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Citizen participation in decision-making on complex and sensitive issues? Experiences with Xenotransplantation: report of the project "Impact of citizen participation on decision-making in a knowledge Intensive policy field" (CIT-PART)

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Citizen Participation in Decision-Making on Complex and Sensitive Issues? Experiences with Xenotransplantation

Report of the project "Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field" (CIT-PART)

EUROPEAN COMMISSION
European Research Area

SEVENTH FRAMEWORK PROGRAMME

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Citizen Participation in Decision-Making on Complex and Sensitive Issues? Experiences with Xenotransplantation

Report of the project "Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field" (CIT-PART)

A synthesis report written by Erich Griessler, Peter Biegelbauer, Janus Hansen, Anne Loeber

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The views expressed in this publication are the sole responsibility of the authors and do not necessarily reflect the views of the European Commission

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executive summary

Objective of the research

CIT-PART comparatively studied the use and impact of participatory technology assessment (PTA) and expert based technology assessment (TA) in science and technology policy in several EU Member States and organizations such as Austria (AT), Denmark (DK), Great Britain (GB), Italy (IT), Latvia (LV), The Netherlands (NL), Sweden (SE), the European Commission (EC), the OECD, Canada (CA), Switzerland (CH) and The Holy See (VA). From that CIT-PART drew conclusions about the use and potential impact of institutionalised citizen participation at the EU level.

In contrast to existing comparative studies on PTA, CIT-PART compared the use and impact of TA and PTA in the context of the same technology.
The main questions were:

- To what extent was TA and PTA used?
- Which factors facilitated and constrained PTA?
- What was the impact of TA and PTA on policy-making?
- How can PTA increase citizen participation on decision-making?

CIT-PART studied these questions by taking xenotransplantation policies in the 1990s and early 2000s as an example. Xenotransplantation involves the transplantation of cells, tissues and organs from animals to humans. It is representative of many contemporary technologies in the sense that it is a complex problem, possibly with huge potential benefits, on the one hand, but also risks and ethical challenges on the other. It is therefore potentially controversial in public.

Scientific approach/methodology

CIT-PART included three phases:

1. Mapping the field including (a) analysis of democracy theory in order to obtain models and instruments of democratic participation, (b) overview on policies on xenotransplantation and the procedures upon which they were based as well as on public attitudes towards xenotransplantation, (c) classification of xenotransplantation policies.
2. Case studies. In-depth case studies of xenotransplantation policies, as well as the use of TA and PTA therein, of selected countries and international organisations.
3. Comparative Analysis.

In addition to wide-ranging analysis of literature and policy-documents, 135 in-depth interviews were carried out at the national and international level with policy-makers, experts, stakeholders and representatives of NGOs involved in TA and PTA.

New knowledge and/or European added value

CIT-PART provides an overview of the use and impact of expert advice and formal citizen participation (PTA) in xenotransplantation policies in the selected countries and organizations. Moreover, it provides examples of good practices of PTA and factors, which facilitated and constrained its use in science and technology policy.

Key messages for policy-makers, businesses, trade unions and civil society actors

One of the most important issues highlighted by CIT-PART is that citizen participation, in terms of PTA, was rarely used in xenotransplantation policy-making. Civil servants and experts were the actors most heavily involved in policy development. They framed xenotransplantation primarily as a technical and scientific problem. The public, on the other hand, was only actively involved to a small degree. Although the three cases of PTA (CA, CH, and NL) did not have a direct impact on decision-making in the strictest sense, they did affect the way that the topic was discussed and handled.

In the future, PTA should be strengthened, particularly in expert advisory bodies at the international level, since these are also pivotal for national policy-making. Narrow scientific framing as well as decision-making by closed and impermeable groups formed out of civil service personnel and experts are major obstacles for PTA.

Key findings

Diversity of policies

In the early 2000s, a diversity of xenotransplantation policies existed across Europe. They ranged from a wait and see position, in which no particular policies were formulated (AT), to permissive ones, which allowed clinical trials following approval by responsible authorities (EC, IT, LV, OECD, CH, GB, VA), to formal and informal moratoria on clinical trials (CA, DK, NL, SE).

Expert advice dominates

Expert TA dominated policy advice on xenotransplantation policies. Only a small minority of governments commissioned PTA to involve the public (CA, CH, NL). In some cases, academics initiated participatory exercises (AT, EC, and GB). These had no direct impact on decision-making in xenotransplantation policies.

Experts and civil servants are critical actors

In almost all of our cases, civil servants and experts were "the" critical actors in policy development. Elected politicians only contributed to policy making in a few countries (CA, CH, DK, NL, SE). Despite the fact that reports repeatedly mentioned ethical issues as critical, ethicists – either in the form of national ethics committees or single experts involved in TA and PTA – played a lesser role and only became strongly involved in a few cases (CA, SE, UK and VA). NGOs also became involved in only a few countries (GB, CA, CH and NL). Particularly animal welfare organisations faced difficulties to participate. In some cases, there was almost no public involvement beyond information being made public (AT, IT, LV, VA, OECD). By contrast, industry and science were able to considerably contribute as stakeholders to policy development. Citizens only became actively involved in xenotransplantation policies in a minority of countries (CA, CH and NL).

Diversity of framing, but organ shortage and risk often dominate

First, xenotransplantation was not a controversial topic or the subject of hot debate in all cases.

- In two countries there was no debate at all (AT, LV).
- In most cases xenotransplantation did not give rise to serious conflicts and was handled as "business as usual" (DK, EC, IT, OECD, SE, VA).
- In two countries a situation of managed tension arose (NL, CH).
- However, in Canada and Great Britain, xenotransplantation was discussed in the context of a serious crisis of trust in government regulation.

Second, framing of xenotransplantation as a topic was contingent on and varied between cases.

- In most countries the topics of organ shortage and risk dominated the discussion.
- In some cases xenotransplantation was discussed in the context of national economic competitiveness (CH, EC, GB, LV, OECD, and SE).
- Less frequently ethical issues (CA, CH, SE, and VA) and animal welfare (CH, EC, NL, and VA) were critical and they became significant topics only in a few cases.
- In two cases trust in government (CA, GB) became critical.
- In one country xenotransplantation gave rise to struggles for competencies between parliament and government (NL).

Weak role of the public

The public was mostly involved in the weakest possible form, i.e. through surveys (in all cases except CH, LV, OECD, and VA). Additionally, with the exception of Austria, almost all countries informed the public in one way or another. This was done to varying degrees, ranging from full-blown information campaigns (CA, CH, NL, SE) to simply publishing reports online (EC, DK, IT, OECD, VA). In a few cases the public was consulted. The intensity of consultation varied and was found to be very strong in some cases (CA, CH, GB, SE), strong in others (SE), or rather weak (EC, OECD). Again, the public was only involved in PTA exercises in CA, CH and NL.

Little direct but broader impact of PTA

Although policy-makers approved in all the cases in which PTA was carried out of both the PTA itself and its results, no unambiguous direct impact of these exercises could be established.

- In the Netherlands, the results of the PTA were available only after xenotransplantation policies were adopted and the organizers of the PTA did not have concrete plans for feeding them into policy-making. As it turned out, PTA results and official xenotransplantation policies were congruent.
- The same was true for Switzerland, where there was again an agreement between PTA results and government policies, which were determined before the end of the participatory exercise.
- In the Canadian case, it was hard to pinpoint a direct impact of the consultation exercise because the government did not make an official statement on its xenotransplantation policies and, in accordance with the public consultations' opinion; thereafter no clinical trials were carried out.

However, adopting a perspective on impact assessment that goes beyond the mere handing over of a final report, all three PTAs had an impact on the development of xenotransplantation regulation. The PTAs contributed to creating public awareness of the issue and to a (re)configuration of the relationship between relevant actor groups. PTAs also played a part in the definition of xenotransplantation as an issue by legitimizing and giving authority to claims made by actors and regulatory procedures. In all three cases, PTA exercises were by and large considered legitimate and meaningful ways to gain knowledge and to involve the public in a debate about science and technology policy.

Varied impact of TA as well

Difficulties in the integration of findings from assessment studies into policy-making are not restricted to PTA. Expert TA also faced difficulties in directly impacting the regulation process. While in three of our cases, expert TA exercises had a strong impact on policy-making (DK, GB, and OECD); in another two cases direct impact was weaker or at best 'mixed' (EC, VA). However, in three cases there was no direct impact on policy-making at all (IT, LV, SE). Important factors that co-determined a study's impact were:

- The kind of institution in which an advisory body is located;
- Its mandate as advisory or regulatory body;
- The extent to which its connection to policy-making was institutionalised, and
- Its reputation as a competent and independent organisation.
- Moreover, the technical development of the policy issue and its framing in political and broader public debate played a role.

Factors facilitating PTA

- Existing traditions that PTA can build on, i.e. commissions involving participatory elements, adult education, direct democracy, consultation;
- Existing practices of accountability and openness;
- Coordination with responsible policy-making authorities and departments;
- Combinations of various methods (e.g., surveys, emails, plays, consensus conferences);
- Involvement of the wider social and political context in the organisation of PTA and dissemination of its results;
- Involvement of antagonistic groups in the PTA.

Factors constraining PTA

- When a topic is not perceived as political at all because it is only framed as a scientific issue excluding questions of collective risk, ethics, human rights, politics and economics or is considered as a matter of individual choice only;
- Case-by-case decision-making on individual clinical trials, which undermine an understanding of xenotransplantation as a fundamentally political issue;
- When the public does not consider itself to be a legitimate actor vis-à-vis policy-makers and experts;
- Traditions of paternalism, neo-corporatism and a strong and exclusive links between elites from science and the civil service that exclude the public;
- Lack of infrastructure and funding.

Recommendations

Use of PTA should be increased

PTA was only carried out to regulate xenotransplantation in a minority of cases and had little direct impact on regulation. However, when assessed in terms of the process-oriented impact assessment framework developed in the CIT-PART project, PTA can be considered a success, given its numerous positive effects in creating and stimulating public debate.

The use of PTA should therefore be increased at the national level in general but in international expert bodies and at the EU level in particular, where discussions of technologies tend to be purely framed in terms of "sound science". This poses new challenges for international organizations of ensuring a broader framing of issues.

Citizen involvement should be at the heart of framing

Expert bodies are advised to increase awareness of how their work may impact on the way that an issue is framed in national and international policy-making processes. In addition to the many mechanisms that increase accountability, the encouragement to include citizens in processes of analysis, judgement and even decision-making should be more than just an appendix to the recommendations. Only if the idea of civic engagement is at the heart of a body's framing of the issue may it further help public involvement on a countrywide level.

Broad framing should be allowed for

Expert advice should allow for a broad framing that not only considers "sound science" but also allows for social, political, economic and ethical questions to be raised by stakeholders and the public.

PTA needs an addressee in policy-making

PTAs should be integrated into organisational practices of formal policy bodies to ensure that they can have an impact and that their outcome is acknowledged in decision-making arenas.

PTA should be embedded in institutions to allow for learning

Institutional learning should be embedded in such organisational practices. Most topics in science and technology policy present issues that cut across institutional borders. Specialisation in departments, however, might reinforce departmental fragmentation and struggles. PTA, as social innovation, must work against organisational fragmentation by involving all responsible authorities, agencies and departments in order to increase the impact of PTA later on.

Existing participatory traditions and practices should be built on

In a number of cases, case studies revealed existing participatory traditions and practices (commissions, adult education, direct democracy, consultation, practices of accountability). PTA can build on and learn from these existing traditions.

International examples to identify and overcome factors constraining PTA can provide valuable lessons

Closeness of policy-making, closely knit policy communities, paternalism, expert orientation, and lack of accountability, transparency and openness, lack of open public debate and of an active mass media might represent severe obstacles for PTA. However, there are a number of international examples that worked to overcome these obstacles. It is possible to learn from and even to improve on these existing examples. Solutions to overcoming obstacles were also found to exist in TA; these were related to critical components such as transparency, openness, accountability, embedding, diversity of methods, involvement of antagonistic groups, overcoming the division between the different cultures of science, opening of framing, improving timing, and enhancing direct impact.

Impact should be planned

Direct impact on policy-making and impact on the public debate in a broader sense has to be planned and actively attended to.

Allow for time

Several cases showed that regulators felt a certain urgency to arrive at policies, which was produced by promises by xenotransplantation researchers that clinical trials were imminent. However, predictions that clinical application was 'just around the corner' turned out to be unrealistic. Participatory experiments need time. Policy-makers should therefore consider not responding to pressures produced by promises from science and industry too promptly. Policy-makers should instead allow sufficient time to stimulate proper civic engagement in procedures for political judgement on issues such as xenotransplantation, which touch on the very basics of our understanding of public health, medical choice, collective safety and human identity.

CHAPTER 1
INTRODUCTION

Citizens, policy makers and social scientists often call for citizen participation to make policies simultaneously more effective and democratic. This claim has been made vigorously in science and technology policy, as shown by new biotechnologies and nuclear energy for example.

During the past two decades, many countries have therefore witnessed the introduction of Participatory Technology Assessment (PTA) exercises in science and technology policy. In contrast to expert based Technology Assessment (TA), PTAs are procedures where lay citizens systematically discuss the pro- and contra-arguments of certain technologies. While most people would probably agree that such forums of debate have inherent democratic merits and a democratizing potential, important questions remain about their actual impacts on policy-making. Impact could be PTA's Achilles heel for reaping the democratizing potentials of enhanced citizen participation.

The CIT-PART project studied the use and impact of PTA and expert based TA comparatively in several EU Member States (Austria, Denmark, Italy, Latvia, Netherlands, Sweden, the United Kingdom), the European Commission, the OECD, Canada, Switzerland and The Holy See (in this report designatied with the more commonly used name the Vatican), and addressed the following research questions:

- To what extent and in what context were citizen participation exercises applied in the case of xenotransplantation across Europe?
- What were the factors that facilitated or limited citizen participation in complex decision-making processes? And to what extent did cultural differences account for variation across countries in this respect?
- What in actual fact was the impact of PTA as one approach to promote citizen involvement on decision-making processes? In which way were PTA processes more or less effective with regard to their impact on decision-making compared with expert based TA?
- What can we learn about the complex relation between lay-peoples' and experts' views and expertise in TA and PTA?
- How can PTA increase citizens' influence on decision making? What are ways to improve the impact of citizen participation on policy-making on national and EU levels? Did citizen involvement increase the democratic legitimacy of policy decisions?

CIT-PART addressed these questions through analysing the reactions of various political systems to the challenge of xenotransplantation.
Xenotransplantation stands for the transplantation of animal organs, tissues or cells into humans. Xenotransplantation is highly controversial: Its advocates perceive it as a promising technology since it could address the shortage of human transplants, but its opponents insist that it involves many risks, most prominently infection from animals to humans, as well as ethical questions about appropriate human-animal relations and economic priorities in the health care sector.
The CIT-PART project assumes 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-making in which PTA is embedded. Following from this theoretical approach the project applied qualitative methods of empirical research such as in-depth interviews and document analysis.

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Outline of this brochure

Chapter 2 provides an introduction to the topic of technology assessment (TA) and participatory technology assessment (PTA). Chapter 3 briefly explains xenotransplantation and why we considered it an appropriate example through which to study TA and PTA exercises comparatively. Chapter 4 compares xenotransplantation policies and expert as well as citizen involvement. Chapter 5 addresses the question of how to assess the impact of the PTA and TA exercises studied. Chapter 6 puts PTA in the context of different strands of democratic theory, and applies a categorisation developed from there on the cases of xenotransplantation policy-making. Chapter 7 provides an overview on political practises applied TA and PTA. The final chapter comprises a summary of the main outcomes and the conclusions drawn from the CIT-PART project.

Chapter 2
Technology assess-ment and participation

Before taking a closer look at the findings of CIT-PART, let us first consider the two issues that are at the heart of this project: Technology Assessment (TA) and Participatory Technology Assessment (PTA) on the one hand, and xenotransplantation on the other. Let us first address (P)TA: what is it and why it is it worth organising?

Since the 1970s, controversies about the physical risks and social impacts of science and technology have given rise to TA in many countries (Van Eijndhoven/ Van Est 2002; Bröchler et al. 1999). TA as a scientific counselling tool aims at broadening the knowledge base of political decision making through comprehensive analysis of socio economic conditions and of possible social, economic and ecological consequences of new technologies. The underlying rationale is that scientific expertise may improve political decisions. Its proponents initially saw TA as an opportunity to add rationality to policy-making by "speaking truth to power" (Wildavsky 1979).

Proceeding from this assumption, the US Office of Technology Assessment's method inspired by the ideal of objective, unbiased, scientific counselling on policy advice was exemplary for many other TA organisations (Grunwald 1999: 174). Over time, this expert oriented approach drew criticism on both normative and pragmatic grounds (Hansen 2010; Joss/Torgersen 2002: 157):

- Insights into the limited scope of technocratic TA approaches to offer solutions were sobering; so were the findings on the actual impact of TA studies, which did not reach the high levels of expectation placed on them.
- In general, doubts arose more about the assumption implicit in TA that firm scientific knowledge about future developments is obtainable, and that authoritative advice on policy decisions can be given.
- The conviction that technological innovation could solve the problems of industrial society was challenged.
- Research carried out in the field of the 'social studies of science' showed that technology is socially constructed and hence can be influenced at the stage of construction; this inspired all sorts of new varieties of TA aimed at influencing technologists and scientists rather than policy-makers.
- The insights into the socially constructed nature of technology also inspired and enforced a less analytical, more political criticism. The assumed objectiveness of the expert's view was demystified in the context of the rise of social movements in the 1970s, such as: the anti-nuclear movement, the environmental movement, and the second wave of feminism as, so to speak, a bias-in-disguise. 'Objective' expert knowledge was exposed for carrying the mark of the money on its production.

This type of criticism led to a call for a 'democratisation' of knowledge and the ways in which it was applied in the production of artefacts and decisions (Liberatore/Funtowicz 2003). Among the developments this set forth were attempts at a broadening of the basis for decision-making on science and technology. This ambition was at the heart of the methodological innovation in TA to include citizens, laypeople and – later on – patients in assessment schemes. Advocates of PTA typically invoke these lines of argument.

On the one hand, PTA has the advantage of taking into account the knowledge and values of laypeople that are normally factored out of experts' discussions. These concern the definition of problems and issues to be investigated, the inclusion of local knowledge, the identification of chances and risks involved in a given technology, and the elaboration of innovative solutions. Thus, participation is claimed to increase the analytical depth of TA.

