads: „With great satisfaction the five authors (of the TA, EG) practically arrived at the same conclusions as we did" (Basler Appell 1998).

Regarding the proceedings, the advisory group worked in meetings. In a kick-off meeting FhG-ISI presented its planned approach to the study. The advisory group was able to make suggestions and ask for amendments to the proposed TA approach. It was not entitled to ask for a complete and fundamental change though. During the project's lifetime the advisory group met several times and discussed interim and final drafts of the TA (Interview 4: 170-18, Interview 3: 237-239).

In the PubliForum the advisory group consisted of representatives from research, politics, industry, public administration and NGOs.[19] It was to safeguard transparency and objectivity but also decided on the final composition of the citizen panel. It helped organizers identify

[18] Members of the advisory group were PD Dr. Alberto Bondolfi (ethicist/theologian, University Zürich), Prof. Marco Borghi (jurist, University Fribourg), Margrith von Felten (Member of Parliament), Dr. Reto Guetg (physician, Konkordat der Krankenkassen), PD Dr. Detlef Niese (physician, Novartis), Andrea Schäfer (Association of Kidney Patients of Switzerland), PD Dr. Rolf Schlumpf (transplantation surgeon, Kantonalspital Aarau), Dr. Theodor Weber (FOPH). As representative of the steering committee: Prof. Thomas Leisinger (microbiologists, ETH Zürich) and Prof. Hans-Peter Schreiber (ethicist, ETH Zürich, ZTA et al. 2001).

[19] Members of the advisory group in the PubliForum were: Andrea Arz de Falco (Präsidentin der Ethikkommission Gentechnik im ausserhumanen Bereich), Daniel Candians (Queen Elizabeth Hospital, Birmingham, UK), Conrad Engler (Interpharma), Pierre-Alain Gentil (Ständerat), Werner Losli (Ehrenpräsident der Patientenorganisation ‚As de Coeur"), Francois Mosimann (surgeon, representative of Swiss Transplant), Catherine Nissen-Druey (Swiss Council for Science and Technology), Kurt Seelmann (jurist, University of Basel), Rosemarie Soldati (former member of Council of State), Verena Soldati (Basel Appeal), Thomas Szucs (health economist, University Hospital Zürich), Rosemarie Waldner (journalist, member of the Steering Committee, ZTA), Theodor Weber (FOPH), Bianca Witvilet (Swiss Association of Nurses and male Nurses) (ZTA et al. 2001: 85).

experts for the list of informants from which the lay panel had to select and recommended experts to the lay citizens. They also provided topics for the preparatory fact sheets (ZTA et al 2001: 6 ff.).

4.5 Difficulties

Drawing from the interviews there were only a few problems during and after the PubliForum. The most important problem was related to the connection between the PubliForum's output and the policy making process. It turned out to be difficult to synchronize these two processes (Interview 9: 109-114). Initially the organizers planned to hold the PubliForum during the consultation of the transplantation law so as to incorporate the lay panel's opinion into the government's bill. However, due to timing problems this plan was not realized. As already mentioned, the lay panel was aware of and in majority explicitly agreed with the FOPH's restrictive position (Interview 9: 202-207).

Recruitment of the lay panel was not a problem then. Nowadays it is more difficult to get participants other than people over fifty to attend. However, by definition, the composition of such pTA groups should consist of different occupations, formal education, ethnicity, age and gender. Thus, today TA-Swiss is therefore thinking about providing compensation as an incentives to participate. (Interview 2: 353-358).

One TA-researcher considered the process of putting together an extensive list of different experts for the lay panel to select informants from as most difficult and time consuming. An advantage of this procedure is that citizens sometimes select unorthodox experts who perceive a topic from a new and different angle in contrast to those experts regularly asked for statements. However, because the process of putting together such a long list is so time-consuming, TA-Swiss nowadays selects the experts themselves.

The common problem for PTA of a knowledge asymmetry existing between experts and laypeople also occurred in the PubliForum. However, according to a TA-researcher the experts were ready to express themselves in a way that laypeople were able to understand (Interview 5: 362-367). Another interview partner thought that the gap between experts and laypeople was softened since the citizen panel was informed about rejection mechanisms, viruses, infections and ethical problems beforehand (Interview 6: 356-361).

4.6 Representation of man and women in the PTA

Regarding questions of gender, the number of male and female participants in the PubliForum was equal (14/14). A professional moderator was responsible for ensuring that men and women had an equal opportunity to contribute to the discussions (Interview 9: 259-261). In the advisory group there was a slight male majority of 8 men to 6 women and the

invited experts who informed the lay panel about xenotransplantation included two women and one man.

4.7 Experiences

Almost all interviewees had very positive experience of the PubliForum. According to a participating scientist the lay panel was very interested, raised good questions and was very knowledgeable after the two weekends of teaching. The PubliForum was a good way to discuss the topic rationally and provided a good link between the public and science:

"I thought this was great. (...) From my perspective this was an opportunity to really involve the public and inform them in depth, to organize a contact and link with science in a close and deep way. It creates a really good dialogue. If we could do this more often, particularly in technology assessment, it is really an opportunity to find out what people want and on the other hand to directly inform them on: 'what the risks are, what the benefits are of a technology and to do that rationally, properly without an underlying idea to profit" (Interview 6. 254-263).

According to another participating scientist the PubliForum was performed in a way, which acted against a dynamic of polemic on the one hand and overrated hopes and prophecies on the other. This was attained by sombrely looking at an issue without falling into any conflicts. He considered this approach as typically Swiss (see below). Researchers did not characterize counterarguments as nonsense and ethical rubbish. Green politicians as well as animal welfare activists did also not take radical positions in his view (Interview 8: 181-195). A xenotransplantation researcher, who participated in the PubliForum as a spectator, described his experience as positive in an article and claimed that it would contribute to a serious and factual debate (Seebach 2001: 17).

Civil servants also recalled having had positive experiences with the PubliForum. They described their engagement with transplantation medicine during the development of a law as an intrusion into a closed caste of transplantation surgeons. These accused them of hindering a life saving technology by taking a regulatory approach emphasizing law, limits and legal certainty. Transplantation surgeons demanded a law that focused on facilitating instead of hampering transplantation by means of what they considered as overregulation. Feeling uncomfortable with this situation the PubliForum gave civil servants an opportunity to learn what ordinary citizens and laypeople thought about transplantation. The PubliForum's results supported their policy approach of introducing control mechanisms into transplantation and increasing transparency (Interview 4: 203-227, 244-247).