On the other hand, the inclusion of affected persons may also improve acceptance of decisions on technology policy (Commission of the European Communities 2001) and help to create arenas where negotiations over competing demands and an elaboration of solutions can take place. PTA procedures are arrangements where not only knowledge, but also legitimacy and trust can be created.
Thus, PTAs are arrangements by which "experts and laypersons, decision makers and affected persons, opponents and advocates, all together try to reach a reasoned decision on whether or not a controversial new technology should be introduced, and if so, how it would have to be regulated" (Bora/van den Daele 1997). Many authors perceive PTA – as with TA as a tool for policy advice, but some see its scope as wider, embracing "decision-making" too (Joss/Durant 1995: 290).

The past fifteen to twenty years have witnessed the development of a wide variety of methods and participatory designs. After years of experimenting with PTAs, the assessment of their impact is now considered a key concern of PTA research (Abels 2007; Loeber et al. 2011).

The CIT-PART project addressed the question of use and impact of TA and PTA from an internationally comparative perspective, focusing on a highly sensitive policy issue. To allow for a comparison of how policy on such an issue is advised and informed, a salient issue was selected that provoked to various degrees decision-making in all countries selected: xenotransplantation.

CHAPTER 3
WHAT IS XENOTRANS-PLANTATION AND WHY DOES IT POSE A PROBLEM FOR POLICY MAKING?

Xenotransplantation is the transplantation of cells, tissues, or organs from one species to another (Council of Europe 2003). It is a medical intervention, the scientific basis and practical application of which are the subject of on-going worldwide research. As with many technological and scientific advances in medicine, xenotransplantation holds the promise to cure diseases, but it also entails risks and ethical problems (Engels 2002; Schicktanz 2002; Sykes et al. 2003).

Xenotransplantation was presented by its advocates as a solution to reduce the shortage of implantable organs, cells and tissues observed in many countries (OECD 1999). Therefore it would, if made available, contribute to saving lives. For that to happen, numerous immunological and physiological obstacles have to be tackled (Beckmann et al. 2000). Among these obstacles is the risk that known or unknown viruses from the so called "source animals" could infect the human recipient and possibly spread to the population at large, thus causing, in the worst case, epidemics of yet unknown diseases (e.g. Butler 1998).

Some of the basic ethical questions connected with xenotransplantation discussed worldwide include:

- Taking into account religious beliefs and/or ethical convictions; is it acceptable to use animals as "sources" of organs, cells, or tissues for human beings?
- Under which conditions is it permissible?
- Would it be tolerable to limit the individual freedom of patients and of their relatives in order to control the risk of infection, e.g. by quarantine, life-long monitoring?
- By whom and in what way could informed consent be given for xenotransplantation?
- What role do arguments based on animal ethics play with respect to the required genetic modification, cloning, breeding and keeping of "source animals"?
- Does xenotransplantation imply a "transgression" over the barrier between species and how is this to be evaluated? What effect would xenotransplantation have on the patients' identities (e.g. Hansson 2011)?
- What are the potential effects of a large-scale implementation of xenotransplantation on public healthcare spending? Is this acceptable, given national and international inequality?

We selected xenotransplantation as a vehicle for studying how and why decision-making on such a salient topic is advised and informed, and the effects of including citizens in such an analytic process, for several reasons:

- Firstly, as mentioned above, xenotransplantation research involves – as many contested modern innovations in science and technology do – questions of risk, uncertainty and ethics.
- Secondly, in the late 1990s and early 2000s many national governments and international organisations had to formulate within a relatively short period of time policies concerning the medical risks and ethical questions posed by xenotransplantation research. Policy makers in different countries and international organisations had to deal with the scientific, social and ethical questions posed by xenotransplantation.
- Thirdly, policy-makers addressed these questions differently with regards to process, as well as content. To support their policies some governments solely involved experts, some also included stakeholders, some tried to represent the interests of the public by including elected politicians, whilst others also asked ordinary citizens. In addition different governments took different policies towards xenotransplantation.

In order to learn from this diversity, as said, we developed a comparative research design including countries in Europe and North America as well as some of the most important international organisations operating in this field.

Thus, in contrast to most impact studies, which centre on the concept of PTA, the CIT-PART project took as a point of departure an ethically sensitive and technically complex technological issue, rather than participatory experimentation per se. Putting the emphasis on substance rather than on procedure as a common

denominator between cases meant that the question about reasons that further facilitate or restrict public engagement could be raised and systematically answered. It implied too that the number of cases, which included elements of PTA or a full PTA, might be low.

CHAPTER 4
TO WHAT EXTENT WAS PARTICIPATORY TECHNOLOGY ASSESSMENT APPLIED IN DECISION-MAKING ON XENOTRANSPLANTATION?

Let us now turn to policy responses to xenotransplantation in our sample of countries and international organisations. Interestingly, in the various countries under study we see a wide variety of policy responses to the issue of xenotransplantation. We will look at the xenotransplantation policies taken, the intensity and framing of public debate, whether TA and PTA were applied, the actors included in policy-making and the way of public involvement.

Xenotransplantation Policies

As Table 1 indicates xenotransplantation policies vary in international perspective.

Table 1: Xenotransplantation Policies in the late 1990s and early 2000

	Wait and see	Permissive	Moratorium
AT	■		
CA			■
CH		■	
DK			■
EC		■	
GB		■	
IT		■	
LV		■	
NL			■
OECD		■	
SE			■
VA		■	

Xenotransplantation policies ranged from a wait and see position in which no particular xenotransplantation policies were formulated (Austria) to permissive policies, which allow in principle clinical trials after approval by responsible authorities (European Commission, Italy, Latvia, OECD, Switzerland, the UK) to moratoria on clinical trials (Canada, Denmark, Netherlands, Sweden).* Moreover, there is also divergence between the countries which opted for a moratorium on clinical trials, with regards to its binding character. Only in the Netherlands did Parliament actually pass a ***de jure*** a moratorium (Versteeg/Loeber 2011). All the other countries decided for a ***de facto*** moratorium. The Canadian government did not make a declaration concerning its proposed xenotransplantation policy after a PTA was carried that resulted in a call for a moratorium, when no clinical trials were carried out either before or thereafter (Einsiedel et al. 2011). In Denmark it was decided that clinical trials need authorisation by the central national bioethics committee (Hansen 2011), and Swedish xenotransplantation researchers voluntarily decided to stop clinical trials (Hansson/Lundin 2011).

Intensity of Debates

How to understand the difference? A working hypothesis of the project was that the policies adapted on xenotransplantation were likely to be affected by the intensity of public attention to the xenotransplantation topic. Applying a distinction used by Joly and Assouline the intensity of public debate can be categorized as "no debate on the issue at all, in any arena", "business as usual", a "managed tension situation", and "crisis". Whilst the meaning of "no debate" is abundantly clear, the other three categories are less straightforward and need some clarification. In the case of "business as usual", the "debate is confined within a small number of specialised arenas, for instance the scientific and legal ones (...). The network of government bodies in charge of the problem and a few stakeholders involved is stable and the definition of the issue ... is not controversial". The debate in a "managed tension situation" by contrast, "involves a greater number of arenas and a greater interaction between" them.

* The OECD and the Vatican have no regulatory power but recommended permissive policies.

There are "intense controversies on the definition of the problem and solutions". The situation of "crisis" takes conflict and uncertainty even further: "The controversy on the specific issue is globalised and may become a serious problem for existing institutions. In terms of political process, actors of the social mobilisation may become as influential as the traditional stakeholders" (Joly/Assouline 2001: 25).

Applying these categories to our cases, Table 2 shows that there was also variation with regard to the intensity of debate across our countries and international organisations: xenotransplantation was not always controversial and hotly debated. Whereas in Austria and Latvia there was no debate at all, xenotransplantation was discussed in most countries and international organisations in our sample in a "business as usual" manner, and did not give rise to severe conflicts. In Denmark , the EC, Italy, OECD, Sweden and Vatican typical, country- or organisation-specific institutional arrangements were used to arrive at xenotransplantation policies. In the Netherlands and Switzerland, it could be argued that a situation of managed tension arose. In Canada and the UK, xenotransplantation policies became connected to previous or current scandals in biotechnology, food or health policies, and were therefore discussed in the context of a serious crisis of trust in government regulation.

Table 2: Intensity of Public Debate about Xenotransplantation

	No debate	Business as usual	Managed tension situation	Crisis
AT	■			
CA				■
CH			■	
DK		■		
EC		■		
GB				■
IT		■		

	No debate	Business as usual	Managed tension situation	Crisis
LV	■			
NL			■	
OECD		■		
SE		■		
VA		■		

(adapted from Joly/Assouline 2001: 25; own research)

Framing

It is not just the intensity and level of controversy of public debate which plays a role in understanding the dynamics of the policy arenas. Equally important we found, is the focus of public debate on how the issue of xenotransplantation was problematized or 'framed'. This process of framing, which also changed over time, varied considerably across our cases, and closely related to existing public debates about novel biotechnologies and the wider cultural context of the countries (Table 3). In the following we will discuss the frames most frequently used.

Unsurprisingly, to assuage organ shortage was a dominant framing in almost all countries and international organisations studied in the CIT-PART project. No less expectedly, the risks of xenotransplantation, mainly of cross-species infection, were another dominant frame in almost all cases of debate.
Several countries and international organisations framed xenotransplantation in terms of economics, either by discussing its consequences on healthcare expenditures, but mainly as a means to boost the country's economic competitiveness. This was particularly important in Sweden (which hosted substantial xenotransplantaion research), Switzerland (which has a large pharmaceutical sector), the European Commission (which for a while perceived xenotransplantation as economically promising), the OECD and the UK (whose government policy rated biotechnology as one of the main and promising sectors for economic growth).

The ethics of xenotransplantation became a topic of discussion only in a few countries. TA and PTA in Switzerland gave much thought to questions of ethics, as, expectedly, was also the case at the Pontifical Academy of Life (Vatican). But the ethics of xenotransplantation were also an important frame in Sweden, as can be seen from the involvement of ethicists in a parliamentary commission (Hansson/Lundin 2011) and in the UK. The latter was particularly influential in international policy development because it was the first country that regulated xenotransplantation.

Animal welfare, though a subcategory of ethics, was also used as a frame in several cases. But there was an obvious division between the cases. In many countries the use of animals for xenotransplantation was mostly considered unproblematic given the already accepted practice of industrial meat production (e.g. Denmark, Italy and the Vatican). However, in several countries animal welfare issues become topical in one way or the other. In the EC the issue of experimenting with non-human primates was raised; in the Netherlands animal welfare issues converged on the question of genetic modification of animals, and the Vatican's Pontifical Academy of Life discussed animal welfare issues at some length.

Table 3: Framing of xenotransplantation in the late 1990s and early 2000s

	Organ shortage	Risk	Technical Challenges	Progress in Science and Technology			Competi-tiveness and Economics	Ethics	Animal Welfare	Trust in Govern-ment	Struggle for compe-tencies
AT		■				AT					
CA	■	■				CA		■		■	
CH	■	■				CH	■	■	■		
DK	■	■	■	■		DK					
EC	■	■				EC	■		■		
GB	■	■				GB	■			■	
IT	■	■	■			IT					
LV		■				LV	■				
NL	■	■				NL			■		■
OECD	■	■	■			OECD	■				
SE	■	■		■		SE	■	■			
VA	■	■	■			VA		■	■		

It is interesting to note that animal welfare organisations in almost all countries, including those which set up participatory arrangements, found entry into the debate difficult (see Box 1). The difficulties mainly resulted from the animal organisations' challenge to the dominant framing of xenotransplantation as a benign economic and medical option. Their failing attempts to be taken seriously as a dialogue partner illuminate the restrictions in the openness of the public debate that some countries organised. The Dutch case is exemplary in this respect.

Box 1 Involvement of Animal Welfare Organisations

The involvement of animal welfare organisations, known to be very critical of xenotransplantation, was largely considered to be a delicate and difficult issue. Within our cases there was great variation in how animal welfare organisations were treated in TA and PTA arrangements.

First, in one group of countries animal activists were simply not present. This is true for Austria, where animal welfare organisations did not engage in a debate due to a lack of resources. In Italy animal welfare organisations had little say in the public debate, apart from a post-card campaign of Nobel laureate Dario Fo against xenotransplantation. The OECD included one animal welfare organisation only as listener at one of her conferences. The opposite was true in Denmark, where animal protection organisations did not engage in the xenotransplantation debate because there were, according to an interviewee, "plenty of other, more pressing animal welfare issues" which did not involve such "complex problems pertaining to the welfare of human beings" (Hansen 2011: 24).

In another group of countries animal welfare organisations were deliberately excluded from the TA, which in some cases caused problems later on.

At the Pontifical Academy of Life animal welfare organisations (as well as patient organisations) did not have a seat in the working group, and later critique by the British group "Catholic Concern for Animals" had little impact in the Academy. In Sweden the animal welfare organisations neither succeeded in presenting their views in the media, nor did they have a seat in the parliamentary commission. They criticized the organisers for not recognising them as legitimate peers in this commission, but rather treating them as stakeholders of an interest group who were invited to a meeting once. The commission considered that animal rights should be appropriately represented by an expert in agricultural science, a claim which animal rights activists contested.

Several British animal welfare organisations voiced immense opposition against xenotransplantation. However, they were excluded from the formal policy process. In a bottom-up attempt to shape the xenotransplantation policy process they submitted reports to United Kingdom Xenotranplantation Interim Regulatory Authority (UKXIRA) commissioned surveys on peoples' attitudes towards xenotransplantation, organised post-card campaigns, petitioned Members of Parliament, attended UKXIRA public meetings, and published leaked confidential data about industry's xenotransplantation research, claiming that industry had failed to make technical progress towards clinical xenotransplantation, and that its research had subjected non-human primates to severe suffering (Diaries of Despair). The influence of these activities on British xenotransplantation policies is contested. Animal activists claimed that the leaked data in particular contributed to the collapse in expectations amongst the UK policy community concerning the future of xenotransplantation, and led to the subsequent disbanding of the UKXIRA. In contrast, some regulators depicted "Uncaged Campaigns", who published this report, as a group of 'extremists' whose submissions could not be taken seriously by a regulatory body (Brown/Beynon-Jones 2011: 29, 36 ff.).

At EC level the involvement of animal rights activists was limited and caused conflicts later on. In November 2008 the Scientific Committee on Health and Environmental Risks (SCHER) organised a public hearing on the use of non-human primates in research. The European Coalition on the End of Animal Experiments (ECEAE), who participated in both the consultation and the hearing, contested SCHER's Opinion. They forwarded a complaint with the Ombudsman of the EU, claiming that the working group did not have enough expertise in the area of non-human primates research and did not take into account the latest scientific evidence and statements made by interest groups on alternatives to non-human primate research. ECEAE challenged the Opinion using scientific arguments, contesting how adequate and comprehensive the

Committee's scientific evidence was (Griessler et al. 2012a).
The involvement of animal welfare organisations was much more intense yet equally delicate in countries with PTA exercises. In Switzerland, civil societies' activities in regards to xenotransplantation contributed and were connected to the legislative process. The Non-governmental organisation (NGO) Basel Appeal was very active in raising and debating the issue of xenotransplantation. It produced an extensive information brochure, collected 6,500 signatures demanding a moratorium on xenotransplantation, contributed to the consultation procedure for the relevant laws, gave interviews to the press, and participated as an invited expert in the PubliForum. Basel Forum also had connections to Parliament since one of the members of its board was also a member of the Federal Assembly. She initiated an interpellation and a motion for a moratorium on xenotransplantation in 1996 (Griessler 2011:22). Also, in the Netherlands animal rights organisations had an active voice in the debate yet experienced considerable opposition. The views of one organisation were included in an educational leaflet, and the animal rights activists' perspectives on xenotransplantation were presented in a theater play which was performed at schools. The small "Working Group Xenotransplantation Question", however, opposed xenotransplantation fundamentally and criticized it from both an economic and an animal welfare perspective. They engaged as activists and visitors in public meetings and complained that the debate did not provide a space for their alternative discourse. Nevertheless their criticism was mentioned in the final report on the PTA. In Canada the most important animal welfare organisations took a moderate stance towards xenotransplantation, and were also involved in the participatory exercise. A more radical animal welfare organisation had little prominence on the public stage.

Another important framing in some countries concerned trust in government regulation which was severely shaken by previous scandals in blood contamination (Canada, Einsiedel et al. 2011: 13), BSE and GMO food (UK).

In the Netherlands xenotransplantation also became framed in terms of a conflict in the executive-legislative relationship between government and Parliament about the mandate of newly established expert commissions, and questioned whether Parliament or this expert body should decide on clinical xenotransplantation research.

Expert TA and PTA

To what extent were TA and PTA used in different countries and international organisations in xenotransplantation policy-making and to what extent were experts, stakeholders and the public involved in these endeavours?

Table 4: To what extent was TA and PTA used in the case of xenotransplantation?

	Expert TA	Stakeholder PTA	Public PTA	Academic Participatory experiments
AT				■
CA	■	■	■	
CH	■	■	■	
DK	■			
EC	■			■
GB	■	■		■
IT	■			
LV	■			
NL	■		■	
OECD	■			
SE	■			
VA	■			

Table 4 shows that expert TA dominated policy advice on xenotransplantation policies. All but one country based their xenotransplantation policies in some way on experts' advice. However, it must be remembered that the scope and thoroughness of advisory exercises and papers varied considerably between countries, ranging from a two page paper to full-blown and elaborate TA studies. In contrast, only a small minority of governments and international organisations commissioned or supported PTA exercises to involve the public (Canada, Netherlands, and Switzerland). In addition, academics in Austria and the UK initiated and carried out participatory exercises to experiment with citizen participation. Also the European Commission supported such experiments within its Framework Programmes. However, these experiments had little direct impact on decision-making in xenotransplantation policies.

Involvement

A further dimension of our comparison relates to those actors that were active in the policy arenas and who shaped policy responses to the scientific developments in xenotransplantation. In order to analyse this, we designed a classification of different types of actors to map our cases, including civil servants, scientists, ethicists, politicians, stakeholders, NGOs and citizens (see Table 5).

Table 5: Involvement in Xenotransplantation Policy-Making

	Civil Service	Scientists	Ethicists			Politicians	Stakeholder	NGO	Citizens
AT	■				AT				
LV	■				LV				
EC	■	■			EC		▪	▪	
OECD	■	■	▪		OECD				
IT	■	■	▪		IT				
V	▪	■	■		V				
DK	■	■	▪		DK	■	▪		
SE	■	■	■		SE	■	▪	▪	
GB	■	■	■		GB		■	■	
CA	■	■	■		CA	■	■	■	■
CH	■	■	▪		CH	■	■	■	■
NL	■	■	▪		NL	■	■	▪	■

Legend: ■ = very strong role ■ = strong ▪ = weak role □ = very weak

As shown by Table 5, the civil service played a very strong and decisive role in almost all cases. The category of civil service includes not only ministries, but importantly also organisations such as parliamentarian technology assessment units and agencies at government's arm's length. In some cases civil service kept xenotransplantation policies completely within its remit (Austria and Latvia), in other cases civil servants organized the TA process, were involved in discussions of regulation, were regulating (United Kingdom Xenotransplantation Interim Regulatory Authority, UKXIRA), initiated (Canada, Netherlands) or contributed (Switzerland) to the PTA process. At the Holy See the civil servants did initiate the TA, but were not influential in formulating its opinion.

Next to civil servants, scientists were the most important and influential actors in xenotransplantation policies. They were crucially involved in TA and contributed to PTA; in Sweden they initiated the establishment of a parliamentary commission to regulate xenotransplantation. Scientists, together with civil servants, formed the core of an international community of experts and regulators who discussed xenotransplantation policies in different international forums, such as the WHO, the OECD and the Council of Europe.

Ethicists played a less important role and were only heavily involved in a few countries (Canada, Sweden, Vatican and the UK). In other countries they played a less important role or none at all. At EC level, for example, ethical issues were regularly mentioned in reports of competent scientific committees but were never actually addressed in detail (Griessler et al. 2012a).

Politicians, including legislative as well as executive, became involved in xenotransplantation policies in a few countries only. In Denmark, the Netherlands, Sweden and Switzerland, xenotransplantation became a topic of – sometimes passionate parliamentary debate. In Canada, the Netherlands and Switzerland the responsible ministers supported the idea of a PTA.

Stakeholder, involvement , i. e. mainly science and industry, was strong in some countries, such as the UK, Canada, Switzerland and the Netherlands. However, in some countries stakeholders were not at all involved and in others less intensely (Denmark, Sweden). At the EC level stakeholder involvement included the possibility of public hearings which, however, were strictly framed by scientific questions.

NGOs were involved in a few countries only. Particularly animal welfare organisations faced difficulties at times to participate (see Box 1) because groups considered radical often found it difficult to participate (UK, EC), whereas moderate activists became involved (Canada, Netherlands). In some countries animal welfare organisations didn't engage in the topic at all, either because of lack of resources (Austria) or because they considered other topics more important (Denmark). Patient groups also acted strategically and either decided to participate in the debate or not (see Box 2).

Citizens became actively involved in xenotransplantation policies in just a small minority of cases. In Austria, Italy, Latvia, the Vatican and the OECD there was almost no involvement of the public apart from information (see Table 6). However, in Canada, the Netherlands, Switzerland, there were attempts to involve the public more strongly.

Table 5 shows that regulation of xenotransplantation was primarily a business of civil servants and experts. Only in a minority of cases elected politicians became directly involved and only in a few countries also stakeholder organisations and citizens had a chance to contribute to policy development.

Box 2: Involvement of Patients Organisations

Patient groups were often considered important actors and stakeholders in the xenotransplantation debate. Again our sample shows the variation in their involvements:

In one group of countries and organisations, consisting of Austria, Denmark, Italy, Latvia, the EC and the Vatican, patient organisations were either not at all, or only very loosely involved in TA or PTA. At the Pontifical Academy

for Life, patients' organisations (as well as animal welfare activists) were considered difficult to include because they would not be ready for dialogue. Instead, it was assumed that knowledgeable experts would take into account what they considered to be the public's concerns. At the OECD level two patient organisations participated in a workshop about xenotransplantation. One of them, the Islet Foundation, strongly supported xenotransplantation as a potential approach for curing diabetes.

But patient organisations also deliberately decided not to engage in xenotransplantation debates, because they considered other alternatives more promising and important. The Dutch Kidney Foundation considered xenotransplantation to be morally sensitive, and not a preferred solution to the shortage of organs. They chose to focus on other measures to assuage organ shortage, and did not actively contribute to the xenotransplantation debate (Versteeg/Loeber 2011: 46). Also in Denmark "the most likely group of patients to benefit from whole organ XTP – kidney patients – expressed an outspoken dismay for the idea and did not engage in the debate at all " (Hansen 2011: 31). Similarly, in the UK, patient groups have been relatively quiet regarding xenotransplantation. The National Kidney Federation, for example, issued a statement cautiously supporting xenotransplantation providing that alternatives were vigorously pursued. However, patient organisation were much less prominent in the debate than opponents (Brown/Beynon-Jones 2011: 36).

By contrast, in Canada a small patient organisation in favour of advancing islet transplantation was involved in stakeholder consultations, and transplant patients participated as 'experts' in the citizen jury public consultations. In Switzerland the advisory groups to the TA and PTA on xenotransplantation included patient organisation representatives. In Sweden patient organisations supported xenotransplantation and were eager to see this research evolve into a viable medical technology. They were able to act as stakeholders in the early stages of xenotransplantation research because scientists regularly disseminated their newest research results in meetings with patients. Some patient organisations also commented on the report of the parliamentary committee.

Public Involvement

Now let us investigate in what way the public became involved in xenotransplantation policies.

Table 6: How was the Public involved?

	Survey	Information	Consultation	Discussion
AT				
CA				
CH				
DK				
EC				
GB				
IT				
LV				
NL				
OECD				
SE				
VA				

Legend: ■ = very strong role ■ = strong ■ = weak role □ = very weak

Looking at Table 6, the weakest form of public involvement was polling. Surveys were done in almost all countries which were EU Member States in the late 1990s, because two Eurobarometer surveys carried out in these years included questions on xenotransplantation (Allansdottir 2010). In addition to these EU-funded Eurobarometer surveys there were national surveys which addressed the general public and potentially affected patient groups in several countries as part of the xenotransplantation policy process and TA (Canada, Netherland, Sweden and the UK). In Italy polling was part of academic research.

A further step towards public involvement was information for the public. In almost all cases information was provided for the public in one way or another. These efforts were strongest in Canada, the Netherlands, Sweden and Switzerland where governments were proactive in using different approaches to inform the public. However, in some countries information was less comprehensive and only meant putting the outcome of TA on the Internet (European Commission, Italy, OECD and the Vatican). A special case was the UK, where annual meetings of the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) were open to the public, and UKXIRA's annual reports were published. In the case of Latvia information for the public included only the participation in the EU-funded project DECIDE, which resulted in the information of a limited number of students who were involved in this project.

In a minority of cases, i.e. Canada, Netherlands and Switzerland, the general public and/or NGOs were involved by consultation, i.e. they were invited by on-line surveys, letters, etc. to voice their opinion about xenotransplantation policies. In the UK, both the Nuffield Council on Bioethics (1996) as well as the Department of Health (Advisory Group on the Ethics of Xenotransplantation 1997, Kennedy Report) invited stakeholders to comment on xenotransplantation policies for TA. Stakeholders were also consulted in the Swiss TA exercise. In Sweden the parliamentary commission on xenotransplantation listened to NGOs as informants. The EC's Scientific Committee on Health and Environmental Risks (SCHER) provided opportunities for NGOs for consultation, however these were limited to purely scientific questions.

The strongest form of citizen involvement was discussing xenotransplantation policies with citizens in two-way communication. As already said, this course was taken in three countries, Canada, Switzerland and Netherlands, where citizen forums (Canada), a PubliForum (Switzerland), and public discussions after a play (Netherlands) were organized. Also in the EC SCHER provided an opportunity for public discussion, although access was limited, and the debate was narrowly framed by scientific questions.

The CIT-PART project shows that citizens were involved in various ways in TA and PTA, and that a focus on those arrangements that are formally labelled "PTA" hides from view the many ways in which citizens were also involved on an issue such as xenotransplantation.

Chapter 5
Impact

Experimentation with public engagement in policy-making on technological developments went hand in hand with a call for a systematic evaluation of its design and impacts (Abels 2007). A wealth of impact studies have been produced since, many of which were funded by the European Commission. The CIT-PART project can be viewed as part of this tradition. A red thread running through these PTA assessment studies is the attention for the complexity of conceptualising the notion of 'impact', and relating it both to a PTA's design and to its wider (national) context. The CIT-PART project is no exception in that respect. The question of what constitutes 'impact' was a dominant theme in the discussions and working documents produced within the project (Biegelbauer et al. 2010). Reminiscent of Abels' (2007: 105) remark that a conceptualisation of impact requires "a theoretical framework about the functioning of policy-making", in the project we developed a way to assess a PTA's impact drawing on McAdam et al. (2001) 'dynamics of contention' (DOC) theory. This approach, which is positioned as an incipient 'third generation' of impact assessment studies, and its up-shot in terms of the PTAs on xenotransplantation included in the project, will be outlined below. First, the CIT-PART project is positioned in the tradition of (EU-funded) impact assessment studies, in what is dubbed here as several 'generations' of impact assessment.

Impact assessment of PTAs

The best way to assess impact is both a conceptual and a methodological puzzle. Moreover, the two questions are interconnected. The methods for assessing impacts depend on the conceptualisation of what counts as impact. Generally speaking, in the conceptualisation of what constitutes an impact, a dichotomy can be observed.

On the one hand, there are studies that focus exclusively on political decision-making as a locus for identifying impacts, and on changes in such decisions as their manifestation. These, we have argued in the CIT-PART project (Loeber et al. 2011), may be referred to as a 'first generation' of impact studies. Additionally there are assessments that embrace a wider range of loci, such as industry and society writ large, and that take into account other manifestations of impact (such as an increase in media coverage) in their analyses, a so-called 'second generation' of impact studies.

First Generation of Impact Criteria

The first generation of impact studies mainly hinges on two assessment criteria: access to political power and participants' influence vis-à-vis formal political institutions (e.g. Fiorino 1990; Laird 1993; Collins/Evans 2002; Rowe/Frewer 2000). Exemplary of this perspective on impact assessment is Renn et al.'s (1993) approach, which defines a PTA's impact as the "[i]ntegration into the political decision process" of the outcome of the PTA that is drawn up after the participatory event has come to an end" (1993:199). In general, assessment studies organised on the basis of this definition of impact have been particularly critical of the impacts of PTA. The general assessment is that "only a few participatory procedures actually have some empirical impact on political decision-making" (Abels 2007: 110, cf. Joss 1998, Bütschi/Nentwich 2002).

Indeed, when judged in these terms, none of the three PTAs under scrutiny in the CIT-PART project has been influential. In the Swiss case, the PTA's impact in terms of 'first generation' assessment criteria may be considered limited simply because the PTA's final plenary session took place a few days after the Health Ministry sent a bill on the issue to Parliament. The PTA in Switzerland, called PubliForum, was designed after the Danish consensus conference model (Klüver 2002), and involved 28 citizens selected to represent the Swiss population. To ensure a connection with the formal policy process, TA Swiss organized this event together with the Federal Office of Public Health and the Swiss National Science Foundation. Still, impact was limited if understood in terms of Renn et al's 1993 definition, which directs the attention to a PTA's influence after the participatory event has come to an end. Since decisions were made prior to the reception of the PTA's output, strictly speaking no impact can be assigned to it (Griessler 2011).

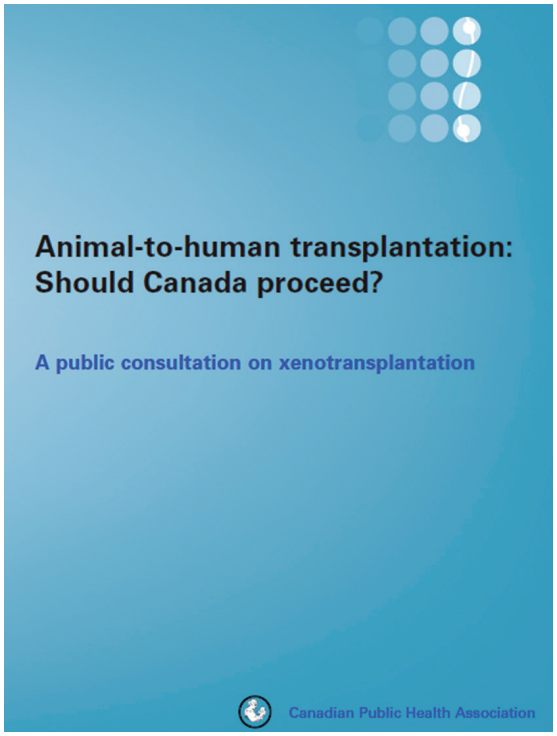
PubliForum Transplantationsmedizin © TA-Swiss

A similar conclusion can be drawn on the Dutch case. In the Netherlands, in 1999, a campaign called "Xenotransplantation, is it and should it be possible?" was initiated by the Ministry of Health. It was initiated on request notably of members of Parliament, who thought the ethical dimensions of the issue warranted the involvement of citizens in the debate and implemented by Consumer and Biotechnology, a small issue organisation. The PTA consisted of an information campaign, followed by a public debate which included various activities, such as surveys, a website, and public discussions. Furthermore, it featured a theatre play dramatizing the discussion on xenotransplantation, which toured schools and other venues, in order to reach a wide, young, audience.

As was the case in Switzerland, timing issues prevent us from assigning any impact to the Dutch PTA in terms of the first generation impact assessment criteria: the public debate started only after parliament had decided for a moratorium and by the time the PTA's final end-report was made public, the Dutch parliament had already decided on a formal ban on xenotransplantation. Judging by this, the PTA came after-the-fact and so cannot be ascribed any formal impact strictly speaking (Versteeg/Loeber 2011).

Invitation to Dutch public consultation kick-off event

In the case of Canada, again impact when assessed in these terms is found to be poor, if not non-existent. In Canada, an extensive design for public consultation and engagement in processes of political will formation on xenotransplantation was developed. The consultation framework consisted of a "representative" model, and an "open" model (see Figure 1, p. 63). These terms were used to reflect the idea of balancing self-selected participation with the ideal of representativeness.



Public Consultation Report © Canadian Public Health Association

In contrast to the Dutch and Swiss cases, Canadian efforts' lack of evidence of impact was not an issue of chronology. Rather, the Canadian PTA's outcome – the decision that Canada should refrain from approving clinical trials of xenotransplantation until critical issues were resolved, and other options to address the critical organ shortage could be explored – failed to have an impact because ever since this verdict the Canadian government has made no definitive statements about xenotransplantation (Einsiedel et al. 2011).

Second and Third Generation of Impact Criteria*

Yet rather than doubting the potentiality of PTAs ever to be effective at all, these CIT-PART findings draw attention to the need to rethink the assumptions underlying this 'first generation' approach to conceptualising impact. This perspective on assessing the impact of citizen participation quintessentially builds on what Warren (2001, 2002) identifies as a "bipolar model" of state-society relations. The bipolar model divides society into two spheres,

a) the sphere of the "coercive, legal, and administrative powers of the state" and
b) the sphere of civil society, dominated by non-state actors and their relations that play out in "norms, cultural habits, discussion, and agreement".

According to Warren, the bipolar model "generalizes by default the idea that the state is the sole agent of power within a society of otherwise voluntary relations" (2001: 43), and obscures the fact that associations of non-state actors, with or without including state-actors "can and often do serve as alternative modes of governance" (2001: 33).

Within the policy sciences the model has been severely criticized for falling short of providing a clear view on the complex networked if not corporatist (e.g. Akkerman et al. 2004) relations between state and society. Likewise, in the field of science and technology studies and TA, authors point out that the 'social map' of deliberation and decision-making on technological development (Vergragt/Jansen, 1993) is far more complex than can be covered with such a dichotomized perspective. Moreover, the process of political decision-making on technology is far too muddled, some argue, to restrict impact assessment to changes in formal policy decisions (Joly/Assouline 2001, Joss/Bellucci 2002, Decker/Ladikas 2004). These reflections have informed what we in the CIT-PART project have dubbed a 'second generation' of impact studies. Rejecting a narrow definition of impact, which restricts the definition of influence of a PTA to the policy-makers' final decision (e.g. a law or other regulation), authors of this generation have developed a "multifaceted view" (Bellucci et al. 2002: 282) on impact assessment. What

* This section draws extensively from Loeber/Griessler/Versteeg 2011.

these studies have in common is that they ignore the traditional distinction between public TA (i.e. TA exercises intended to influence policy-makers) and constructive TA (i.e. TA schemes intended to influence technologists to include societal and user perspectives in their designs; cf. Schot/Rip 1997). Instead they seek to include a wide range of actor groups as potential addressees. Additionally, they broaden the definition of impact so as to include a TA event's 'resonance,' in the words of Hennen (2002: 262), such as its effect on raising awareness, shaping attitudes and initializing (non-state actor's) actions. Thus, this second generation of impact assessment studies emphasizes the need to look at the full plethora of relevant actors when assessing the impact of a PTA, as well as to acknowledge 'softer' impacts such as policy-oriented learning, in addition to concrete policy change (Abels 2010; cf. Jamison 1998; Joly/Assouline 2001; Joss/Bellucci 2002; Decker/Ladikas 2004; Bora/Hausendorf, 2004).

Building on these views on impact, and given the project's focus on the political context of PTA, the CIT-PART project has developed a take on impact assessment which emphasises a PTA's role in providing an additional arena of political contestation. We understand the, often multiple, events comprising a PTA as sites for deliberation on the issue under scrutiny, which are called into being next to other, more permanent arenas for deliberation and contestation, and as such may influence processes of meaning-making and will-formation in their particular contexts. Building on McAdam et al. (2001) "dynamics of contention" (DOC) theory, the CIT-PART project developed an understanding of impact that includes:

1. The extent to which a PTA enables "diffusion": does the PTA provide an opportunity for state and non-state actors to make (aspects of) the issue known to a broader audience that previously wasn't aware of it? The focus on diffusion builds on the contention that it should not be taken for granted that a (policy) issue has a given audience of interested citizens. As various authors have pointed out (Dewey 1991 [1927], Marres, 2006), issues do not form in splendid isolation, nor do their publics: issues and publics presuppose one another. More particularly, in the case of newly developing technologies, such as xenotransplantation, an issue may be taking shape out of sight of potentially interested or otherwise affected citizens. A PTA may well present a first source of information, and may present the very reason for citizens to become involved (rather than being a means to express their prior engagement). To take this into account, the temporal aspects of the staging of the PTA in view of the issue's development require attention, beyond the mere 'one-off' moment of handing over a final report.