4.8 Impact

The question of what impact the PubliForum made on policy making is difficult to answer. The PTA certainly had some impact because the PubliForum and its results were noticed by relevant actors. Both the TA and the PubliForum were connected to the policy process since civil servants and politicians were in the advisory group (Interview 2: 199-209, Interview 9: 223-224) and since its results were presented to policy makers, both from the executive and legislative. Both were at that time dealing with the development of transplantation law, which, as previously mentioned, was to include a xenotransplantation regulation. This follows TA-Swiss's aforementioned policy to analyse and discuss technologies that are topical on the political agenda. Placing TA and PTA processes at the early stages of regulatory processes as well as involving and informing policy makers about their results increases the chances of these making an impact on the political system (see also: Pfersdorf 2008: 66).

A press release from May 2001 provides evidence that the FOPH noticed the PubliForum. The office reported the implementation of the xenotransplantation regulation and referred to the PubliForum. It mentioned that the lay panel was concerned about the medical and psychological consequences of xenotransplantation and that they did not demand a moratorium but instead strongly emphasized alternatives to xenotransplantation so as to alleviate organ shortage (Eidgenössisches Department des Innern 2001).

The PubliForum was also mentioned in the governmental bill, the so-called message (Botschaft) sent to Parliament. The message includes the history and main arguments for and against a bill as well as its proposed formulation. It is also the main basis for political debate in parliamentary commissions and the plenum (Interview 1 151-154, Interview 9: 214-219). An entire section of the message was dedicated to the PubliForum (Schweizerischer Bundesrat 2001: 74 ff.). It describes the PubliForum in detail; its aim, process and main points of discussion. It refers to the citizen's report and summarizes its recommendations. The message states that the PubliForum had an impact because the government wanted to "handle the regulation of xenotransplantation restrictively" (Schweizerischer Bundesrat 2001: 75). The document concludes that "the PubliForum documented that so called lay persons are ready to look into a complex issue, to discuss with experts at a high level, to insist on delicate issues without timidity, to produce an outstanding final report in due time until the early morning hours and to wittily present it at a public event" (Schweizerischer Bundesrat 2001: 76). TA-Swiss was actually surprised by the extent to which the results of the PubliForum were reported in the message (Interview 9: 223-224).

At the same time the direct impact of the PubliForum on political decisions is hard to pin down because the initial plan to base the governmental bill on the PubliForum's output was not accomplished due to timing problems. When the PubliForum started (24.11.2000), the consultation of the bill was already finalized and the results were published in November 2000 (Interview 4: 305-314, Schweizerischer Bundesrat 2001: 70). On 22.11.2000 the

Federal Council ordered the responsible ministry to work out a draft bill based on the results of the consultation process (Schweizerischer Bundesrat 2001: 73).

Because the PubliForum's recommendation did not contradict the ministry's position it is hard to see whether it made a difference. It referred to the FOPH's bill and, in majority, considered it as sufficient. Basically, the FOPH had already made up its mind before the public plenum of the PubliForum (Interview 4: 285-287) and there was no need to change the regulation since the PubliForum shared their view (Interview 4: 293-304). An interviewed TA-researcher therefore considered the impact of the PubliForum as legitimizing (Interview 9).

Turning away from this "hard" understanding of impact to wider notions of the term the PubliForum certainly can be regarded as having made an impact (see Versteeg/Loeber 2011).

PTA provided 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 (Versteeg/Loeber 2011). An important prerequisite for impact, as explained by one TA researcher, is that people know about the PTA. In her view it was therefore necessary to organize a public event and to invite a broad range of people. (Interview 9: 165-166). TA Swiss therefore took particular care to disseminate and diffuse the results of the PTA to various audiences. The final event was open to the public and the results were presented to members of Parliament as well as to civil servants of the responsible ministry. Furthermore, the results were also published and sent to Parliament (ZTA 20011).

Another notion of impact is brokerage, in the sense that an active connection is made between two (or more) previously unconnected social sites or actors and actor groups (Versteeg/Loeber 2011). PTA certainly had an impact in this sense. The setting of the PubliForum allowed advocates and opponents of xenotransplantation, invited as experts, to exchange their views. Moreover, lay citizens were informed about xenotransplantation and were thereby enabled to form their own opinion. Connections were also created between the PubliForum (in terms of results) and the actors normally involved in law making, i.e. the Parliament and the FOPH. It was particularly important for the FOPH, who also sponsored the PubliForum, to get a public opinion on the issues of transplantation and xenotransplantation because it was in conflict with experts about its cautious approach. So, for the FOPH it was an instrument for incorporating "public" input into lawmaking. The results of the PubliForum were also noticed by Parliament since they were reported in the message.

Moreover, the PubliForum created an opportunity for citizens to engage in the topic and for advocates and opponents (also from civil society) to present their positions and discuss the issue.

The PubliForum also had an impact because in the context of Swiss direct democracy and law making, the PubliForum was considered as an additional valid instrument for learning about public views on controversial scientific issues.

The PubliForum also contributed to the policy process because the FOPH thereby felt strengthened in its cautious approach in relation to transplantation surgeons. But there were also other impacts of the PubliForum. For example, one individual hospital started providing psychological care in transplantation medicine.

5 Social Practices

The following description of the Swiss political system is taken from a brief portrayal in Pfersdorf (2008: 44-48). The political practices sketched in this section have been identified in the interviews carried out during research.

5.1 Social Practices in the Field of Policy Making

The Swiss political system is located between a presidential and parliamentary system. The government, or Federal Council (Bundesrat), consists of seven members who as a collective form the head of state. The two chambers of Parliament, Council of State and National Council, annually elect one member from the Federal Council as head of state (Federal President, Bundespräsident), who only has coordinative functions.

5.1.1 Government

Government has a strong and independent role from Parliament. Federal Councillors are elected for four-year terms and cannot be deselected, whereas re-election is possible. The composition of the Federal Council is governed by the so-called magic formula (Zauberformel) which, according to a fixed key, determines how seats are allocated to parties since 1959.[20] Parties adhere to this very slowly changing distribution of power, which is not dependent on the latest election results. Thus the system only accommodates only slowly, with some time delay and only after major shifts in election outcomes. The magic formula not only recognizes the long-term relative strength of political parties in the political system but is also a compromise between different political parties, Swiss ethnicities (German, French, and Italian), confessions and gender. Though Parliament often asks government to take regulatory steps by means of motions (see below), it is the Federal Council that prepares laws and has a main role in law making.

5.1.1.1 Political Practices of Government

During the law making process government prepares a draft law and sends it into a formal consultation process (Vernehmlassungsverfahren, see also Linder 1999a: 470). In this procedure stakeholders can express their opinion about a bill and propose changes (Interview 3: 429-437). The call for a consultation process is published. For each policy field different lists exist of who to involve in this process. Government addresses the so-called invited parties; such as the 26 cantons, other ministries, representatives of interest groups and other interested associations. (Interview 5: 392). However, consultation is also open to so-called uninvited parties, which in the case of xenotransplantation were critical NGOs. In

[20] The rioseof thepopulist conservative SVP since the 1990s changed the distribution of government seats for some time but so far did not lead to the abandonment of the concordance system (see Appendix).

principal the consultation is open to each citizen, though judging from the interviews this seems to be little known and made use of (Interview 8: 212-226, Interview 5). If a governmental bill is opposed by too many relevant actors, it is changed by the responsible ministry. An interviewed politician considered the consultation a good procedure in which concerned organizations can make suggestions, which are often also taken into account (Interview 3: 515-519). Another purpose of the consultation is to avoid referenda (see below), which might cause a defeat of government by voters.

After the responsible ministry has taken into account the statements of invited and uninvited parties and redrafted the bill, the Federal Council sends its bills as a so called message (Botschaft) to Parliament. Only then does Parliament start its process of discussing and formulating the law in its respective commissions.

The message is a comprehensive text, which includes the bill and background information on the proposal. In the case of the Amendment on the Federal Decree on the Control of Blood, Blood Products and Transplants, for example, the message is a well-arranged 28 page document, which in detail analyses the development of xenotransplantation, medical aspects (rejection, infection, physiological compatibility), ethical aspects, preceding parliamentary initiatives, current Swiss and international regulation (Council of Europe, WHO, OECD, UK, USA), conclusions, results of consultations, an explanation of the bill, forecasts of consequences regarding finances and personnel, consequences related to European Union and the Council of Europe and, finally, the bill itself (Bundesrat 1998). The message on the transplantation law is more than 200 pages booklet (Schweizerischer Bundesrat 2001). The bill therefore included a clear and highly qualitative regulatory impact assessment.

5.1.2 Parliament

The Parliament, the Federal Assembly (Bundesversammlung), consists of the National Council (Nationalrat) and the Council of States (Ständerat). The National Council is the bigger chamber. It consists of 200 members who are elected by proportional representation. The Council of States is composed of 46 members and is elected by a majority vote system. Both chambers have equal political weight and their separate commissions for individual policy fields. In cases of disagreement between the two chambers (as in xenotransplantation) a procedure for settling differences (Differenzbereinigungsverfahren) is initiated so as to find a compromise. If this cannot be accomplished the bill fails.

In comparison to the government the resources of the Parliament, e.g., regarding support staff, are limited. The government therefore (and because of its daily routine of implementing laws and administration) has an advantage in comparison to Parliament in terms of knowledge and resources available and plays a very active role in legislation. However, Parliament also has a decisive part to play and the government’s bills do not always pass the

two chambers without substantial amendments. The parliamentary commissions deliberate bills in depth and in the case of xenotransplantation the FOPH failed with its proposal (Interview 4: 151-158).

In the case of xenotransplantation the FOPH used formal and informal consultation processes order to develop its policies. These processes resulted in a message to Parliament. The FOPH also used the PubliForum as an information source to support its position, which is partly critical of experts from transplantation medicine.

Important documents of this policy process include draft bills, statements made during the consultation, the report on the consultation procedure and the message to Parliament.

5.1.2.1 Political Practices in Parliament

In the case of xenotransplantation Members of Parliament used the instrument of interpellation, in which they address government and ask questions. This is a parliamentary instrument of the first choice (Interview 3). Another instrument is the parliamentary initiative in which Members of Parliament address the responsible parliamentary commission, which deliberates and decides on the proposal. Finally there are motions, either addressed at the government or the plenary, asking for certain steps, to be taken or for amendments of proposed laws to be made for example. An important mechanism is the procedure followed to settle differences between the two Chambers. All of these practices were applied in the regulation of xenotransplantation (see also Appendix).

5.1.2.2 How to get information

Policy makers used various sources In order to get information:

- The FOPH used reports on international regulatory initiatives and expert opinions. Moreover it was involved in discussions with the Council of Europe, the OECD and the WHO.
- Critical members of Parliament used materials from NGOs (such as Basel Appeal) and press reviews compiled by the parliamentary staff.
- The responsible parliamentary committee organized a hearing with experts for and against xenotransplantation.
- In the plenary debate speaker mention informal negotiations between Members of Parliament and interest groups' representatives. But there are no documents available which would corroborate this claim.

5.1.3 Features of the Political System

Federalism is an important element of the Swiss political system. The 26 cantons have their own constitution and have tax authority on most taxes. The Federation has competence in questions of technological development. Policy, education and churches are regulated by the cantons.

The Swiss political system is characterized by a division and an interconnection of power between the executive and legislative but also by the autonomy of cantons, interest groups, parties and single institutions such as the government. All of these are proportionally represented in decision-making processes and have veto power. Switzerland is therefore the ideal *concordance democracy*. Advantages of this system include the integration of interest groups, the protection of minorities and that solutions find broad acceptance. Disadvantages include lengthy decision-making processes, a strong notion of elite cooperation and a lack of transparency to outsiders of the system.

Election results do not determine the composition of government because of the magic formula. Members of Parliament must not be instructed and are only responsible to their conscience. Parties therefore play a less important role than in other democracies.

Another of the main features of the Swiss political system is its orientation towards *consensus*. The constitution lays down the principle of collegiality in government, i.e. the Federal Council has to find a common policy. Single Federal Councillors have an absolute veto but taking a vote is always a possibility. This orientation towards consensus is also expressed in the magic formula. The already described consultation procedure in law making is another expression of this consensus orientation. Swiss decision-making processes therefore take a long time but the resulting compromises are often widely accepted by Parliament, parties in Parliament, interest groups and the electorate.