2. The extent to which a PTA performs a "brokering" role: did it contribute to connecting previously unconnected social sites or actors and actor groups engaged in will-formation and decision-making on the issue? Understanding the state as a multitude of venues for participation in public conversations and political judgement as opposed to a uniform, bounded political unit with a singular, linear process of will-formation, the question is not only which venues are more decisive in terms of formal political power, but also one of effective accumulation or 'brokerage', connecting actor groups. This is tied up with the extent to which the TA is complementary to existing platforms, for citizens and others (state-actors, experts, civil society organisations etc.) to meet and engage in an exchange of thoughts on an issue.

3. The extent to which a PTA contributes to the "formation of new categories", the drawing or activation of boundaries between existing categories and the development of a 'shared identity' between actors who identified themselves previously in other terms: did the PTA enable a so-called 'issue public' of interested citizens or actor groups to emerge? In social theory on the issue, the emergence of a public, if not considered a 'given', is often assumed to take place spontaneously (Marres, 2006). Yet in the case of a PTA, the parties responsible for designing the PTA events may well have an active role in creating a public as a new category, questioning existing roles and forging a new identity in the light of the issue at stake, and/or shifting the focus of an actor group's attention.

4. The extent to which a PTA serves to (de-) legitimize and (de-) validate actors' claims, that is, in terms of McAdams et al. (2001) to (de)certify claims and their claimants: did the PTA present an opportunity for certain actor groups to strengthen their claim to validity, legitimacy or truth? Attention to this issue opens up a way to assess a PTA's impact in challenging or reinforcing (aspects of) the existing regime and claims on dominance of certain mechanisms and actor groups in handling an issue.

Although this list is by no means exhaustive, it provides a starting point for exploring the various ways a PTA may impact on the policy-field in which political will-formation and judgment on a (newly developing) technology are playing out.

Netherlands

The PTA in the Netherlands was initiated in 1999 by the Ministry of Health, at the request of Members of Parliament, who thought the ethical dimensions of the xenotransplantation issue warranted the involvement of citizens in the debate. The objectives were to stimulate the opinion shaping of the regulation of xenotransplantation and associated issues, and to generate input into that process.

Its impact in terms of the assessment criteria laid out above may be assessed as follows:

Diffusion

The PTA may be considered a success. It succeeded, using a website, free cards and free publicity in the national media to make xenotransplantation known to a wider audience that it was previously unaware of it. In turn, it helped to shape the issue by sparking new publics into being: because of the PTA, one-time anti-biotechnology campaigners established the "Working Group (Xeno-)transplantation Questions". While not too successful at getting its views acknowledged in the PTA, members agree that the TA provided a platform for voicing their views, whilst enabling other actors to express their views in its slipstream.

Theatre performance "Dierbaar Leven" by Science Theatre Pandemonia (original play "Pig in the Middle" by Y touring) © Science Theatre Panedomia

Brokerage

The PTA had a distinct impact. Most notably, an unexpected, temporary coalition emerged between animal welfare organisations, rallying against the genetic modification of donor animals for xenotransplantation, and patient interest groups focusing on xenotransplantation in the context of a shortage of organ

donors. In the first place, both groups were unhappy with the PTA. Patient organisations argued that it addressed 'the wrong issue' (they preferred a discussion about the donor registration system) and feared that talking about xenotransplantation would discourage human donors. The animal welfare organisations, who vehemently opposed xenotransplantation, could not afford to look self-centered, as if they cared only for the interests of animals and not the people dying due to the dearth of organ donors. Subsequently, animal welfare organisations found themselves encouraging their members to register as donors. While this coalition dissolved in the face of subsequent issues, the PTA definitely implied a brokerage between these groups. The resulting alteration in relations between claimants and objects of claims may be understood as an example of an object shift resulting from it.

Category formation

In these terms the PTA had quite an impact. Through its staging a common identity was forged between a diverse set of actors, namely patients and vegetarians. Both were considered to hold privileged positions within the debate, as if they were endowed with an intrinsic right to speak. Yet interestingly, this identity cum right was to a large extent fictitious. The xenotransplantation protagonists and opponents' debate created a discursive identity of these groups, while actual patient organisations were in fact wary of the new technology (see Box 2) and vegetarians did not claim their right to speak (Versteeg/Loeber, 2011). Furthermore, evidence of boundary activation is found in parliamentary proceedings that show how the PTA gave rise to reflections about the primacy of politics and, more particularly, about the appropriate role of parliament vis-à-vis the public and the expertise of scientists.

(De)certification

The PTA was regarded as a satisfactory arrangement by various actors to different degrees, and served, in turn, to lend certain actors relevance and legitimacy. Some doubted the PTA's relevance (notably biotechnologists), and/or its timing. Government actors questioned the representativeness of the PTA. The above mentioned "Working Group (Xeno-) transplantation Questions" wrote its own, critical evaluation of the debate. Yet the debate was certified and considered to be legitimizing by the Minister of Health when she wrote in a letter to Parliament that the results of the debate corresponded with her own views on the subject, and so she used them to defend her policy decision to ban xenotransplantation.

Switzerland

The Swiss PTA was preceded by an expert TA on xenotransplantation, which also had elements of consultation by inviting stakeholders to comment on their view on this medical technology. PTA built upon lessons learned from other PTAs initiated by TA Swiss and in other TA-related organisations. To ensure a connection with the formal policy process, TA Swiss organized this event together with the Ministry and the Swiss National Science Foundation.
Its impact in terms of the criteria laid out here can be assessed as follows:

Diffusion

The PTA was a success. It was one among several instruments used by TA Swiss as a means of examining xenotransplantation, and it also served to spread information about the topic to the public. TA Swiss published the results of their TA studies and presented them to the media and Members of Parliament. PubliForum's results were published, thus helping to make (aspects of) xenotransplantation known to a broader audience, who had previously been unaware of it.

Brokerage

The PTA had an impact in these terms. It helped to make a connection between the actors professionally involved in law-making (Parliament and the responsible ministry), ordinary citizens and several NGOs (Griessler 2011). For the Ministry, the PubliForum was a way of obtaining additional input into the law-making process about what 'the public's' thoughts on transplantation were. This served the Ministry well as it conflicted with some experts over the cautious approach towards transplantation and xenotransplantation that it had developed. Some experts thought that the Ministry might hamper medical progress. Furthermore, it served as a broker by connecting previously separate policy fields (biotechnology and organ donation), and their associated actor groups.

Category formation

PubliForum was one of an assortment of arrangements which contributed to processes of category formation and boundary activation. In the early phases of xenotransplantation regulation, a social democrat Member of Parliament who was also a biotechnology-opposing NGO board member, voiced concerns about infection risks and animal rights in an interpellation in Parliament (Nationalrat 1996). She pleaded for a moratorium on xenotransplantation research. Although her interpellation failed to achieve a majority in its favor, it did lead to the responsible parliamentary committee asking for provisional regulation of xenotransplantation, until such time as a transplantation law could be enacted (Nationalrat 1997). From then onwards, xenotransplantation was predominantly considered to be a public health issue. PubliForum strengthened this framing and contributed to marginalizing animal rights issues further still.

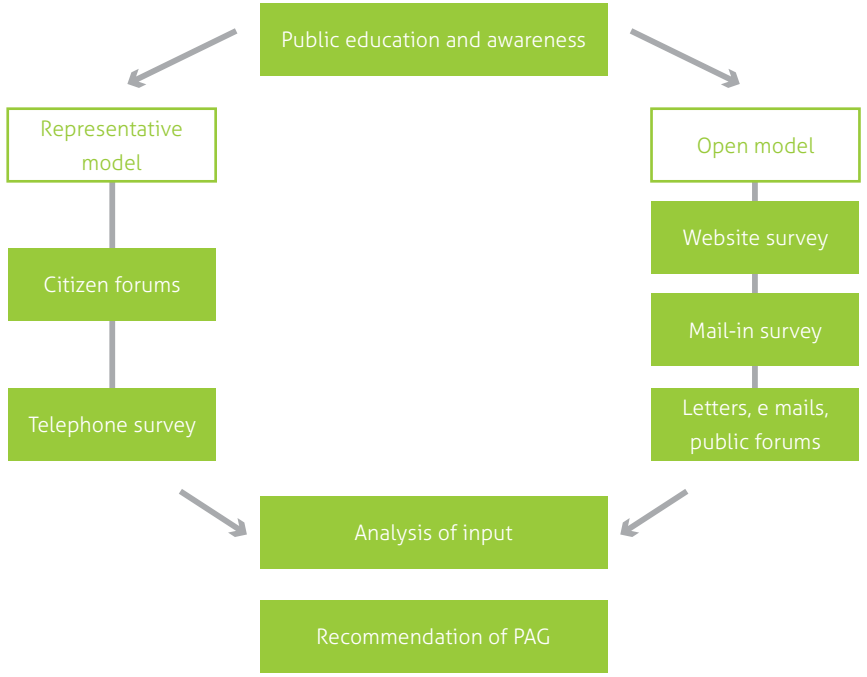
(De)certification

Supported by important stakeholders, PubliForum was considered a valid approach to obtaining the views of 'the public'. The Ministry used the resulting data to defend a cautious approach towards transplantation and xenotransplantation. Like the Dutch case, but with a different result, PubliForum's outcome was in line with the Ministry's view and that of the Federal Assembly: a majority voted against a moratorium.

Canada

The PTA in Canada was initiated by Health Canada and supported by the responsible Minister. It was part of a more comprehensive strategy to acquire information about xenotransplantation, which included expert, stakeholder and public involvement. It was motivated by the need to define Canadian policies in the unchartered area of xenotransplantation, as well as a lack of trust in government regulation at the time, resulting from a previous scandal involving contaminated blood supplies. The carefully planned PTA approach, which, because xenotransplantation was recognized as a cross-cutting issue, was preceded by intradepartmental consultations, included a representative model with citizen forums in different Canadian regions and a telephone survey. Moreover there were activities based on an open model, which provided an opportunity for self-selected participants to voice their opinions on xenotransplantation. This included a website survey, a mail-in survey, letters, e-mails and public forums (see Figure 1). The outcome of the consultation was that "Canada should refrain from approving clinical trials of xenotransplantation until critical issues were resolved, and other options to address the critical organ shortage could be explored" (Einsiedel et al. 2011: 28). So far there have been no clinical xenotransplantation trials in Canada.

Figure 1: Public Engagement Consultation Framework



Source: CPHA Report Animal-to-Human Transplantation: Should Canada Proceed? [2002]

Diffusion

As already described there was more than adequate information provision to the public available in the Canadian case. This included ministry websites on the issue, some media coverage (television, radio and print media) and considerable information provided to the PTA participants.

Brokerage

In the mid-1990s Health Canada, the responsible federal department for health, faced several severe problems regarding xenotransplantation. It considered applications for clinical trials imminent, at which point it would have to respond within a 30-day review period. However, Health Canada at that time lacked the appropriate expertise for such decisions. Moreover a previous scandal involving contaminated blood supplies severely undermined public trust in government regulation. In addition Health Canada recognized that xenotransplantation would not only include technical, but also inherently basic ethical questions. It therefore took an approach which included national and international experts, stakeholders and the Canadian public. The events organized in the course of consultation such as, for example, The National Forum and the Public Engagement Planning Workshop, extolled this approach of bringing together these different groups.

Category formation

PTA participants were able to reframe the issue of xenotransplantation as suggested by Health Canada. The question posed to the PTA participants was very specific: should Canada proceed to clinical trials. The citizen participants considered the xenotransplantation issue to be much broader and discussed issues of health resources, animal welfare, ethics, and alternatives to xenotransplantation, regulatory standards and regulatory preparedness (Einsiedel et al. 2011: 34).

(De)certification

Two evaluations commissioned by Health Canada assessed the design and implementation of the public consultation positively. The citizen forums were considered "as the most valuable method to glean public input, transparency, and the capacity for individuals without professional scientific training to quickly become informed on xenotransplantation" (ibid. 35). There is evidence of institutional learning – expressed in established routines – as a medium- and long-term effect of the public consultation. This includes openness towards actors outside the sanctioned regulatory offices, transparency and accountability in the governance of Canadian health (ibid. 36 ff.).

Conclusion

Of the three cases of formal PTA included in the CIT-PART project, none could be argued to have had an impact on the formal decision-making process in traditional, direct, 'first generation' terms. When assessed in terms of the proposed political process-oriented framework, this image of a total lack of impact shifts towards a more subtle understanding of how the three cases influenced the field in which the policy-making processes took shape.

The use of the framework for impact assessment developed in the CIT-PART project, drawing on McAdam et al.'s (2001) DOC theory, helped us to see that, although the impact of the investigated PTAs was limited in terms of the traditional first generation assessment approach, nevertheless important changes occurred due to a PTA. While a cross-country comparison is inevitably complicated by the incompatibility of the national, political, cultural and institutional contexts in which the PTAs were staged, we can draw several inferences from the data collected in the CIT-PART project.

In the Netherlands and in Switzerland, xenotransplantation did not present a major societal controversy. In fact, the respective PTAs in both countries generated public attention for the issue. The Dutch and the Swiss PTAs each offered a timely occasion and a new space for actor groups that were previously uninvolved or only loosely involved and interconnected, to learn about xenotransplantation, to help frame it in the context of their respective professions, and to relate to one another in previously unexpected coalitions. While the PTAs may have had little 'formal' influence on the decision-making process, judging from the timing of their output, they both provided an opportunity for citizens to become active and presented them with a space where new coalitions could emerge. Furthermore,

at least in the Swiss case, it is clear that the staging of the PTA was a means of developing a consensus on how to regulate xenotransplantation (with caution yet without recourse to a formal moratorium). This consensus developed along with the PTA exercise without its entering the formal process, strictly speaking, as a concrete external input at a specific moment in time. With regard to the Dutch case it is, of course, hard to ascertain whether the effects that were observed would also have occurred without the PTA. This particularly applies to the observed effect on legitimisation and 'boundary activation': the debate gave rise to meta-reflections in parliamentary politics e.g. on the relevance of initiating public debates such as this PTA.

In Canada the promises and unpredictability of, and the insecurity about science, the regulatory challenges posed by xenotransplantation, and a crisis of trust in government regulation resulting from the previous scandal about contaminated blood supplies provided a fertile ground for institutional innovation and learning towards accountability, transparency and openness. Though it is hard to link the outcome of public consultation directly – a call to refrain from clinical trials – to present Canadian xenotransplantation policies – a de facto moratorium – the public consultation scores well in terms of diffusion, brokerage, category formation and (de)certification.

What was the direct impact of TA on policy-making?

Table 7 provides an overview on the direct impact of TA activities in our cases on policy making.

Table 7: Overview on impact of TA exercises on policy-making

	High direct impact	Mixed or little direct impact	No direct impact
AT			
DK			
EC			
GB			
IT			
LV			
OECD			
SE			
VA			

Table 7 shows that TA had a high direct impact in some cases. In Austria no TA was carried out. In Denmark a conference was organized at Copenhagen University and was picked up by concerned politicians from a Christian Democratic party, which in general was sceptical towards modern biotechnology. They initiated a hearing for parliamentarians and questioned the responsible ministers for health and justice. They initiated a debate in Danish Parliament. This resulted in an informal, *de facto* moratorium not by legislation but by instruction from the Ministry of Health to public universities and research hospitals. In addition an expert commission (Genetechnology Commission) was formed, which concluded that apart from this *de facto* moratorium no further regulatory measures were required.

In the UK the TAs had a high impact on national policies because their recommendations became UK policy. In response to the Kennedy report's recommendation, the UK Xenotransplantation Interim Regulatory Authority (UKXIRA) was installed from 1997 to 2006 as a non-departmental expert advisory body which reported to the Secretary of State (Brown/Beynon-Jones 2011: 26). UK TA exercises also had a tremendous impact on an international level because reports by the Nuffield Council and the Department of Health Kennedy Report as the first studies on the ethics of xenotransplantation were repeatedly used in other countries and international organisations as points of reference. UK policy initiatives also had an impact on the formation of EU xenotransplantation policy since it was among the first countries to develop a cautious yet permissive position, and members of UK policy initiatives became expert participants in international policy processes (Brown/Beynon-Jones 2011: 19).

The OECD does not possess strong generalized symbolic media to advance its policies. It is therefore bound to playing the ideas game to promote its policies. Together with the Council of Europe and the WHO, the OECD played an important role in putting xenotransplantation on the international agenda. It assembled key actors, provided an international platform, published documents, co-operated with the WHO to initiate international standards for surveillance and clinical practices, and finally moved the topic to the WHO.

However, there was also a group of cases in which TA had mixed or little Impact. The European Commission mainly used expert TA to get information and advice for its xenotransplantation policies. The impact of TA differed according to advisory body. The Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) raised xenotransplantation on its own initiative without connection to a legislative activity; consequently it only had limited impact on policy-making (Griessler et al. 2012a). In contrast, Borrás et al. (2007) consider the impact of the EMEA/EMA decisions in general to be substantial. The Commission's decision on the use of non-human primates in research was made before the final opinion was adopted by the SCHER. However, the opinion was in line with the Commission's general policy (Griessler et al. 2012a).

The impact of the TA by the Pontifical Academy for Life is assessed ambiguously. Insiders and outsiders of the Church differed in their assessment of the status of the document. Whereas the former qualified the document as not being definitive and as guidance only, the latter considered the status of the text as much more definitive and used it to legitimize xenotransplantation research.

Finally there is a group of cases in which TA had no impact on policy making whatsoever. In Italy the opinions of the National Bioethics Committee (CNB) and the National Committee on Biotechnology and Biosecurity (CNBB) were recommendations to the President of the Council of Ministers. Neither recommendation had any impact on law-making at the parliamentary level. The reasons for that were that: (1) clinical trials of xenotransplantation were stopped due to the self-imposed moratorium of xenotransplantation researchers, which was supported by many Italian researchers, (2) xenotransplantation regulations began to emerge in other countries and on international level, (3) the CNB does not have the power to impose its recommendations, (4) ethics is not a topic the Italian Parliament relishes tackling (Griessler et al. 2012b).

In Sweden the parliamentary committee submitted its report to the Minister of Social Affairs. Thereafter, the report was sent to select reviewing bodies in Sweden. That was as far as the TA got, because around the turn of the millennium, the political and media focus had shifted to stem cells. In addition, the moratorium had been in place for so long by the time the committee finished its report that most of the bigger research groups in Stockholm and Gothenburg had already split. Many of the researchers had moved on to other research fields or other tasks. The report remained with the Ministry of Health and Social Affairs and was not submitted to the Parliament as a bill (Hansson/Lundin 2011: 70).

Box 3: What explains impacts of (P)TAs?