During an interview a politician considered her work in the regulation of xenotransplantation as rather successful because she was able to create a certain public audience for the topic. Because the final outcome of the political process was a compromise; there was, on the one hand, not a complete ban of xenotransplantation and on the other hand, obligatory governmental authorization creating oversight on xenotransplantation in clinical trials. The solution to allow xenotransplantation after prior authorization was a kind of middle ground. This notion of finding a *compromise* is, from her perspective, rather typical for Switzerland. (Interview 522-534).

Another characteristic of the Swiss political system identified by an interview partner is its *general pragmatism*, in the sense of concentrating on given circumstances. In her opinion basic questions about society's ideas in general are increasingly rarely debated since 1968. Instead, there is a dominant notion of pragmatism in Swiss society. This attitude was

expressed in the context of xenotransplantation since animal welfare and the question of viruses was taken seriously but pragmatically integrated into the xenotransplantation regulation by stating that organs have to be tested for viruses before transplantation (Transplantation Law Article 47). The fundamental question, however, whether xenotransplantation as a technology should be further pursued at all, was hardly debated in this pragmatic approach (Interview 3: 138-177).

Although TA as a concept and process in the way xenotransplantation was dealt with in policy making was new, the problem nevertheless was framed by this general pattern of pragmatism where problems were identified, addressed and finally ticked off. The notion of pragmatism implies a technical solutions, i.e., that organs should not be afflicted with viruses, animals should be kept according to regulations and that the question of xenotransplantation should be settled by experts, i.e., scientists and physicians (Interview 3:410-425).

Another way to describe this typical pragmatism is to describe the Swiss, as opposed to the technology affine US-Americans and the technology skeptical Europeans, as very realistic and belonging to the middle ground. To substantiate this claim one interviewee pointed out the public referenda in which the Swiss would vote on factual issues every two months. In these the Swiss would be very realistic and reasonable (Interview 8: 192-209). This kind of pragmatism is also expressed in the repeated insistence of TA-researchers during interviews that it is justified that firms should yield profit from xenotransplantation.

5.2 Social Practices in the Field of Citizen Participation

The social field of citizen participation is particularly rich in Switzerland. Elites play a strong role in the political system but the electorate can play an active role by means of initiatives and referenda. Since the threat of a referendum that might overturn a law always exists, "the entire Swiss political system is intended to avoid a referendum" (Interview 9: 300).

However, in this area interest groups are also important. They raise issues for direct democracy and try to create majorities in referenda and initiatives. Thus the people are a control factor in most important questions and a significant veto player that can force the political elite to react by threatening with loss of power and reputation. Overall, there are general elections, referenda, initiatives and consultation procedures that involve citizens.

In the case of xenotransplantation citizen participation consisted of a petition signed by 6,500 citizens demanding a moratorium. There was also a formal consultation procedure for the law on transplantation and the informal consultation procedure on the Federal Decree on Blood and Blood Products, which NGOs used as an opportunity to voice their critique. Moreover there was a referendum on whether or not to take the regulation of transplantation to the federal level. No evidence of any demonstrations was found.

6 Conclusions

6.1 Xenotransplantation Policy

Swiss xenotransplantation policy is cautious but in principle permissive. Clinical trials are allowed after prior authorization and when meeting strict requirements. This policy was actually decided on when in 1999 a majority in parliament turned a governmental proposal on the prohibition of xenotransplantation with exceptions into permission with certain requirements and prior authorization. This turn of policy was justified with the argument of not wanting to isolate and harm Swiss businesses and the Swiss research location. This approach, despite wide criticism from NGOs, was continued in 2001 in the new transplantation law and was also supported by the majority of the PubliForum.

The regulation of xenotransplantation is connected to two strands of legislation, which reach back into the early 1990s.

First, it is linked to the development of a transplantation law. Until a federal law was passed in 2004, which came into effect in 2007, transplantation was under legislation of the 26 cantons and thus regulated rather diversely. In the 1990s the Federal Assembly asked for federal competence in this area. For this a constitutional amendment was necessary which the electorate had to approve by referendum. The regulation of xenotransplantation fell into this lengthy process of passing a new transplantation law. It was only one of several issues that were raised and was primarily discussed in the context of concerns about risk and public health. It was also discussed in relation to the Swiss research and business location. Issues of animal rights and ethics were less central.

Secondly, xenotransplantation was framed in the context of regulating blood, blood products and transplants regarding a risk of infection. When the issue of xenotransplantation entered the political agenda in 1996, basically on the initiative of the biotechnology critical NGO Basel Appeal and a Member of Parliament who was connected to this group, government initially planned to regulate the topic within the then pending comprehensive transplantation law. The government suggested regulating the topic by amending the Federal Decree on the Control of Blood, Blood Products and Transplants, which regulated protection against infection. It did so after a parliamentary initiative by a biotechnology critical Member of Parliament and a subsequent motion of the responsible parliamentary commission to regulate xenotransplantation quickly and to make it subject to prior authorization. It was through this process that the basic elements of a xenotransplantation regulation were debated and finally decided on. After a heated debate in both chambers, which resulted in diverging decisions, the National Council finally agreed with the Council of States. They decided against the governmental proposal of a ban on xenotransplantation with exceptions and against motions by Social Democrats and Greens for a ban or moratorium respectively.

They did so with the votes of both conservatives and liberals and, because of arguments for securing the Swiss research and business location, decided for a permissive regulation. This regulation included prior authorization after certain requirements regarding safety and liability have been met.

Important actors in this legislative process were the responsible FOPH, both chambers of the Federal Assembly, the National Council and the Council of States, and the electorate. The responsible authority, the FOPH drafted the regulation but both chambers of Parliament were also important because they initiated the regulatory process by making interpellations to government, addressing parliamentary initiatives at the responsible parliamentary commissions, making parliamentary motions to government and finally by changing the governmental bill significantly in regards to the ban of xenotransplantation. Other important actors were biotechnology critical NGOs, namely Basel Appeal, various interest associations, the pharmaceutical industry, namely Novartis and experts from science, medicine and ethics.

Civil societies' activities in regards to xenotransplantation contributed and were connected to the legislative process. The NGO Basel Appeal was very active in the field of xenotransplantation and collected signatures for a moratorium on xenotransplantation in 1996. This NGO also had connections to Parliament since one of the members of its board was also member of the Federal Assembly. This person initiated an interpellation and a motion for a moratorium on xenotransplantation in 1996.

Important procedures within the law making process were parliamentary initiatives, interpellations to government, motions by Parliament, and procedures of parliamentary negotiations (Differenzbereinigung). Moreover, at the level of drafting a law, formal and informal consultation processes were important in which cantons, ministries, representatives of interest groups, civil society organizations and, in principle, each Swiss citizen can voice his/her opinion about a bill. Another important practice is the sending of a message (Botschaft) to Parliament in which the executive proposes a draft bill to Parliament. Finally internal rules of procedure of Parliament are of importance.

Throughout the policy making process a number of (mostly written) artifacts w produced. However, they are mostly available to the researcher in their final and official form. These documents include reports on the consultation process and extensive messages to Parliament, both written by civil servants, as well as interpellations, parliamentary initiatives and motions, formulated by members of the legislative and their staff. These documents are both the result of and means of policy-making. In addition there are verbatim records of parliamentary debate. A different kind of artifact is provided by press debates. Press releases are another kind of document and these are not directly addressed to the policy-making process and its actors but to the general public. Media reports, authored by

journalists, are yet another kind of kind of document. They often provide background information, which is not available in official sources.

6.2 TA and PTA

In Switzerland two expert TA studies on xenotransplantation were carried out. They were commissioned so as to get an overview of the field and its implications for Switzerland. TA Swiss, which by then was connected to the Federal Assembly, took the initiative to organize these TA exercises. It did so because it perceived xenotransplantation as an up and coming biomedical development of which the social and ethical impact required closer investigation. After an open call for tender, TA Swiss commissioned the FhG-ISI to carry out an expert TA study on solid organ xenotransplantation which, by asking stakeholders for their written opinions, also included elements of invited participation. By the means of an advisory group staffed by experts, Members of Parliament and representatives of the FOPH TA Swiss already tried to connect the study with the social and political context of xenotransplantation. The project results (Hüsing et al. 1998) were presented to policy makers and the public.

TA Swiss thereafter organized a PTA, called PubliForum, to get a qualitative picture about what lay citizens thought about the regulation of transplantation medicine more generally and about xenotransplantation in particular and what policy they recommended as appropriate. For this exercise TA Swiss took into account the results of the aforementioned TA study, lessons learned from their first PubliForum and international research on PTA. They decided to broaden the topic of their planned PubliForum from xenotransplantation to transplantation because of the then discussed transplantation law. By involving the responsible FOPH and the Swiss National Science Foundation as co-financers they also connected the PubliForum to the policy process and broadened its financial basis. The FOPH was interested in the PublForum because it wanted to gain more information on what the public thought about transplantation.

Based on the Danish consensus conference model, the PubliForum involved 28 citizens who were selected to represent Swiss population. The citizens had significant influence on framing the issue by raising the questions they wanted to discuss, and inviting the experts they wanted to hear. They were able to discuss the issues with experts and were considered knowledgeable. Supported by TA Swiss and the moderator, they formulated a report, which they presented to members of Parliament, the responsible ministry and a main Swiss research funding organisation. Thus the outcome of the PubliForum was well disseminated into and connected to established policy-making mechanisms. However, it seems the results of the PubiForum were not disseminated as widely to the general public.

Swiss xenotransplantation policy cannot be directly linked to the outcome of the PTA because the basic decision on this policy was already made prior to the PubliForum. Moreover, the majority of the PubliForum supported government policy. Thus, the

PubliForum had a legitimizing impact on policy making since the recommendation corresponded with and supported government policy. It is hard to predict what would have happened if the PubliForum had not agreed with government policy. In addition, there were also other important and indirect impacts of the PubliForum on the policy field.

Expert TA and PubliForum were well received in the political system. The TA study was discussed in Parliament and its quality was recognized in the parliamentary debate. It was extensively referred to in documents of the responsible ministry and in the message to Parliament. The opinion of the PubliForum with regards to xenotransplantation was also shared by the FOPH and the Federal Assembly. The high quality of TA and PTA established the legitimacy of the processes. Their quality was neither questioned in interviews nor official documents. In general policy makers had good experiences with the TA and PTA. A press release of the FOPH referred to the PubliForum and its outcome and claimed that these had an impact. The PubliForum was also well received within the executive and by researchers. In summary, TA Swiss carried out a high quality TA that was followed by a state of the art PTA.

The PubliForum on transplantation, which also included the question of xenotransplantation, was not the first of TA-Swiss's PTAs. It became a standard procedure, which is not used in all cases of TA however. Additional instruments are shorter versions such as PubliTalk and PubliFocus. Other PubliForums on other topics followed but these were more infrequent. However, interview partners also expressed their impression that PTA was kind of en vogue in those days and that interest in them recently dwindled to a certain extent (Interview 4: 327-344).

6.3 PTA in the context of Swiss politics

The Swiss political system is characterized by *subtle balances* between four language groups, cantonal and federal competencies and different political parties. In addition there are tensions between representative democracy and direct democracy as well as a strong emphasis on civil society, eulogizing independent citizens.[21] In an environment of latent tensions and a delicate balance between these positions there is a strong notion of *compromise* ensuring that a shared community is sustained. This is expressed, e.g., in mechanisms such as the magical formula, the principle of collegiality and the consultation procedure in law making. Compromises are facilitated by a political discourse with a particular notion of sobriety, *pragmatism* and orientation on factual questions as well as, at least in the context of xenotransplantation, avoidance of radical stances and questions. Thus, to a certain extent PTA fits well with the main characteristics of the Swiss political system and serves several of its basic needs; i.e., a need for factual and sober discussion by

[21] Swiss direct democracy developed from a 19th century grass roots movement which distrusted representative democracy and wanted to limit the power of parliament and control the most important decisions (Linder 1999a: 463).

ordinary, independent citizens in order to inform policy makers, who in a fragile and polycentric political system are always threatened by a popular veto power. As one researcher expressed his opinion, PTA fits direct democracy since it provides new information, discusses things and does not remain on a polemic level of newspapers (Interview 8: 375-389). In this way a PTA such as the PubliForum can be interpreted as another mechanism within Swiss *concordance democracy* (Interview 9: 348-351).