As shown above, the CIT-PART project compiled a series of dense case studies, mapping a lot of the variations of the proper role of PTA in formal and complex terms, assessing how xenotransplantation was responded to in legal decision making. This is a problem in different settings. One ambition of the project was to explore what knowledge might be gleaned from a generalisation of these findings. This required, in the first instance, a systematic way of reducing some of the rich complexities of the material into some relatively concise indicators.

One approach to this included in the CIT-PART project consisted of applying a more formalised approach to analysing causal patterns in qualitative data, known as Qualitative Comparative Analysis (QCA) (Ragin 2000). We used QCA as a first approach to explore if we could detect any generalisable patterns in the policy outcomes across 11 of our cases (for further details see Hansen/ Allansdottir 2011).

To make the question operational, we made a relatively crude distinction between 'restrictive' and 'permissive' policies, where 'restrictive policies' in most cases meant those where a formal or de-facto moratorium was imposed on clinical trials with xenotransplantation, whereas 'permissive policies' meant that research and innovation was actively encouraged (or in some cases that no policies were adopted at all, making it 'permissive' by definition). We looked at a series of factors including: 1) the presence or absence of PTA in the context, 2) the level of involvement of politicians, 3) the level of public attention to the issue, 4) the presence or absence of business interests in the context, and 5) the history of biotech regulation (i.e. whether any regulatory failures or scandals in other fields impacted on the discussions about xenotransplantation).

Our analysis showed that across 11 of our cases we could not establish any general links between the presence or absence of PTA events and the policy outcomes. PTAs were applied both in cases with a restrictive and a permissive outcome. Instead our data indicated that the combination of involvement of politicians and public attention and the absence of business interests correlated restrictive policies, whereas the inversion of those factors (absence of involvement by politicians, absence of public attention and presence of business interests) were correlated with permissive policies.

From these results it cannot be concluded that there are no effects of (P)TAs on policy making or specific policy outcomes, but only that those effects are likely to be more subtle and indirect than the relatively crude measures in our initial formalised exploration allowed us to examine. Hence, in the next step it was important to delve deeper into the individual cases and apply some more sensitive measures of impact, which also allowed us to analyse the more intermediate effects of such procedures and events.

Our cases also show that the direct impact of TA on policy making is not a matter of course. It is dependent among other things: (1) the placement of the advisory body (internal, arm's length, external); (2) it's connection to policy-making (3); it's reputation (unchallenged or contested); (4) it's mandate (advisory or regulatory); and (5) the development of the issue to be regulated (in the case of xenotransplantation the science turned out be much more difficult and risky than previously assumed and stem cells appeared as alternative research field); and (6) the framing in political and broader public debate.

As we have observed, the public was engaged in the countries and organsiations under scrutiny in various ways. While only in three countries this involvement was organised in arrangements that may be formally labelled PTA, citizen and stakeholder engagement – though sometimes only in terms of information – was observable in many cases. Having observed in detail the level of public engagement, the question arises how to assess these developments and efforts in terms of democratic theory.

Chapter 6
How Democratic Were the Regulatory Processes?

The questions at the focus of our attention in the following are:

- How democratic were the attempts to regulate xenotransplantation?
- How did PTAs fare in this respect in comparison with TAs?
- What explains the differences between the different cases regarding usage of instruments and approaches to democracy?

In order to answer these questions we must first turn to democratic theory in order then to build indicators for the evaluation of TAs and PTAs. Next we analyse the differences between the cases in a case-by-case comparison in order finally to reach an explanation of the variation between the cases.

Development of major strands of democratic theory

A number of models of democracy are relevant for evaluating the regulation of xenotransplantation (Biegelbauer et al. 2010). Some of these are more confined to theoretical thinking, whilst others are directly linked to empirical research.

In contrast to a large part of classic democratic theory with its often deeply philosophical reasoning, optimistic and also idealistic outlook on the world (e.g. John Locke, J.S. Mills) 20th century elite democratic theories are based less on normative idealisations, than on the discussion and indeed critique of actual politics. Max Weber is often seen as the forerunner of elitist democratic theory. He is pessimistic about the effects of the rise of large organisations and bureaucracies on political life and sees the role of democracy in curbing the excesses of the rising political system (Weber 1985). He affirms a trend of "elected dictatorship" in a "plebiscitarian leadership democracy", equalising elections with plebiscites (Held 2006: 141). Joseph Schumpeter owes a lot of his ideas on democracy as formulated in "Capitalism, Socialism and Democracy" (1975, originatl 1942) to Weber and sees modern democracy as a set of institutional arrangements with the goal of generating leadership and producing legislative and executive decisions (Held 2006: 142).

In 1961 Robert Dahl published his study "Who Governs?" in which he empirically analysed the political structures of New Haven, a town in Connecticut, USA. The study serves as the empirical basis for his variant of pluralism, from then on the most influential example of pluralist democratic theories (also liberal democratic theory; compare with Goodwin 1997). Dahl developed his theory further over the following decades (Dahl 1998, 2003). He contends that a considerable number of groups take part and indeed make up US politics, with all of them getting (if not necessarily equal) access to policy-making. Thus, pluralist democratic theory, in contrast to elite democratic theories, advances that policy-making in liberal democracies is determined by a large number of groups, which effectively mirror the interests of society through the interplay of the different interest groups and organisations.

Pluralist democratic theory has been created to understand US politics and has been charged with being US-centric and indeed with idealising the political system of the USA (Goodwin 1997, Crouch 2004). Nevertheless it is the dominant account of modern democracies, providing a flexible framework for the understanding of contemporary democratic regimes (Laird 1993). Pluralist theories are linked with representative democracy, granting elected political representatives, who can look after the common good; a stabilising function for the political system (compare with Abels/Bora 2004).

Conceptions of direct democracy, in which citizens have a more direct access to decision-making through instruments such as, for instance, plebiscites and popular initiatives, are at the heart of participatory democratic theories, which came out of the new social movements of the 1960s and 70s (Goodwin 1997: 299). David Held notes that the term "participatory democracy" was until the early 1990s the "leading counter-model" of the New Left to the notion of a legal democracy as forwarded by the New Right, which was based largely on the vision of Friedrich Hayek of a minimal state tightly controlled by a civil society through the means of legal instruments (Held 2006: 209). Proponents of participatory democratic theory criticise currently existing representative democracies for

offering only very limited possibilities of participation to individuals, which ultimately leads to disappointed citizens in the increasingly depoliticised public. In order to counter this problematique a societal transformation is suggested, in which citizens should get more possibilities to participate in politics (Abels/ Bora 2004: 26). Democratic procedures, participatory democracy theorists insist, should not be restricted to politics in its more narrow and legal sense, but also extended to other key institutions of society, such as the workplace, and also decision-making at the local level, through which citizens can take control over the course of everyday life.

Representative democracy is also criticised by deliberative democratic theories, which originated in the 1980s and continue to raise interest. Instead of the width and the mechanics and institutionalisation of participation, deliberative democratic theories stress the importance of the quality of political debate. They attack one of the central tenets of pluralist democratic theory: that democratic politics are primarily an expression of private views and interests (Goodwin 1997: 300). The focus of a deliberative democratic process then is on the way in which different political actors learn from each other's points of view and, through a process of considerate deliberation of the different positions, arrive at a better understanding of the problems at hand (Held 2006: 233). Many contributions to deliberative democracy are based on the work of Jürgen Habermas (Webler/ Tuler 2000, Held 2006, McLaverty/Halpin 2008) in which different modes of decision-making are discerned: on the one hand bargaining is associated with instrumental rationality, a logic in which actors try to defeat opposing views and to "win" an argument. On the other hand deliberation is based on communicative rationality, in which actors stay open-minded, try to listen to opposing views, and are ready to change their own standpoint. In order to have a meaningful deliberation an "ideal speech situation" has to be striven for, free of coercion and power relations (Hansen 2005).

These conditions have been deemed unrealistic, because power differentials, differing rhetorical abilities of discourse participants and other problems are likely to arise in an actual case of deliberation (Abels/Bora 2004: 29). Amy Gutmann and Dennis Thompson argue that for a deliberative practice the concentration on the establishment of highly complex framework conditions and abstract sets of rules are less important than a concentration on more realistic, if non-ideal, situations (see Held 2006, 241). Their argument is that self-interested actors cannot be turned into altruistic persons, and that the most difficult real-world political problems to solve rest on what have been called intractable arguments (Pellizzoni 2003; Hansen 2005, 2006) or wicked problems (Roberts 2004). In these cases, conflicting interests are based on worldviews and rest on norms and values, which differ fundamentally and are therefore incommensurable. Conflicts on moral grounds might not be resolved, but mutually acceptable reasons should be sought before deciding on a course of action - and if that is not possible, a position of accommodation should be found that is consistent with mutual respect. A majority vote should only be taken when all discursive efforts have failed (Held 2006: 243).

Leaving aside the differences between the various strands of the respective democratic theories, a number of important differences emerge by way of comparison of a pluralist/liberal representative and a participatory/deliberative direct democracy model. The most striking difference is that the most active role in the representative democracy model is that of the politician, whereas citizens have a more passive role - in the direct democracy model this dynamic reverses (see Table 8).

Table 8: Comparison of Representative and Direct Democracy Models

	Representative Democracy	Direct Democracy
Role of Politicians	Provide authority	Meet demands
Role of Citizens	Elect politicians Support organisations to represent their interests	Articulate and develop own interests Participate in all stages of the political process
Prime Legitimation	Indirect: politicians are elected by citizens	Direct: through citizen participation in different stages of the political process
Role of Civil Service	Effective and efficient professionals	Facilitators of collective decision making, co-learners
Role of Experts/Scientists	Producers of value free knowledge Offer cognitive support to particular causes	Support the (self-) enlightenment of citizens by acting as co-learners

Building indicators for the evaluation of (P)TA from democratic theory

We would like to propose a set of indicators for the evaluation of TAs and PTAs, deduced from the very representative and direct democratic theorising presented above (Biegelbauer/Hansen 2011).

We explicate three central differences between the two models of democracy, which we often see articulated in discussion about how (P)TA processes ought to be organised to be 'democratic', as well as the kind of criticisms these standards may invoke. The differences relate to the following headlines: 'Principles of inclusion', 'Issue framing' and 'Quality of decision-making'.

Principles of inclusion: In the representative tradition, an important aspect of democratic sovereignty pertains to the equality of citizens; the interests of all citizens should be given equal weight in decision-making processes. It is therefore essential that those passing judgement on behalf of the citizenry are representative of the larger public. This usually leads to demands that participants in such procedures must be statistically representative of the general population. From this perspective, criticism is due when processes are captured by minority interests.

In the direct democratic tradition, the ideal of sovereignty places more emphasis on the ideal of self-governance; the possibility for those affected by decision-making to be able to take part in and influence decisions. The central criterion for public involvement is therefore whether all legitimate interests have been given the opportunity to articulate their concerns. In this perspective, criticism is due when particular voices are excluded, especially those of vulnerable, affected groups that may find it difficult to mobilise collectively.

Issue framing: In the representative tradition it is considered essential that the citizenry is enabled to make informed decisions. Therefore, it is important that participants in (P)TAs are provided with adequate and unbiased information. This can be achieved either through institutionally 'independent', or a plurality of information sources. Criticism is due if information is incomplete or prejudiced by actors serving their own interests.

The direct democratic tradition stresses that 'information' cannot be provided out of context. Therefore, it is equally important that participants in deliberations are allowed and enabled to frame questions according to their own problem horizons, rather than simply act as recipients of authorised knowledge claims. Criticism is due when debates are cast in narrow, technocratic frames, excluding broader issues of social concern.

Quality of decision-making: The representative tradition assumes that citizens have relatively stable, pre-defined interests. Politics is therefore an arena where different groups struggle to get their interests recognised. For this struggle to play out in a fair manner, it is essential that decisions are made in a transparent fashion and that decision-makers can be held accountable for their decisions. Criticism is due when it is not transparent on what basis decisions are made and who is held accountable (Rowe/Frewer 2000).

In the direct democratic tradition, interests and preferences are not considered pre-given, but rather they are shaped in deliberations. Therefore, the critical standard is not (only) whether the decision-making process is transparent and decision-makers can be held accountable, but whether decision-makers are genuinely open to arguments. Criticism is thus due when decisions are reached through bargaining and compromise in the absence of deliberative argumentation (Webler/Renn 1995).

The differences between the two traditions and the questions they generate for (P)TAs are outlined in Table 9 below.

While derived from theoretical models with different normative foci, the criteria need not be mutually exclusive in practice. However, the organisation of (P)TAs is likely to involve trade-offs on all three criteria. In order to examine this closer, we have classified and compared the CIT-PART data on xenotransplantation policy-making according to the three pairs of criteria.

Table 9: Two Democratic Traditions and Criteria for Assessing TA/PTAs

	Representative ideals/ criteria for TA/PTA	**Direct democratic ideals/ criteria for TA/PTA**
Principle of inclusion	*Equal weight to all citizens:* Are the participants representative of the citizenry in general?	*Inclusion of all affected (groups):* Are all legitimate interests given a voice?
Issue framing	*Adequate information provision:* Is information provided by independent sources or a plurality of sources	*Framing by the participants:* Are the included enabled to query the issues according to their own criteria of relevance the political process
Quality of the decision-making process	*Accountability of decision makers:* Is it transparent how decisions are made and where complaints/ dissatisfaction can be registered?	*Attention to arguments:* Is the process genuinely open-ended, and are decision makers willing to give reasons and engage in argumentative processes process

Analysing the differences between the cases

The countries included in the CIT-PART-project arrived at xenotransplantation regulation in different ways. Whereas Austria had virtually no discussion on xenotransplantation, Canada, Denmark, Italy, The Holy See, Latvia, the Netherlands, Sweden, Switzerland, the UK, the OECD and the EU all had various kinds of expert TAs; the UK engaged in TA studies which included invited participation of stakeholders, whereas Canada, the Netherlands and Switzerland performed PTAs.

In Table 10 we present a summary of the cases, ordered according to the criteria discussed above, of which we shall interpret selected aspects below.

For Austria there are no entries in the table because xenotransplantation was discussed exclusively in the civil service and with a few experts. Civil servants produced internal reports on OECD meetings they attended. Although a scientific committee at the Health Ministry said in a short statement that regulation of xenotransplantation might be necessary, no such steps were taken. This is rather typical of Austrian regulatory activities in science and technology governance: decisions often come late, if ever, and discussions are restricted to a narrow elite of civil servants and experts (Griessler 2010, 2012b).

Table 10: Governance of xenotransplantation in Selected Countries

	Criteria from representative democratic theory				Criteria from direct democratic theory			
	Equal weight to all citizens	Adequate information provision	Accountability of decision-makers		Inclusion of all affected (groups)	Framing by participants	Attention to arguments
AT				AT			
CA				CA			
CH				CH			
DK				DK			
EC				EC			
GB				GB			
IT				IT			
LV				LV			
NL				NL			
OECD				OECD			
SE				SE			
VA				VA			

By stark contrast, Canada featured public discussions, expert TA and PTA on xenotransplantation (see Figure 1, p. 53). The public consultation approach included a representative and open model. The latter included – beside a telephone survey a number of citizen forums in six Canadian regions. Adequate information was provided to the public in this public consultation by various means. Public consultation emphasized accountability of decision-makers and inclusion of affected groups. Participants of the citizen forums were able to change the framing of how xenotransplantation was perceived as a problem. The specific question posed to the PTA participants was rather narrow: Should Canada proceed to clinical trials? The citizen participants considered the issue of xenotransplantation to be much broader – an issue of health resources; animal welfare; ethics; alternatives to xenotransplantation, regulatory standards and regulatory preparedness. Finally in accordance with the opinion of the PTAs, Canada adopted a restrictive policy, however, it is not clear to which extent the PTA contributed to this decision (Einsiedel et al. 2011).

In Switzerland two expert TA (solid organ and cellular xenotransplantation) as well as a PTA on xenotransplantation were organized. In addition the two chambers of Parliament debated the issue thoroughly. Political decision-making and PTA were running in parallel and along similar lines to the Dutch case; the decision to regulate xenotransplantation came before the report of the PTA was published. However, the time lag was only a few days and, again similarly to the Dutch case, the opinions of politicians and PTA participants were congruent. In Switzerland xenotransplantation is permitted, if only with requirements and prior authorisation (Griessler 2011).

In Denmark a small party instigated a parliamentary debate on xenotransplantation. Soon a conference including international experts was held, followed by a parliamentary hearing, which led to a de facto moratorium on xenotransplantation (Hansen 2011). Since only experts and politicians were involved in decision, participants were not involved equally. Also not all affected groups were present because animal rights activists and patient groups decided on their own accord not to participate in a public discussion.

In general, xenotransplantation policies at a European level can be characterized as enabling. Xenotransplantation was not subject to a fierce public dispute and scrutiny at the EU level. The European Parliament did not debate the issue at any length. The European Council briefly discussed xenotransplantation in the context of the Clinical Trials Directive. Two scientific committees of the Commission, the SCMPMD and the SCHER, dealt with the issue in their opinions. In addition, the Commission funded xenotransplantation research and ELSA* projects in its successive Framework Programmes. The EMEA/EMA issued guidelines for xenogeneic cell-based products in the 2000s. Though the EC also funded research into ethical, legal and social aspects of xenotransplantation and participatory experiments therein, the public was almost entirely absent in advisory and decision-making processes leading to European policies, except for the SCHER's public consultation and hearing on the use of non-human primates in research in 2008 (Griessler et al. 2012a).

In Italy two expert committees (National Bioethics Committee, National Committee for Biosecurity and Biotechnology) voiced opinions on xenotransplantation, which were not taken up by the government and from which no policy was adopted (Griessler et al. 2012b). Both opinions were initiated by the respective committee and framed by participants. These Committees did not give equal weight to all citizens because they only included appointed experts and civil servants. They did not provide adequate information, because the documents only became available online, in one case only after a lengthy delay. The accountability of these Committees was also found wanting because nomination in one case is inspired by politics, in the other based on nomination by various ministries. The committees included experts and civil servants and no representatives of affected groups. Finally there was no attention to the committees' arguments, because: (1) neither expert body has any regulatory power; (2) politicians had little interest in the topic; and (3) the promises of xenotransplantation did not become a reality in the short term. Calls for a public debate from both Committees remained unaddressed.

* ELSA = Ethical, Legal and Social Aspects

In Latvia a standardized form of application has to be submitted to the responsible government agency. Each case is reviewed by civil servants evaluating the safety and cost-effectiveness of the technology proposed. Since Latvia has no particular xenotransplantation regulation it also had no effect on government (Putnina/ Kaleja 2011). Apart from that no TA or PTA was carried out.