The interviews showed that PTA such as a PubliForum is particularly well suited to complement existing possibilities of the Swiss electorate to participate in legislation and political decision-making: A *consultation* is only carried out in the context of legislation. Moreover, in reality the consultation mechanism is geared towards involving organized political actors. The right to initiative is a way for citizens to become active but is always geared towards constitutional changes. A referendum is always post-festum, when a law has been passed and the electorate can vote on it.

In contrast, the PubliForum provides a means for the executive to actively approach a group of citizens, composed as much as possible of representatives of the population, and to invite them to voice their opinion on a topic. Being open to normal citizens it is a much more informal and low-threshold[22] approach than a consultation because ordinary citizens are often not conscious of their right to voice their opinion in a consultation. This consultative instrument is mostly used by established political organizations and authorities. In contrast the PubliForum is much more open and the quality of the output is different because it is less controlled by politically active and mobile institutions or organizations and is much closer to the "real citizen" (Interview 4: 255-281).

On the other hand, it seems that the PTA is less directed at the general public than at policy makers. It was more noticed by policy makers than by media and was relatively well integrated into the political decision-making processes.

It should also be kept in mind that the embedding of PTA in the Swiss system draws a perhaps too idealistic picture. Neither TA nor PTA is uncontested in the Swiss political system (Interview 4: 327-344). TA-Swiss had to face criticism from political parties advocating a lean state and glorifying the role of individual citizens and the electorate in referenda. One interviewee recalled that TA Swiss had to justify itself as an organization at the time when they started the TA on xenotransplantation and were still young as a TA-institution (Interview 2 70-72). However, it seems that TA Swiss has gained in reputation by now. Though politicians from the left and the right were skeptical in the beginning, the acceptance of PTA by politics has increased since politicians became accustomed to the procedure and the fact that PTA delivered qualitatively good reports. Although there are still

[22] In the sense of providing in principle easy access for ordinary citizens.

some politicians who remain skeptical, TA-Swiss has a good image in general and the value of the PTA process is accepted (Interview 1: 402-407).

The dividing line with regards to TA and PTA seems to follow the distinction between left and right. One interview partner emphasized a different aspect regarding the question of PTA acceptance. In his view parties from the political right perceive PTA as unnecessary given that there is discussion in Parliament and the option for a referendum would always exist. One TA researcher assessed the situation of PTA in Switzerland as follows: Some politicians doubt the necessity of a PubliForum because they argue there always the opportunity for a referendum and they would know what people think anyway when they visit markets and shake people's hands. Since they already represent the people, a PubliForum is not necessary would only be expensive. In general there is therefore no big euphoria for these instruments but some politicians remain enthusiastic (Interview 9: 378-387).

The political left on the other hand is more positive about PTA. In general acceptance of PTA is also dependent on the particular topic and, if connected to an ongoing regulatory process, PTA might help suggestions and concerns to be accepted at an early time (Interview 5: 46-464).

Parliament, according to an interview partner, leaves great leeway to experts when topics of science and research are raised. The idea that every man and woman could discuss societal and psychological consequences in cases such as xenotransplantation did not meet with much conviction. It was often said that one would see the dangers and that they should be clarified by experts (Interview 3: 200-205). However, this politician was also skeptical about the PubliForum; she thought that the format might be too much open to the threat of manipulation by the way in which experts are selected. The PubliForum might also ask too much from citizens without prior information (Interview 3: 443-463).

7 Annexes

7.1 Outline of the Political System

The following short and rough outline of the Swiss political system shall help to embed the case study within the context of the Swiss political system and is mainly derived from Linder (1999a, 1999b, 2009) and Lüthi 1999.

7.1.1 Cabinets

Were the governments in the last two decades single party (UK) or coalition governments (NL, Ger), minority or majority governments; were they dominated by a certain party?

Swiss Government, the Federal Council (Bundesrat) is composed of seven members (Councilors) who are elected individually by the United Federal Assembly (National Council, Nationalrat and Council of States, Ständerat) for a four years term. There is no possibility of deselect or a vote of no-confidence of a single member or of the entire Federal Council.

The composition of the Federal Council acknowledges the country's multi-ethnicity as well as the strength of political parties in long term perspective. German speaking Swiss have 4 seats, French speaking 2 and the Italian speaking 1 seat. Since 1959 the Federal Councils is composed of representatives of the four major parties. Until 2003 the so called magic formula (Zauberformel) stipulated that the Free Democratic Party (FDP) had 2 members, the Christian Democratic People's Party (CVP) 2 members, the Social Democratic Party (SP) 2 members and the Swiss People's Party (SVP) 1 member. The rule of proportional representation of language groups and parties is a major characteristic of Swiss concordance democracy and is not laid down in the constitution but is a tradition followed by political actors voluntarily (Linder 1999a: 459-460). Since the 2003 elections which made the conservative populist SVP the strongest party, the concordance system is under pressure but nevertheless – with slight modifications - is still in place after some turbulences (Linder 209: 571, 573, 597).

The Federal Council is a collegial organ and its decisions are made with single majority. In reality the position of Swiss government is close to a presidential system.

7.1.2 Legislature

Does it feature two chambers (Ger, I) or one (F)? Who are they representing and which one is more powerful? Where do the Members of Parliament get their information from (own staff, scientific service of parliament, federal ministries, interest groups/social partners)?

Parliament is the highest political institution. However, its competences are delimited by the strong role of government, the strong elements of direct democracy and the involvement of interest organizations (see below). Swiss Parliament is a working parliament, however in comparison to the executive with a much smaller infrastructure. It has the right to initiate and pass laws and budget, financial planning as well as to supervise government and administration. It elects the Federal Council and the Federal Court and the army chief in war. Its two chambers, the National Council (200 seats) and the Council of States (46 seats) are equally important. In order to pass, a bill has to find a majority in both chambers. In cases of disagreement between the two chambers - which deal both with each bill separately and completely - a procedure is launched to settle the difference. If these negotiations do not succeed, the law fails (Linder 1999a: 461ff.). Swiss parliamentarians are working in a the so called "Milizsystem", i.e. they have a civilian profession and their political mandate is considered an additional occupation.

7.1.3 Executive-Legislative Relationship

Is it a relatively more consensual (B, CH) or rather antagonistic (US) relationship? Is the legislative more independent with a number of control rights (US) or less so, with most laws being steered through Parliament by the executive (A)?

The Swiss parliament has a strong formal role in legislation. It can refuse a governmental bill without discussing it in content and can make detailed changes. By parliamentary initiatives it can also make laws without the involvement of Government and administration. It has a question right ("Anfrage") and the right to request from a comment to a question ("Interpellation"). Moreover, there are the instruments of "Postulat" in which Parliament asks Government to examine whether it would be possible to draft a law and the "Motion" which orders a law by Government. Because of the strong role of the Federal Council in the Swiss political system the political majority in Parliament is less concerned with retaining the power of Government and can play an independent and strong role as well (Linder 1999a: 462).

7.1.4 Bureaucracy

What is the role of the bureaucracy in all of this? is it dominant (J, classical Westminster model) or dominated (US), is it large (NL) or small (S), does it operate at arm's length from government (UK, S) for is it more directly attached (Ger, I)?

Switzerland features a relatively small bureaucracy (Linder 1999a: 476). The public administration plays an important role in lawmaking since expert knowledge and experience with implementation of laws accumulate in the civil service (Linder 1999a: 469). In most cases bills are prepared by the Federal Council and administration (94.2% of all laws between 1991-1995, Lüthi 1999: 139). The influence of the parliament on legislation is perceived differently in the literature. While some authors only see a marginal role of

parliament in legislature and emphasize the importance of the Federal Council as well as public administration other authors call attention to the fact that government drafts are often modified during parliamentary negotiations (Lüthi 1999: 142). Lüthi therefore concludes optimistically: “Das Parlament greift also in den Rechtsetzungsprozess ein, allerdings selektiv” (“Parliament engages in the legislative process, though selectively”, ibid.).

7.1.5 Judicial Review

Are the courts important for political decisions (US, Ger) or relatively less so (A)?

The Federal Court rules about conflicts regarding the implementation of federal law. It examines the constitutionality of cantonal and communal regulations and guarantees the basic rights.

7.1.6 Party System

How many parties have been represented in Parliament, is any of these dominant?

Parties lack a strong role in the Swiss political system. They are neither mentioned in the constitution, nor are they subject to a specific law or financed by the state. They are organized on cantonal level. Large parties are included in Government (FdP, CVP, SPS, SVP), whereas smaller parties remain in opposition (Linder 1999a: 471ff.). Within concordance democracy which does not know the regular change between government and opposition competition between parties is restricted to increasing the proportional representation in Government. During referenda, however, political parties can occasionally take the role of an opposition party (Linder 1999b: 25). Since the 1990s the SVP acts as a opposition party against the other government parties as regards European integration and in this way accomplished to become the strongest political party (Linder 2009: 587).

7.1.7 Interest group system

Is the country more corporatist with powerful trade unions, collective bargaining of wages and cooperation between the state, trade unions and business interests (A, NL, S) or is it rather pluralist with a lot of interest groups and little coordination (US, UK)? Are business interests privileged and in which way?

The political system is also characterized by a strong role of interest organizations which contribute to the policy making process. Swiss corporatism is not only focused on the conflict between capital and labor and is characterized by the fact that employees organizations are less well represented than in comparable countries such as Austria (Linder 2009: 590). The interest group systems has two layers, on the first level there are several occupational and branch organisations, on the second level umbrella organization, e.g. Swiss Business

Federation, Swiss Farmers Union, Swiss Federations of Trade Unions. They integrate the interest of their member and try to influence regulation. Interest ogranisations play a strong role, particularly in economic policy. Recently Swiss corportatism faces difficulties due to less cohesion within the interest organizations but also because of globalization. Beside these organizations there are numerous NGOs in the area of social, consumer and environmental policy.

7.1.8 Direct Democracy

What instruments of direct democracy are provided for by the constitution (e.g. plebiscite, popular initiative by a certain number of signatures, mandatory referendum in the case of constitutional changes, petitions signed by a certain number of MPs/voters to be processed by Parliament) and have they been important until now?

Direct democracy plays a central role in the Swiss political system. The instruments of direct democracy developed from a distrust in the representative system (Linder 1999b: 463) and include

1. obligatory constitutional referendum

2. facultative referendum on laws

3. people's initiative.

Obligatory constitutional referendum is necessary for constitutional amendments and treaties dealing with the accession to organization for collective security and supranational communities.

The facultative referendum entails that laws and some international treaties have a referendum clause that means that if 50.000 voters are calling for a referendum within three months after signature the decision is made subject to a plebiscite.

A minimum of 100.000 citizens can call for constitutional amendments (abolishment, change or creation of a new paragraph). If such a people's initiative succeeds in getting enough support the Federal Council and Parliament have to deal with the subject and suggest to the electorate a - in most cases negative - recommendation. Parliament can also make a counterproposal. The people's initiative is an instrument that brings many innovations in the political system. Though only 10% of them are successful, their issues are sometimes taken up by Parliament and are included in subsequent legislation.

Annually the electorate has to vote on approximately six constitutional changes and two to four referenda on laws (Linder 1999a: 462 ff.).

Because of the check and balance between Federal Council, Parliament and electorate, in other words between representative democratic and direct democratic elements, which should enable co-determination of the voters not in all, but the most important matters (Linder 1999a:463), the system is also called “half-direct-democracy” (ibid.).

7.1.9 Political culture

How strong is civil society, is there a tradition of participation in politics, how open is decision-making?

Switzerland is the model of consensus democracy which involves federal structure, concordance and power sharing. Power sharing is based on federalism, subsidiarity and voluntary proportional representation in assigning different political offices with regards to language, party affiliation and gender (Linder 1999a: 467 ff.). The concordance system can be explained against the background of direct democracy, which poses a continuous threat to decisions taken in the representative system. Involving the main political parties considerably reduces the risks for plebiscitary defeat. Thus the voters’ rights in the Swiss political system pose a strong coercion towards concordance. However, it has to be kept in mind that the concordance system developed slowly over decades since the mid 19th century from a political struggle with the then dominant Liberals in which different political movements struggled for political power and were subsequently included in government (i.e. Catholic-Conservatives in 1891; Farmers-, Trading and Citizens-Party after World War I and finally the Social Democrats only in 1959, Linder 1999a: 468, 1999b: 14ff).

7.1.10 Science-Society Relations

What is the role of scientific experts and of expertise in society and in policy-making?