In the Netherlands parliamentary discussions took place, an expert TA, a PTA and public communication exercises were carried out. The decision of the responsible minister to stop xenotransplantation and of Parliament legally to ban xenotransplantation came before the PTA was concluded and the results were only relayed informally to the political system. Though procedurally problematic, there was a high level of correspondence between the PTA and the adopted policy. The Netherlands banned xenotransplantation (Versteeg/Loeber 2011). In this process adequate information was provided by various means, decision-makers were accountable, and all affected groups were involved,

OECD activities were mainly triggered by the Member States (USA, the UK and Canada) and contributed to putting xenotransplantation on an international agenda. The OECD achieved this by providing a policy forum of mutual exchange with its workshops and reports (Griessler 2012a). Instead of a moratorium, the OECD favored harmonized international surveillance. It contributed to the formulation of elements of just such a global surveillance system. Finally, the OECD moved the agenda to the WHO. Whereas national governments' representatives, the OECD staff, researchers and industry were strongly involved in OECD activities, only representatives from two patient groups and one NGO advocating animal welfare were present in the audience of a conference organized by the OECD. Thus, the OECD used a close and closed international network from national and international policy-making, research and industry to develop its policies. The public was only included via press conferences and the availability of the reports, which were published on paper and online. Though only recommendations, the output produced by the OECD was considered to have considerable impact on policy-making because it was developed in close collaboration between experts and representatives of national governments (Griessler 2012a).

In Sweden there were discussions in parliament on xenotransplantation. A parliamentary committee on xenotransplantation was established, which carried out a TA on the basis of expert hearings, an opinion survey and a subsequent conference, which was open to the public. Though the report took a permissive stance towards xenotransplantation its recommendations were never translated into law because of the risks of xenotransplantation and the voluntary moratorium of Swedish researchers on clinical trials. Thus, Sweden adopted an informal de facto moratorium on clinical trials (Hansson/Lundin 2011).

In keeping with UK policy approaches to science at this time, several expert TAs were carried out, as a result of which an agency (UKXIRA) was established with the aim of advising the health minister on matters relating to xenotransplantation. Subsequently, annual public meetings were organised in such a way that allowed members of the public to ask questions of the UKXIRA, but without any expectation that public views should inform UKXIRA policy; these exercises cannot therefore be considered PTAs. The table entries concentrate on the expert TAs. In the UK clinical trials of xenotransplantation are permitted in principle (Brown/Beynon-Jones 2011).There was not adequate information available in the UK on xenotransplantation, since it mainly derived from a company conducting xenotransplantation and the promissory claims they were making.

At the Holy See, the Pontifical Academy for Life was in principle positive and supportive towards xenotransplantation, so long as certain conditions were met. The Academy considers itself a scientific expert organisation. Therefore, only experts in science and ethics participated in the process. Participation was based on self-selection and appointment. Participation of the public is not part of the Academy's self-perception. Thus, there was no public involvement. The public was informed about the document only later on in press releases, publications and online. Policy-makers were encouraged in the document to stimulate public discussion. The public was defined in the document as lay citizens, individual patients and relatives (Griessler et al. 2012b).

When comparing the results of the different cases one can see that Switzerland and Canada score best on both sets of criteria, whereas Austria, Italy and Latvia show the lowest scores. The other countries are lined up in between, with the Netherlands next, followed by Denmark, Sweden, the EC, the OECD, the UK, and finally the Holy See. The two sets of criteria are therefore not mutually exclusive, but rather seem to co-vary to a significant extent. This is perhaps not surprising, given that democracies have a systemic quality a fact reflected in democracy indices, where countries feature consistently high or low scores over most criteria (Müller/Pickel 2007, Campbell/Barth 2009). We also observe that the PTA cases scored better both on criteria drawn from representative and direct democratic theory than the TAs, and that the countries with a history of public engagement exercises, Switzerland, Canada, Netherlands and Denmark, in general had higher scores than those without.

Nevertheless it is important to notice that all of the PTA cases reviewed here produced, as already said, ambiguous results when it comes to the direct impact on policy-making in the sense of first generation of impact studies (see Chapter 5). In Switzerland and in the Netherlands the delivery of PTA results were in a tight race with the parliamentary decision-making procedures that in the end was lost in both cases - which incidentally highlights an issue frequently raised against PTAs, namely that they are time-consuming (Abels/Bora 2004: 53; Montpetit 2008). Moreover in both the Netherlands and Canada it is unclear how influential the PTA results were for actual xenotransplantation policy-making.

This observation provides two results:

- the question about the actual impact of PTAs on decision-making presents a methodological challenge to empirical analysis, especially when adhering to the demanding criterion derived from direct democratic theory, which call for the willingness of decision-makers to give reasons for and engage in argumentative processes with open results;
- the unclear results of PTAs on the regulation of xenotransplantation may also be interpreted as part of a series of rather disappointing results of public participation exercises in the governance of science and technology (Seifert 2003, Abels/Bora 2004).

In our use of democratic theory we have decided to take a systemic view on deliberation (Mansbridge et al. 2011), thus enabling us to see the "larger picture", including the effects of TAs and PTAs not only on parliament or some specialised bureaucrats, but on the political system. With such a broad view of political processes we decided to relax some of the strict conditions often propagated in relation to deliberative democratic instruments, and so we were able to look differently at political actors such as campaigning animal-rights activists or lobbying industrialists. We interpreted these activities as being a legitimate part of the political process and not as a disturbance of idealised communicative exchanges. Similarly we took into account international, transnational and supranational discussions on xenotransplantation, which were influencing the debates on the national level.

In the following section we will look at the question of why public participation exercises seemed to take root more in some cases and less so in others.

Explaining the differences between the cases

As described above it seems to be difficult to make processes and results of participatory policy advice compatible with representative political systems (Biegelbauer/Hansen 2011). The problem has been identified already for some time (e.g. Joly/Assouline 2001, Joss/Belucci 2002, Bütschi et al 2004, Bora/Hausendorf 2004, Hansen 2010) . Yet the difficulties of creating some kind of "resonance" (Bütschi et al 2004) in the political systems of modern democracies persist. Our analysis shows that at least a part of this problem arises from differences in the normative foundations of PTA compared to existing representative institutions. This constitutes a dilemma for the proponents of PTAs: if such procedures are to deliver genuine alternatives to politics as usual, they need to distinguish themselves from other modes of policy advice. On the other hand, if they are too 'alternative', they risk being ignored.

The question of whether representative democratic political systems are able to deal with the challenge of integrating participatory practices of policy-making is

still undecided. In principle representative democracies have shown that they can adapt to changes and over the last decades have reacted, amongst other things, to citizens disappointed by the welfare state, the strengthening of new forms of protest and participation influenced by social and technological developments, and the rise of non-governmental organisations. This has been described as a change from "government to governance", a path that comparative political science studies have shown that some countries have followed further than others (Rhodes 1997, Hajer/Wagenaar 2003, Sorensen/Torfing 2008).

In the regulation of science and technology we can observe that some countries have changed their ways of decision-making more than others. The historically contingent flexibility of political systems is important among the cases analysed in this paper. Austria, for instance, is traditionally a structurally conservative neo-corporatist case with tightly coupled institutional structures allowing only for a limited input from outside the neo-corporatist policy communities in many policy fields. STS research indicates that in the governance of science and technology there has been an emphasis on experts and stakeholders in the country until the present day (Biegelbauer 2010). In the structurally less conservative Dutch case neo-corporatist institutions are relatively less privileged, merely some of the voices in the large chorus of societal interests trying to make themselves heard in policy-making (Karlhofer/Sickinger 2000). Scientific experts and stakeholders still hold a dominant position, but critically they have been supplemented by the public in the form of various public participation measures. In the structurally more dynamic case of the UK, decision-making on science and technology has a two-tier structure: on the one hand there has been a real proliferation of public engagement exercises of various sorts during the 2000s, making an effort to complement decision-making, while on the other hand the older forms of policy-making processes in which experts play the key role still are dominant, if perhaps somewhat less visible (Brown/Beynon-Jones 2011).

Those countries have been more susceptible to the new public engagement instruments, in which different factors come together:

- Of prime importance is a general openness of policy-making of the respective political system (compare also with Joly and Assouline 2001).
- Equally important seems to be the absence of closely knit policy communities, as described by comparative political science for Austria and those of the British "administrative villages" before the Thatcherite "New Public Management" reforms kicked in (Peters/Pierre 2001).
- Since many issues in the governance of science and technology do not necessarily involve politicians, but stay in the remit of the civil service, it is important that the bureaucracy is not paternalistic, but heeds accountability, transparency and openness as important factors in democratic decision-making processes (as is the case for Canada).
- All of these factors make policy-making more permeable and more susceptible to new ideas. This susceptibility goes hand-in-hand with a pluralist political culture, in which public debates are led openly and indeed often intensely when it comes to value-laden intractable policy problems. Indeed the countries featuring PTAs on xenotransplantation, Canada, the Netherlands and Switzerland, are all societies with a tendency of having open(ed) political debates.
- In addition active mass media play an important role in creating public discussions, for example in the UK.
- Finally there is also a recognizable "memory effect" as countries that have already carried out PTAs are more likely to have them again. In most of these cases the dominance of experts in the governance of science and technology is gradually reduced, thus further enhancing the chances of PTAs to become institutionalised.

Chapter 7
Political Practices

Let us now return to the micro-level of our cases and address the question how civil servants, politicians and experts actually did cope with the complex problem of xenotransplantation. Which political practices of involving experts and the public did they use? In what way were they contributing to or limiting citizen participation? To address these questions several political practices are investigated: agenda setting; setting up a committee and working processes within the committee.

Agenda Setting

The ability and legitimacy of actors to set and frame a political agenda is critical for exerting influence on any policy field. Whether actors – may they be elected politicians, civil servants, experts, stakeholders, NGOs, media, or the public – are implicitly or explicitly legitimatized and able to raise and define an issue as a policy problem that would need analysis, debate or regulation is of utmost importance for the direction and outcome of a debate.

However, it is not only important to know which actors in a particular society or organisation are entitled to raise an issue, but also the specific political practices how this is done. An important question within the CIT-PART project is whether such practices work towards inclusion of the public or tend to exclude people. Table 11 provides an overview on the actors that set the agenda in xenotransplantation policies. It shows that different actors became primarily active in agenda setting.

Table 11: Significant Actors in Agenda Setting

	Civil servants	Politicians	NGOs	Advisory or TA Body	Researchers
AT	■				
CA	■				
CH		■	■	■	
DK		■		■	
EC	■			■	
GB	■			■	
IT				■	
LV	■				
NL		■		■	
OECD	■				
SE					■
VA	■				

Most often, it was civil service that became active in raising xenotransplantation as a policy issue. In many cases, public administration played a crucial role in agenda setting: In Austria, civil servants raised the topic because of their involvement in OECD activities (Griessler 2012b). Similarly, Latvian xenotransplantation policies were controlled by civil servants (Putnina/Kaleja 2011). Also in Canada public administration took initiative in xenotransplantation policies because it became aware that it was ill prepared for potential applications for clinical trials (Einsiedel et al. 2011). The process of agenda setting was supported by the minister. In the UK, both the Department of Health as well as the independent Nuffield Council were prime movers in xenotransplantation policies (Brown and Beynon-Jones 2011). Civil service also managed agenda setting at the OECD level.

This can be explained by the OECD's function as international political and expert organisation which almost entirely is comprised of national and international civil servants as well as experts. Several member states were interested in putting xenotransplantation on the international agenda. Civil service also initiated the xenotransplantation debate within the Vatican. After several inquiries from local bishops for guidance on the issue, the Curia, the highest level of the Catholic Church's administration, asked the Pontifical Academy for Life, an expert body of natural scientists, physicians, theologians, lawyers and bioethicists, to provide an opinion on xenotransplantation (Griessler et al. 2012b).

Elected politicians were considerably less active in agenda setting than their administrative staff. Cases in which politicians were crucial in agenda setting include Switzerland, Denmark and the Netherlands. In Switzerland, the work of one MP was critical for putting xenotransplantation on the agenda, but it was a number of other actors as well – a NGO critical of biotechnology and a parliamentary TA organisation – who contributed to initiating a discussion about xenotransplantation as a policy problem (Griessler 2011). In the Netherland too, it was a number of actors – elected politicians among them – who became critical in initiating a debate. The Health Council, an expert advisory body to government, was the first that raised attention for the topic, and advised the Ministry of Health, after its request for counselling, to take a permissive policy. Thereupon it was the Minister of Health – with the usual support of the department's civil service – who took a lead in setting the agenda, commissioning advice on the topic and, eventually, taking into account various forms of advice (including legal advice from the state's main juridical advisory board), issued a change of the respective law and formalised a de facto ban on research in the field of xenotransplantation. During this process, members of parliament called for a PTA (Versteeg/Loeber 2011). In Denmark, TA organisations raised the topic, because of possible public concern about xenotransplantation and because they considered it an appropriate topic for inter-institutional cooperation between TA organisations which was demanded by politicians (Hansen 2011: 22). After a hearing on the issue at Copenhagen University, organised by TA organisations, a small conservative party instigated a debate in parliament (Hansen 2011).

In several cases it was an independent advisory body that was particularly active in agenda setting. At the European Commission several departments – so called Directorate General (DG) – and the European Medicines Agency (EMA) became active in xenotransplantation policies. Different DGs had different reasons for dealing with xenotransplantation, including the risk for infection and epidemics, the use on non-human primates in research, and the promise to boost European economy. In some DGs it were civil servants themselves, in others members of scientific committees (Griessler et al 2012: 10) or working parties (ibid. 26) who put xenotransplantation on the agenda. In Italy, both the National Bioethics Committee (CNB) as well as the National Committee for Biosecurity and Biotechnology (CNBB) produced recommendations on their own initiative (Griessler et al. 2012b: 17, 19). In Switzerland, TA-Swiss took the initiative for a TA and PTA study because of international research and regulatory activities as well as an incipient public debate (Griessler 2011: 32).

In the Swedish case xenotransplantation researchers themselves played a critical role in putting the issue on the political agenda: They contacted the Ministry of Health and requested an inquiry into necessary regulatory measures to carry out xenotransplantation research (Hanson/Lundin 2011).

Only in Switzerland NGOs were critical in putting xenotransplantation on the political agenda.

Openness of Agenda Setting

An important characteristic of agenda setting is its openness or closeness to the public, i.e. the extent to which the general public is able to influence agenda setting. Table 12 shows that in most cases agenda setting was closed to the public.

Table 12: Agenda Setting – Openness to the Public

	Open	Closed
AT		
CA		
CH		
DK		
EC		
GB		
IT		
LV		
NL		
OECD		
SE		
VA		

In Austria, the process of agenda setting was controlled by civil service and the discussion was almost entirely kept within the ministry (Griessler 2012b). Also in Denmark the debate remained an "elitist undertaking restricted to some rather narrow – and to some extent – closely intertwined expert circles" (Hansen 2011: 32). This is also true for Italy and the Vatican, where agenda setting was controlled by expert committees. At the OECD, agenda setting was completely shut off from the public and remained in the realm of experts as well as national and international civil servants. At the European level, the public was neither involved at the European Commission nor at the EMA in the process of selecting xenotransplantation as a topic for discussion and regulation (Griessler et al. 2012a). In Latvia, the public was not involved in discussing xenotransplantation at all (Putnina/Kaleja 2011: 19). The process of agenda setting was basically closed to the public in the UK as well, though invited stakeholders had an opportunity to send in written responses. However, members of the expert advisory group and their secretariat had a strong "gate-keeper position", because they determined the format of possible responses and were "free to interpret the relevance of the submissions which they received" (Brown/Beynon-Jones 2012: 31). The UKXIRA also held annual open meetings, where members of the public were invited to respond and contribute to discussions concerning the regulation of xenotransplantation (ibid.). In Sweden, agenda setting was limited to experts, civil service and politicians and excluded the public (Hansson/Lundin 2011: 48). NGOs such as animal welfare activists were denied the opportunity to participate in the parliamentary xenotransplantation commission to the extent they would have liked (ibid. 61 and 89 ff.).

The case was remarkably different in the Netherlands: Though agenda setting was closed to the public as well, the actors who initiated the debate called from the very beginning for public involvement in terms of information and discussion.

In contrast to most of the cases, the Canadian health ministry opted for opening up the policy-making process and including other actors and the public in a complex process of stakeholder and public involvement. The ministry put xenotransplantation on the agenda with the explicit goal to consult with the public. Attempts were made to open the debate and to include stakeholders, national and international experts as well as the public (Einsiedel et al. 2011). In Switzerland, several mechanisms of direct and representative democracy were used to initiate a debate. NGOs collected signatures for their cause and – via their connection with a MP – were able to use established mechanisms of parliamentary democracy such as interpellations and motions to make parliament and government aware of the problem. This contributed to the issue being taken up by Parliament and TA Swiss (Griessler 2011).

Creating a Committee

Once it is accepted that an issue is a problem to be attended, it has be decided who actually is going to analyse it and will work out recommendations. A resulting question is: How to create expert committees and to recruit its members? In the context of the CIT-PART project an important question concerns the openness and accountability of expert committees. Openness and accountability starts, with the way committee members are selected: Is their appointment solely based on scientific qualification or are other reasons important as well, such as political affiliation? Does a published set of selection criteria exist or are nominations only based on undisclosed, implicit criteria? Are members appointed after an open call for tender or is it a self-selecting process, based, e.g., on personal acquaintance? Do committee members have vested interests, which are never announced or are they obliged to provide a declaration of conflict of interests?

Openness of Recruitment

Table 13 shows whether recruitment for expert TA and PTA was open or not and whether it was based on explicit selection criteria. In addition it provides an overview whether declarations of conflict of interests were required or not.

Table 13: Openness and Accountability in Recruitment

	Open call for tender	Explicit selection criteria	Declaration of conflict of interests
AT			
CA			
CH			
DK			
EC			
GB			
IT			
LV			
NL			
OECD			
SE			
VA			

Most often, recruitment processes were characterized by little openness and accountability.

In Austria, no formal TA process was initiated and the civil servants who dealt with xenotransplantation were appointed by the ministry. Likewise, there were no attempts in Latvia to carry out a TA or PTA process on xenotransplantation (Putnina/ Kaleja 2011: 30). Typically, decision-making with expert involvement tends to happen in Latvia "behind closed doors" (ibid.). Expert TA is "institutionalized as a routine case-to-case decision making procedure within governmental agency" (ibid. 27). Generally, "the composition of the committee is closed and its members are often chosen on a basis of acquaintanceship" (ibid.).

Danish TA organizations arranged a number of small- and medium scale TA activities which included hearings at Copenhagen University and the Danish Parliament as well as a report by the Gene-Technology-Commission. In none of these exercises, explicit recruitment criteria were made public (Hansen 2011).

Recruitment processes were also closed and little accountable in Italy. The CNB's mandate covers broad advice to government, parliament and other institutions on ethical and moral issues in the area of biomedicine and life science. Appointment of its roughly 40 external experts depends not solely on qualification but also has a "fairly strong political component" (Griessler et al. 2012b: 18). Another expert advisory body, the CNBB, advises government in technical matters concerning new biotechnology and consists of delegates from ministries as well as of institutions which deal with research and health.

Members of the Dutch Health Council, which performed expert TA in the Netherlands, are often recruited from a limited circle of researchers in the field. Further criticism regarding recruitment concerns two contributors to the xenotransplantation report who faced a conflict of interest, since they had links with pharmaceutical industry which also carried out research in xenotransplantation (Versteeg/Loeber 2011: 30). Thus, recruitment processes for expert TA were little open and accountable. As regards Dutch PTA, the approach towards public engagement included inter alia larger national and smaller public discussions with "as diverse a part of society as possible". This included "public organizations, interest organizations and professional organizations, experts, politicians, and policy makers. Individuals could participate via website, local debates and survey; youths were approached via the schools" (Versteeg/Loeber 2011: 41). How institutions for PTA were selected remained unclear.

Also the OECD's nomination processes for national experts and representatives was and still is little open and accountable. Both are nominated by member states.

In Sweden, the Health Ministry first appointed a MP as chairperson of the parliamentary Xenotransplantation Committee. The chairperson was given a fairly free hand to choose committee members in a process of self-selection. Implicit selection criteria included not only scientific qualification but to a great extent also political considerations. For instance, the political parties present in the committee, which nominated their representatives, had to represent parliamentary majority. Experts were selected from a rather small circle, "since Sweden is a relatively small country [and] many of the members knew each other and worked together in other areas" (Hansson/Lundin: 53).

The recruitment process at the Vatican was self-selecting as well and of little openness. Members of the working group were chosen on basis of previous acquaintance as well as on recommendation of an Italian xenotransplantation researcher (Griessler et al. 2012b: 34).

In the UK, the Department of Health's committee was set up by a single civil servant, "who would research the field, determine who the relevant experts were, and (with agreement from relevant superiors) recruit them" (Brown/Beynon-Jones 2012: 50). Though recruitment practices since then changed towards more transparency, they were rather opaque in the mid-1990s.

In Canada, a number of committees were created which subsequently dealt with expert TA and PTA in the field of xenotransplantation (c.f. Einsiedel et al. 2011). Focusing this assessment on recruitment processes carried out by the citizen forums of six provinces, PTA exercises were organised rather openly. They were based on voluntary application after random mailing of 2.500 invitations in each of the six regions. Participants were selected by a committee considering "gender, age, mother tongue, urban/rural location, occupation" (ibid. 27).

Also in Switzerland a number of bodies had to be considered when analyzing recruitment processes of TA and PTA bodies. The contractor who performed the TA studies on solid organ xenotransplantation was selected after an open and international call for tender. Appointment of the members of the advisory committee who accompanied the expert TA as well as the PTA process was based on their expertise and on the fact that they represented important stakeholders.

Lay participants of the PTA (PubliForum) were selected from a group of about 100 people who had volunteered to participate by responding to an invitation which had been send out to about 10.000 randomly selected Swiss residents. Selection of participants took in account gender and regional representation (Griessler 2011: 37).

At European Commission level, two scientific committees advising the Commission dealt with xenotransplantation, the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) and the Scientific Committee on Health and Environmental Risks (SCHER). The Commission's advisory system had been reorganized in the mid-1990s following a severe political crisis in order to reestablish public trust in EU regulation. In order to reach this goal, recruitment procedures should meet the principles of excellence, independence and transparency (Griessler et al. 2012a: 7). They therefore include elements such as open calls for expression of interests in which researchers can apply for membership, the publication of selection criteria and of the names of selected members as well as declaration of conflicts of interest (ibid.: 8). Besides ordinary members, scientific committees also comprised of external experts, who contributed to the work on xenotransplantation. In contrast to ordinary members, they were appointed in a self-selecting process, identified either from committee members' own scientific network, from a pool of experts within the Commission or from literature review.

Interdisciplinarity

Xenotransplantation is a topic which not only includes different research disciplines in the natural sciences but also raises ethical and societal questions. To which extent does the composition of TA and PTA processes recognize the consequent need for collaboration between natural scientists (weak interdisciplinarity), natural and social scientists as well as ethicists (strong interdisciplinarity) and between researchers and other societal actors?

Table 14 Level of Interdisciplinarity in TA and PTA

	Weak interdisciplinarity	Strong interdisciplinarity	Transdisciplinarity
AT	■		
CA		■	■
CH		■	■
DK		■	■
EC	■		
GB		■	■
IT		■	
LV			
NL		■	■
OECD		■	■
SE		■	■
VA		■	

Table 14 shows that TA processes in two cases were characterised by weak interdisciplinarity and involved solely natural scientists (AT, EC). In another group of cases expert TA can be categorised as strongly interdisciplinary only (IT, VA). Most cases, however, were marked by a combination of strong inter- and transdisciplinarity, the latter either by involving politicians or the general public. Both Canadian and Swiss TA and PTA processes had elements of strong inter- and transdisciplinarity. In Denmark, TA bodies varied as regards interdisciplinarity. A one-day seminar at Copenhagen University included only scientists working in the field (Hansen 2011: 41). The parliamentary hearing included MPs, scientists,

ethicists, economists. The Gene-technology Commission was comprised of scientists, ethicists, staff of a TA organisation and civil servants (ibid. 42). In Britain, the committees that produced the Nuffield Council and the Department of Health's report were marked by strong interdisciplinarity; however, both also had an element of transdisciplinarity because they invited stakeholders for comments. In the Netherlands, the Health Council can be characterized as a strongly interdisciplinary committee, comprising of medical doctors, researchers, but also of jurists and ethicists (Versteeg/Loeber 2011: 31). The Dutch PTA exercises commissioned by the Ministry of Health on the other hand can be considered transdisciplinary. The OECD involved mainly natural scientists who dominated the discussion, but conferences were also attended by a small number of ethicists and an even smaller number of NGO representatives (Griessler 2012a). Finally, the OECD also involved the civil servants who could consider its recommendations. The parliamentary Swedish Xenotransplantation Committee was transdisciplinary and included MPs, a researcher, a physician and an ethicist, a civil servant from the Health Ministry and the Swedish Institute for Infectious Disease Control.

Working Process

Another aspect of openness and accountability concerns the quality and amount of information which is available to the public about a committee's proceedings. This concerns the publication of agendas and records of meetings, reports or even the possibility to attend meetings.

Table 15: Accountability of Working Processes

	Agenda	Records	Reports	Public attendance of meetings
AT				
CA		■	■	■
CH			■	■
DK		■	■	
EC	■	■	■	
GB			■	■
IT			■	
LV				
NL			■	■
OECD			■	
SE	■		■	
VA			■	

Table 15 shows that most countries and organisations provided information in terms of publishing reports on the Internet. Only in a few cases the public had an opportunity to attend meetings of TA and PTA processes (CA, CH, GB, and NL). A remarkable exception to the often practiced principle of confidentiality of meetings was the British UKXIRA, which held annual public meetings. The European Commission together with Canada scored amongst the best regarding openness of the working process. Scientific Committees of the Commission have to publish agendas, minutes and opinions (including minority opinions), without undue delay, taking into account the need for commercial confidentiality (Griessler et al. 2012a: 9). However, there is still room for improvement.

Transparency was considerably curtailed by the fact that the minutes were often rather brief and only comprised of a participant list, an agenda and a short summary. Information about proceedings of the scientific commissions and working groups was not provided (Griessler et al. 2012: 9). In addition, public participation in the Commission's scientific committees was severely restricted by strict framing by sound science and confidentiality (Griessler et al. 2012a: 37). The Canadian Public advisory group formulated principles of transparency: "the public involvement plan would strive to respect the following principles: a visible/transparent process, credibility (includes honesty and willingness to discuss hard issues), equal opportunity for all to participate, each participant will be considered as contributing valuable input, willingness of Health Canada to seriously consider all the input from the public involvement process" (Einsiedel et al. 2011: 22).

Types of Working Processes

Once an agenda is set, a committee furnished, and it is decided how open and accountable a committee should be towards the public, there has to be defined how the committee will actually arrive at its recommendations. Is the method used made explicit or does it remain implicit? Is the report a single-authored paper or is it discussed in depth and approved by the committee? Is a moderator present who manages the process?

Table 16: Type of Working Processes

	Hearing/ Conference	Paper discussed in the committee	Specific method applied	Facilitation
AT				
CA	■	■	■	■
CH	■	■	■	■
DK	■	■		■
EC	■	■		
GB		■		
IT		■		
LV				
NL		■		■
OECD	■	■		
SE	■	■		
VA		■	■	

Most often papers – or parts of them – were drafted by single committee members and then discussed in meetings with the group. Often, hearings and conferences were used to collect necessary information and discuss xenotransplantation policies. In three cases particular methods for PTA and TA were chosen. In Canada and Switzerland the Danish consensus conference model was applied. The working group of the Pontifical Academy for Life followed the bioethics textbook of its chairman and produced its paper during one year in a series of interdisciplinary seminars which first considered scientific aspects and problems, thereafter discussed anthropological aspects and finally drew ethical conclusions (Griessler et al. 2012b: 37). Facilitators were present in PTA exercises (CA, CH and NL) but also in expert hearings in Denmark.

Conclusions

In order to increase the chances of PTA being applied, it is particularly important to understand the role of civil servants and experts in decision-making in science and technology policy. In many cases, civil servants played the most eminent role in agenda setting. Also researchers, either in advisory bodies or as individuals, were critical in putting xenotransplantation on the agenda. In contrast – despite the fact that xenotransplantation might be a highly sensitive area – activities of elected politicians were less frequent. Only in one case NGOs were critical in agenda setting.

Agenda setting repeatedly was a process closed to the public. Moreover, it was often a little formalized process. In many cases it was not clear from hindsight how xenotransplantation actually became a policy issue. This lack of formalization makes it rather difficult for outsiders to set a topic on the political agenda.

Openness and accountability of recruitment are necessary elements to create trust in regulation. However, recruitment processes were often closed and based on nomination (relying on acquaintance, self-selection) with criteria that remained opaque and implicit. Only in a few instances declarations of conflicts of interests were provided.

Xenotransplantation as a research field necessitates strong interdisciplinarity and transdisciplinarity. This need was in principle recognized in many cases, though actual public involvement was infrequent. Methods applied in working processes often remained implicit.

Openness and accountability also requires information. Most often reports were made available on the Internet. Publication of agendas and records was considerably less frequent and public attendance of meetings was only possible in a few exceptional cases and in cases which included PTA exercises.

Box 4: Gender Aspects

The CIT-PART project looked into some gender aspects of xenotransplantation policies as well as TA and PTA. In most cases, gender was not an issue in the debate and the topic was hardly addressed. The few exceptions were a Dutch animal welfare organisation and a Swedish Green Party who claimed that xenotransplantation was an approach connected with low representation of women in medical sciences (Versteeg/Loeber 2011: 66) or an exploitive relationship towards nature, respectively (Hansson/Lundin 2011: 96). Surveys conducted in Italy and Canada showed minor differences between men and women regarding their attitude towards xenotransplantation. According to these studies, men were more likely to approve of this medical approach than women (Einsiedel et al. 2011: 19, Griessler et al 2012b: 17).

With the exception of the Swedish Xenotransplantation Commission (Hansson/Lundin 2011: 96) and a Danish Genetechnology Commission (Hansen 2011: 43), there was a clear male bias in terms of scientists participating in many expert committees. This was not the case in PTA exercises. In Canada, 56 of 107 lay panellists in PTA were women (Einsiedel et al. 2011. 27). In Switzerland, the number of male and female participants in the PubliForum was equal (14/14). A professional moderator was responsible for ensuring that women and men had an equal opportunity to contribute to the discussions. 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 (Griessler 2011). In the Netherlands, a relatively large number of women participated in the public discussion (Versteeg/Loeber 2011: 66).

conclusions

Advocates of Participatory Technology Assessment (PTA) claim that this approach to public engagement could improve the quality of decision-making in science and technology policy, enhance citizen involvement in complex policy issues and increase the public acceptance of decisions made. Yet, more often than not, even in cases of technically and ethically highly complex issues, policy-makers do not opt for such a form of public engagement. Instead, policy-makers make use of expert-led Technology Assessments, or refrain from commissioning any specific technology-oriented policy analysis at all. The question is why? To what extent is PTA or TA applied? What explains the choices made, what are the experiences of using either, and what is their impact on policy-making?

Extensive research on PTA has provided a comprehensive overview of PTA methods and the use and impact of PTA. However, characteristically, such research compares cases in which different PTA methodologies are used to investigate different technologies. In addition, TA is seldom included in such studies and there are hardly any studies analysing how PTA processes are incorporated into policy-making.

The CIT-PART project addressed these research gaps. Comparing different countries and international organisations, it focused on how one particular policy problem, the issue of xenotransplantation, was approached. Centre stage were the PTA or TA procedures that were initiated to support policy-making processes. Thus the CIT-PART project was set to find out what factors facilitated and restricted the use of, and impact of citizen participation on decision-making.

Xenotransplantation as a policy issue

A first, striking, observation was the sheer variety of ways in which the cases under investigation dealt with xenotransplantation. While in principle the issue could be addressed uniformly in all cases given its technological aspects, the risks involved and its potential benefits, huge differences were observable in how the issue was approached between countries, and how it was regulated. From the variation in policy response that we found in our cases we conclude that context-specific national and historic factors to a large extent co-determine the choice for including a (P)TA arrangement in the policy preparation process. Culture plays a significant role in science and technology policy-making. The CIT-PART project thus empirically underscored the contention of Science and Technology Studies literature that a problem is not 'given' but is contingent on the way an issue is perceived in a certain setting, and is subject to particular framings. Framings cum circumstances can either provoke discussions or not, and can render some issue controversial or not. We found that the ways xenotransplantation was perceived and treated depended significantly on the way it was framed, and on previous experiences in a country. In Canada for instance the issue was considered potentially socially explosive, another potential test of the trustworthiness of a government that had recently been hit by a scandal over HIV-infected blood, while in Austria xenotransplantation was not identified as a policy problem at all.

The xenotransplantation issue was framed in various ways. Whereas organ shortage and risks – mainly of cross-species infection – were dominant frames in almost all of our cases, ethics and animal welfare were only important in a minority of them. In some cases, business interests provided an important framing. International organisations in particular, which influenced xenotransplantation policy development significantly, dealt with xenotransplantation mostly within a strict framing of sound science, evading – though recognizing – ethical, social and political implications. Only a minority of cases, among them Canada, Switzerland, the Netherlands, Sweden, the UK and the Vatican discussed the ethics of xenotransplantation thoroughly.

In other words, we observe that framing was a decisive, basically contingent factor. The way the issue was framed in a nation or organisation was highly dependent on a country's or international organisation's previous experiences and history, and, in the case of international organisation, its mandate.

Xenotransplantation regulation

Not just the framing of xenotransplantation and the intensity of (public) discussions differed between countries. A second observation was that the way the topic was translated in public policy and regulation varied (Tallacchini 2011). Our international comparison showed a diversity of xenotransplantation policies. Most countries and international organisations decided upon permissive policies, but in a minority of cases countries opted for a de facto or de jure moratorium. One country, Austria, took a 'wait-and-see' position.

Technology Assessment on xenotransplantation

A third observation concerns the forms of policy analysis used to channel (societal and expert) discussions to inform the policy decisions made. Expert TA turned out to be the dominant way to deal with xenotransplantation. Most countries and international organisations, which were influential in international xenotransplantation policy development, applied expert TA only. This group included the OECD, Sweden, the Vatican and the EC scientific advisory system. International organisations played an important role in the dissemination of technical information on xenotransplantation. Networking by and through international institutions such as the Council of Europe, the WHO, the OECD and at an EU level provided civil servants with knowledge on the issue. An interesting observation we identified was that in most policy efforts of international organisations, experts who advocated xenotransplantation were dominant, whereas positions opposing xenotransplantation were weakly represented. We found that this potentially created a dangerous in-group thinking effect, especially since the same studies and reports were used as authoritative sources of information in policy processes throughout Europe. Dissenting views were thus already put in a disadvantaged position at the very onset of policy dialogues and public debates on the topic.

The staging of PTA remained a minority in xenotransplantation policy-making. Only three countries in our large sample carried out a PTA (Canada, the Netherlands and Switzerland). The reasons why PTA was set up in these three countries varied, as did the way it was organised.

As concerns the reasons why some countries opted for a PTA: The federal department Health Canada decided for a broad consultation strategy which included expert TA and public consultation. This decision was made for various reasons: a) there was uncertainty about the promises and risks of xenotransplantation, b) it was assumed that applications for clinical trials were imminent, which Health Canada was legally bound to address within a short period of time, and c) there were concerns over a previous scandal (see above) which had undermined the government's regulatory credibility. The Dutch case revealed a different set of reasons. In the Netherlands, the responsible minister, while herself initially in favour of a permissive policy on xenotransplantation, answered demands for a public debate by Parliament with an initiative for public consultation. A PTA was then organised to stimulate debate but also notably to inform the public on the issue of xenotransplantation; a new episode in what was seemingly becoming a tradition of broad societal debates on life-science issues in the Netherlands. In Switzerland, it was TA-Swiss, a TA organisation then linked to Swiss Parliament that initiated a PTA. Reasons for doing so included the international developments, namely forecasts that clinical trials in xenotransplantation would be imminent and promised a huge economic market, and because a NGO criticising xenotransplantation triggered a public discussion on the topic in this country which had already reached Parliament.

In addition to these three instances of PTA in policy-making on the issue of xenotransplantation, there were a variety of Technology Assessment exercises that sat on a sliding scale between 'full-blown' formal public engagement and mere expert advice. In the UK, TA exercises were expert-led but also involved invited stakeholder discussions. Furthermore, in Canada, the Netherlands and Switzerland the PTAs were staged alongside expert TAs of various kinds. Academics in some other countries and at EC level took initiatives to experiment with PTA on xenotransplantation, yet did not link these efforts to policy-making.