Experts are involved in commissions in the pre-parliamentary process of legislature (Linder 1999a: 476 ff.).

7.1.11 Constitutional Division of Territorial Power

Is the central state more powerful (F) or are the regions important (B, CH, Ger), and which issues are decided by the regions and are there veto points arising from federalism?

Switzerland is a state with strong federalist elements. Federalism was important for a peaceful coexistence of different ethnicities and religious groups. The Federation and the 26 cantons have their own constitutions and the about 3.000 communities enjoy large autonomy. Federation, cantons and communities levy income and property taxes. The implementation of the concept of subsidiarity turns Switzerland into one of the most decentralized countries (Linder 1999a: 457).

7.1.12 Electoral System

Is it relatively more disproportional (US, UK) or less so (Ger, I) and how strong are minority rights (could green parties come into existence).

The seats of the National Council are distributed by proportional representation. The Council of States is elected according to different cantonal rules, mostly majority vote system.

7.2 Policy Field

7.2.1 Cabinets

Did they have a role in the policy field for the problems handled by e.g. the bureaucracy?

During the 1970s and 1980s federal government refused to create a specific law on biotechnology. This ended in 1987 with the people's initiative for "Restricting the abuse of reproductive medicine and gene technology in humans", which was accepted as revised version with 74% in favor. In the 1990s the discussion about biotechnology got more controversial and in 1992 another people's initiative was launched ("Gene-Protection-Initiative") and received necessary support in 1993. Government by this pressure was forced to leave its laissez-fair approach and accepted to develop a regulation.

7.2.2 Legislature

Did it have a role (if yes, which chamber) in the policy field for the problems tackled by e.g. the bureaucracy?

In 1997 the biotechnology critical peoples' initiative ("Gene-Protection-Initiative") had realistic chances to succeed. As a reaction the "pro-gene lobbyist in parliament" (Bonfadelli et al. 2002: 114) drafted a law to regulate the issues which were not covered by Swiss legislation so far and counter the critical initiative. The Federal Government produced in a record time a second draft of this law, the "Gene Lex Package", to show that government was willing "to seriously take into account the concerns of the Swiss population, and to develop strict regulations for gene technology" (Bonfadelli et al. 2002: 115). Government opposed the "Gene-Protection-Initiative". After the rejection of the Gene-Protection-Initiative in June 1998 by 66.6% of the voters (at a turnout of 40.6 %) – after a fierce and controversial campaign - the "gene law" was drafted and debated in 2000 (ibid.) and finally adopted in 2003.

7.2.3 Executive-Legislative relationship

Is there a history of adversarial relations between executive and legislative in the policy field (e.g. over leadership on issues, media attention?

There seems to be no history of adversarial relations between executive and legislative in this policy field.

7.2.4 Judicial Review

Are the courts important for the policy field?

The courts dealt with biotechnology repeatedly, e.g. in the case of ART the Federal Court ruled against restrictive cantons and contributed in this way to a law which did not totally ban ART (Rothmayr 2006: 607).

7.2.5 Party system

Were some parties represented in Parliament interested in the policy field (e.g. the Greens)?

Conservative parties opposed the Gene-Technology-initiative, while the political left, part of the Social Democrats and the Green party were in favor.

7.2.6 Interest Group System

Were some interest groups involved in the policy field (e.g. pharmaceutical industry, Chamber of Commerce, professional associations)?

Opponents of the Gene Protection Initiative were university researchers and the pharmaceutical industry, who considered this initiative as a threat to their existence (Bonfadelli 202: 115). Switzerland has a “powerful pharmaceutical industry, which on other occasions had successfully campaigned in favor of red biotechnology (i.e. medical applications)” (Rothmayr 2006: 615). There are also a number of NGOs which are critical of biotechnology, e.g. Basler Appell.

7.2.7 Political Culture

Has civil society been involved in the regulation of XTP or in similar problems, how open is decision-making in this policy field?

Because of its large involvement in pharmaceutical and agricultural industries by multinational companies and many start-up firms biotechnology policy is high on the political agenda in Switzerland. Several people’s initiatives dealt with the topic of biotechnology (Beobachter-Initiative in 1998, Gene-Protection-Initiative 1998, Bonfadelli et al 2002: 113, Rothmayr 2006: 611 ff.).

7.2.8 Science-Society Relations

What is the role of scientific experts in this policy field?

Scientist tried to promote their cause successfully in the “Gene-Protection-Initiative” (Bonfadelli et al. 2002) and less successfully in the “Beobachter Initiative” which led to a restrictive regulation of assisted reproductive technologies (ART, Rothmayr 2006: 611). They even made a protest march against the “Gene-protection-Initiative” in 1998 (Bonfadelli et al. 2002: 115).

7.2.9 Direct Democracy

Were there attempts to use instruments of direct democracy in the policy field (e.g. petitions on GMO, BSE)?

Policy development was heavily influenced by subsequent peoples’ initiatives on the issue of biotechnology (see above).

7.2.10 Constitutional Division of territorial power

Were some regions more active than others in the policy field (e.g. in the form of funding programmes, regulations?

In the case of ART (Rothmayr 2006: 598, 607) as well as transplantation medicine competencies were first with cantons and were later transferred to the Federation.

7.3 Literature

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7.4 Interviews

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Interview 2: TA-researcher, 16.9.2010

Interview 3: Politician, 20.9.2010

Interview 4: Civil servants, 21.9.2010

Interview 5: TA-researcher, 21.9.2010

Interview 6: xenotransplantation-researcher, 21.9.2010

Interview 7: Ethicist; 22.9.2010

Interview 8: xenotransplantation-researcher, 22.9.2010

Interview 9: TA-researcher, 22.9.2010

Interview 10: xenotransplantation-researcher, 23.9.2010

7.5 Abbreviations

ART	Assisted Reproductive Technology
CIT-PART	Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field
CVP	Christian Democratic People's Party
FDP	Free Democratic Party
FhG-ISI	Fraunhofer Institute for Systems and Innovation Research (Fraunhofer Institute für Systemtechnik und Innovationsforschung)
FOPH	Federal Office for Public Health (Bundesamt für Gesundheit)
PTA	Participative Technology Assessment
SNF	Swiss National Fund
SPS	Social Democratic Party
SVP	Swiss People's Party
TA	Technology Assessment
TP	Transplantation

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