Actor group involvement: the 'social map' of xeno-debate

In keeping with the framing of the issue and the intensity of the debate, varied the range of actors that got involved in discussions on xenotransplantation and its regulation. In most cases, civil servants interacted not only with researchers, physicians and other experts, but also with patient organisations, animal welfare organisations, ethicists and the lay public at large so as to inform political judgement and decision-making.

Yet the group of actors that was most intensely involved in the preparation of policy on xenotransplantation in almost all cases was the civil service. They served as a bridge between engaged politicians, knowledge providers, and in those cases where there was a PTA initiated. Another actor group heavily involved were scientists and physicians. They operated in multiple roles, acting not only as neutral experts, but also as spokespersons for patients and representatives of their own and the industry's interest (see also Gottweis 1998). Together with civil servants they formed the core of an international epistemic community, which met on repeating occasions to discuss the regulation of xenotransplantation in different forums such as the Council of Europe, the OECD, and the WHO but also on national level. The strong involvement of the two groups and the formation of an epistemic community that started to share policy ideas contributed to a dominant technocratic framing in discussions on xenotransplantation policies.

In contrast to civil servants and scientists, ethicists were less strongly involved in TA, with the exception of Canada, Sweden, the UK and the Vatican. In Denmark, Italy, the Netherlands and Switzerland they contributed less strongly to the debate. Ethicists played only a minor role in the OECD and none in EU advisory bodies. In general, systematic investigation into ethical arguments was therefore less frequent, despite the fact that documents repeatedly emphasised its significance given the characteristics of the issue of xenotransplantation. Early documents on the ethics of xenotransplantation prepared by the Nuffield Council of Bioethics (1996) and the British Advisory Group on the Ethics of Xenotransplantation (1997) therefore often became important points of reference to various regulatory bodies on a national and international level, which were used to legitimate xenotransplantation research.

Only in a minority of cases politicians, i.e. members of parliament and ministers, got involved in xenotransplantation policies (Canada, Denmark, Netherland, Sweden, and Switzerland).

NGOs were involved in some TA and PTA exercises (UK, Canada, Switzerland, and Netherlands), however, in many cases they did not participate, either because they were excluded or they themselves decided not to engage in the debate.

Although many TA documents demanded public debate, actual and direct citizen involvement was an exception. As has been said, only in Canada, the Netherlands and Switzerland were citizens strongly involved in PTA exercises. Thus, xenotransplantation policies remained primarily the domain of policy-makers and experts.

Of the many ways in which the public may be involved in policy development, polling can be seen as the most passive. This was most often used. In addition, in most countries, though with different intensity, the public was informed about xenotransplantation. As already mentioned, public consultation and discussion, which gives citizens the most active role, was only carried out in a minority of countries.

Incorporation of (P)TA in the policy process: impact

A fifth observation concerns the way in which TAs and PTAs were included in processes of xenotransplantation regulation, and the extent to which they impacted on these. We found that, in general, open political systems were more likely to integrate public engagement exercises such as PTAs. Yet it is not enough simply to suggest institutionalising public engagement exercises as a suitable way forward. Our findings show that the mere fact that such exercises were carried out did not mean that they had a clear effect on the regulation of the new technology. This was the case in all three countries in which a PTA was staged. Though policy-makers in all the cases in which PTA was carried out approved of the PTA and its results, we could not to establish an unambiguous direct impact

of these exercises. In the Netherlands, the results of the PTA were available only after xenotransplantation policies were adopted and the organizers of the PTA did not have concrete plans for feeding them into policy-making. As it turned out, PTA results and official xenotransplantation policies were congruent. The same was true for Switzerland. Again there was an agreement between PTA results and government policies, which were decided before the end of the participatory exercise. In the Canadian case, it was hard to pinpoint a direct impact of the consultation exercise because the government did not make an official statement on its xenotransplantation policies, and, in accordance with the public consultations' opinion, thereafter no clinical trials were carried out.

However, adopting a broader framework for analysing impact as developed in the CIT-PART project, the PTAs can all be argued to have had an impact on the development of xenotransplantation regulation. The PTAs contributed to creating a public to the issue, to a (re)configuration of the relationship between relevant actor groups, to the definition of xenotransplantation as an issue and to a (de) certification of claims made, and of actor positions in the debate and regulatory procedures. In all three cases, PTA exercises were considered legitimate and meaningful ways to gain knowledge and to involve the public in a debate about science and technology policy.

PTA exercises also turned out to be helpful in including opposing views on an issue (e.g. animal-rights). This was effective in Canada and Switzerland but only partly successful in the Netherlands, where a small group of animal welfare activists fundamentally opposed to xenotransplantation literally remained on the margin of public consultation events. However, experiences with TA on xenotransplantation at European level and in the UK showed that the exclusion of antagonistic NGOs can have negative consequences. Necessary conditions for including opposing interest groups are: a real willingness on the side of democratic institutions to include representatives of dissenting interest groups and to accommodate their views up to a point, instead of shutting them out; and a willingness on the side of interest groups to reach a compromise. Yet, we recognize that some groups may prefer to use the public arena outside of an institutional forum – through media or street protests – to make their case.

The case studies revealed that difficulties in the integration of findings from assessment studies in policy-making is not a problem restricted to PTA. Expert TA also had some difficulties to directly impact the regulation process. While in three of our cases, the TA exercises had a strong impact on policy-making, in another two, direct impact was weaker, or 'mixed' at best. However, in three cases there was no direct impact on policy-making at all. Important factors that co-determined a study's impact were: a) the institutional locus of the advisory body, b) its mandate as advisory or regulatory body, c) the extent to which its connection to policy making was institutionalised, and d) its reputation as a competent and independent organisation. Moreover, the technical development of the policy issue and the issue's framing in political and broader public debate played a role.

Citizen participation in technically and ethically sensitive policy issues

To sum up, the CIT-PART project showed that in spite of a strong call for citizen engagement (in circles of experts and professionals, rather than among the public), the extent to which citizens were actually engaged in processes of debating and regulating xenotransplantation was very limited. Initiatives to that end were strongly contingent on context-specific national and historical developments, and were influenced by the way the issue of xenotransplantation was initially framed in expert reports prepared by international organisations and 'first mover' countries, as primarily a technical problem.

More generally, as regards the question whether PTA would inevitably lead to a restrictive policy, our analysis showed that two of the three political systems that made use of participatory instruments featured restrictive regulations on the risky new technology xenotransplantation. Equally, not all countries and international organisations that favoured expert advice ended up with permissive regulations. The CIT-PART project thus gives evidence of the perhaps counterintuitive observation that the involvement of the public does not necessarily lead to a 'Not-In-My-Backyard' sentiment resulting in a non-introduction of the (new) technologies discussed, nor that a concentration on

expert advice in decision-making makes acceptance of a new policy more likely. As concerns some questions of gender, our study showed that women were more equally represented in advisory bodies and as participants in citizen forums and public discussion than in expert TA. There was more awareness towards the composition of such bodies in PTA than in TA arrangements. PTA therefore has the potential to further the cause of women in discussion, consultation and decision-making in science and technology policy.

Our research also showed a number of factors which can restrict citizen participation.

- The case of Latvia showed that a topic has to be perceived as political to be meaningfully addressed by participatory practices. Citizen participation simply does not make sense as long as xenotransplantation is exclusively perceived as a matter of individual choice about a medical treatment made by a single patient and his/her physician, rather than a political issue concerning society at large. Understood as a matter of individual choice, questions of collective risks, ethics and human rights are bracketed out of the discussion. This observation has far-reaching implications. It draws attention to the need to frame an issue as a matter of political judgement rather than (or in addition to) individual (medical) choice in early (international) reports that mark the beginning of processes of policy-making regulation. The xenotransplantation case studied in the CIT-PART project shows that the predominantly technical framings of the authoritative reports of the OECD and the WHO, among others, impacted the way the issue was picked up and understood on the national level. Furthermore, on the national level, decisions on individual clinical trials made by expert commissions on a case-by-case basis also undermined an understanding of xenotransplantation as a fundamentally political issue.
  As the case of Latvia and Austria showed in order to give the notion of 'citizen participation' any meaning, the public has to see itself as a legitimate actor vis-à-vis policy makers and experts in discussing some issue. A lax attitude among the public is reinforced by policy makers' and experts' attitude of what one may call the paternalism of adopting a 'deficit model' in organizing public debate (Felt/Wynne 2007).

  Also traditions of neo-corporatism in which strong interest groups dominate policy-making and exclude direct citizen involvement (Sweden, Austria) can hinder PTA.
  This is also true for the strong and exclusive link between elites from science and civil service observed, e. g, in the OECD. Adopting such deficit models, as was the case to various degrees in our cases (Austria, Latvia, Sweden, Vatican, and even in the staging of a full PTA in the Netherlands), implies denying the public a legitimate voice. Yet, what CIT-PART also shows is that a PTA often presents a first occasion for people to encounter an issue, and as such is instrumental in creating a public for the issue in the first place. Awareness of that role, in addition to an acknowledgement that this does not necessarily imply the attitudes associated with the deficit model may help set the stage for proper public engagement.

- As already mentioned, framing turned out to be a critical issue in citizen participation. Who is allowed to determine what framing counts as legitimate in a (P)TA setting? In several cases TA only allowed for downstream-oriented and strictly scientific framing with an emphasis on "sound science" and risk evaluation. It sometimes explicitly excluded a broader framing by social, ethical, economic and political questions. Scientific commissions who subscribed to a strict scientific paradigm sometimes delegated these questions to ethics commission, which in fact rarely convened. Often it was solely experts and policy-makers who framed the topic and controlled access to TA, while the public was left out or, as was sometimes the case in Sweden, was considered represented by experts and elected politicians. The PTA examples of Canada, the Netherlands and Switzerland showed that broader and up-stream framing was possible, overcoming a narrow scientific framing and downstream orientation.

- In addition, in some countries such as Austria, Latvia and Italy the lack of organizational structures and funding for PTA badly impeded the potentiality of citizen engagement.

The cases studied in the CIT-PART project revealed a number of elements in existing TA and PTA exercises which might facilitate public involvement.

- In several cases countries could build on existing traditions and practices of citizen involvement in policy-making. This includes the Canadian tradition of including individuals and groups in Royal Commissions; Denmark, though it did not use PTA in xenotransplantation, in many other cases has a strong tradition of adult education; in the Netherlands a tradition of policy negotiation exists (the so-called Polder Model), which puts consultation at the heart of policy preparation and formulation. This idea is also present in the country's approach to PTA, where the tradition of stakeholder consultation is broadened to include the wider public; Switzerland, finally, has a strong tradition of direct democracy. It was obvious in our cases that countries lacking such traditions of citizen participation did not consider PTA or attach meaning to the notion of citizen engagement.

- In order to get to a broad framing of the issue and to involve citizens in as many ways possible, it is necessary to apply a multiplicity of methods. The Canadian PTA is a good example in this case. In a representative and an open model, a number of different methods were applied to encourage public consultation and public participation.

- Xenotransplantation is a multidisciplinary research field, which involves scientific areas such as surgery, physiology, immunology, genetics, infectious diseases, and veterinary medicine and therefore it also crosscuts policy fields and departmental responsibilities. This poses a particular challenge to TA and PTA. Canada provides a good example of how to deal with this challenge. Recognizing that xenotransplantation was a crosscutting and inter-departmental issue which concerned human health, animal issues and ethics, Health Canada took particular care to create interdepartmental coordination and to embed a new instrument for public consultation in its organisation. PTA was meticulously planned and later evaluated. The overall positive evaluations of PTA and its prior embedding in the organisation enabled long-term institutional learning which established public consultation as a routine tool in a ministry (Einsiedel et al. 2011). Together with Switzerland (Griessler 2011), Canada is a good example of how to adapt the Danish consensus conference model successfully (Klüver 2002) in another country.

- Transparency and accountability are important challenges for TA and PTA. In this respect we can learn both from cases of TA and PTA. In Switzerland the organisation actually carrying out PTA was selected after an international open call for tender. This contrasts with some examples where recruitment was based on opaque political nomination or self-selection by personal acquaintances and on unclear selection criteria. The advisory system at EC level that dealt with xenotransplantation is another example of good practice in this case. In the aftermath of the BSE scandal it developed routines of recruitment and committee work that contribute to accountability (Griessler et al. 2012a). This includes the recruitment of members after an open call for expressions of interests and the publication of selection criteria. Moreover there are established working routines such as regularly demanding declarations of conflicts of interest, publication of agendas, meetings, reports, and public consultation. Though there is always room for further improvement, these routines established in EC scientific advisory bodies might serve as examples to increase accountability (Griessler et al. 2012a). Openness is another important element in PTA. The British UKXIRA's approach of holding its annual meeting in public (Brown/Beynon-Jones 2011) might provide an example for the increasing accountability of advisory bodies.

- As can be seen from our study, the creation of impact on the regulatory process is a particular challenge to TA and PTA. The Swiss TA and PTA on xenotransplantation provide good examples how to make an effort to embed such exercises in the wider social and political context in order to increase direct impact on policy-making. TA-Swiss involved the Ministry as co-organizer and member of the advisory boards that accompanied the studies. It presented the results both to Parliament, the Ministry and to the general public at a press conference.

- Involving antagonistic groups in PTA and TA is also a particular challenge. Again TA-Swiss provided an example how to involve groups critical of xenotransplantation fruitfully into TA and PTA by including them in advisory boards and involving them as experts and informant NGOs (Griessler 2011).

- The division between natural sciences on the one hand and social sciences, humanities and ethics on the other is a particular challenge to both TA and PTA. In our cases there were several examples of how successfully to address and partly overcome this division. In Sweden natural scientists and social scientists started to collaborate in research projects that also investigated the meaning of xenotransplantation for patients and the social dimension of xenotransplantation (Hansson/Lundin 2011). The methodology used in the Pontifical Academy for Life, in which scientists and ethicist discussed questions of science and ethics was highly appreciated by interviewees (Griessler et al. 2012b). This example might need further investigation in order to remedy the obvious lack of ethical considerations in many of the TA studies.

Recommendations

1. PTA was carried out only in a minority of cases in regulating xenotransplantation, and had little direct impact on it. Still, when assessed in terms of the process-oriented impact assessment framework developed in the CIT-PART project, PTA can be considered a success, given its numerous positive effects in creating and stimulating public debate. It is recommendable therefore that the use of PTA should be increased, particularly in expert international bodies and in the EU advisory system, which despite their high significance for international policy development tend to frame discussions of technologies purely in terms of sound science.
2. International expert bodies are advised to increase awareness of how their work may impact the way an issue is framed in (national) policy-making processes. In addition to the many mechanisms that increase accountability, the encouragement to include citizens in processes of analysis, judgement and even decision-making should be more than just an appendix to the recommendations. Only if the idea of civic engagement is at the heart of a body's framing of the issue may it further help public involvement on a countrywide level.
3. CIT-PART shows that a PTA often presents a first exposure of people to a particular issue. The instrumental role of PTA in creating a public in relation to the issue should not be confused with, or understood per se in terms of the deficit model. The deficit model implies denying the public a legitimate voice. A perspective on reaching out to an audience to create a public implies setting the stage for genuine civic engagement in political judgement. The theatre play included in the Dutch PTA setting, based on a British play, which toured schools and other young people's meeting places, presents a good example of how to establish such an involvement practically. However, the case of Denmark revealed that in some cases it might not be useful to plead for a PTA, because, depending on a country's history, culture and specific setting, the topic is considered benign, uncontroversial or untimely, or only relevant in too distant a future.
4. Allow for a broad framing that not only considers "sound science" but also allows for social, political, economic and ethical questions raised by stakeholders and the public.
5. Try to embed PTA as much as possible in an organisation to increase its impact and instigate institutional learning. Most topics in science and technology policy present issues that cut across institutional borders. Take into account departmental specialisation, which might be connected to departmental fragmentation and struggles. Work against organisational fragmentation by involving responsible authorities, agencies and departments in order to increase the impact of PTA later on.
6. Build on existing participatory traditions and practices.
7. Take also into consideration factors that might hinder PTA such as closeness of policy-making, closely knit policy communities, paternalism, expert orientation, lack of accountability, transparency and openness, lack of open public debate and active mass media. Learn from and improve existing international examples that worked to overcome these obstacles. There are good examples not only in PTA but also in TA for critical elements such as transparency, openness, accountability, embedding, diversity of methods, involvement of antagonistic groups, overcoming the division between the different cultures of science, opening of framing, improving timing, and enhancing direct impact.

8. Think about how to increase direct impact on policy-making but also on broader terms of impact in the public debate.
9. Timing turned out to be a problem in two cases of PTA, i.e. the result of PTA came shortly or long after a political decision was made. Only in Canada was it stated that no decision would be made until the PTA was finished. Several cases showed that regulators felt a certain urgency to arrive at policies, which were produced by the promises of xenotransplantation research that clinical trials would be imminent (Beynon-Jones/Brown 2011). However, predictions that clinical application was 'just around the corner', it turned out, were unrealistic. Participatory experiments need time. Policy-makers therefore should consider not answering the pressure produced by promises from science and industry too promptly, and allow sufficient time to stimulate proper civic engagement in procedures for political judgement on issues such as xenotransplantation, which touch on the very basics of our understanding of public health, medical choice, collective safety and human identity.
10. For researchers of public engagement in science and technology policy, it is recommendable not to take formal arrangements for public debate as a point of departure in designing research. As the CIT-PART project shows, wider perspectives of how science and technology policy unfolds, for instance by taking a particular issue as a starting point in the analysis, shed light on subtle and complex conditions under which civic engagement is stimulated or hampered in today's networked arenas for public policy-making.

annex

List of abbreviation

BSE	Bovine Spongiform Encephalopathy
CIT-PART	Project Acronym for "Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field"
CNB	National Bioethics Committee (Italy)
CNBB	National Committee for Biosecurity and Biotechnology (Italy)
DGs	Directorate General
DOC	Dynamics of Contention
EC	European Commission
ECEAE	European Coalition on the End of Animal Experiments
ELSA	Ethical Legal and Social Aspects
EMA	European Medicines Agency
EMEA	European Agency for the Evaluation of Medicinal Products
EU	European Union
GMO	Genetically Modified Organism
MP	Member of Parliament
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
PAG	Public Advisory Group
PTA	Participatory Technology Assessment
QCA	Qualitative Comparative Analysis
SCHER	Scientific Committee on Health and Environmental Risks
SCMPMD	Scientific Committee on Medicinal Products and Medical Devices
STS	Science and Technology Studies
TA	Technology Assessment
UKXIRA	United Kingdom Xenotransplantation Interim Regulatory Authority
WHO	World Health Organisation

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