

# **Decision-making on Complex and Sensitive Issues – A Case for Citizen Participation?**

## **Experiences with Xenotransplantation**

### **CIT-PART**

Documentation of the Final Workshop  
12 June 2012, Wien-Haus, Brussels



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# **Decision-making on Complex and Sensitive Issues – A Case for Citizen Participation? Experiences with Xenotransplantation CIT-PART**

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Founded in 1963 by two prominent Austrians living in exile – the sociologist Paul F. Lazarsfeld and the economist Oskar Morgenstern – with the financial support from the Ford Foundation, the Austrian Federal Ministry of Education, and the City of Vienna, the Institute for Advanced Studies (IHS) is the first institution for postgraduate education and research in economics and the social sciences in Austria.

Das Institut für Höhere Studien (IHS) wurde im Jahr 1963 von zwei prominenten Exilösterreichern – dem Soziologen Paul F. Lazarsfeld und dem Ökonomen Oskar Morgenstern – mit Hilfe der Ford-Stiftung, des Österreichischen Bundesministeriums für Unterricht und der Stadt Wien gegründet und ist somit die erste nachuniversitäre Lehr- und Forschungsstätte für die Sozial- und Wirtschaftswissenschaften in Österreich.





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## 1 The CIT-PART Workshop

Citizens, policy makers, and social scientists often call for citizen participation to make policies more effective and democratic. A field in which this has been vigorously claimed is science and technology policy, as examples, such as new biotechnologies and nuclear energy, clearly show. Many countries therefore witnessed the introduction of Participatory Technology Assessment (pTA) exercises in science and technology policy, in which lay citizens systematically discuss the pros and cons of certain technologies. However, the ultimate test of such exercises and of citizen participation more generally is its actual impact on policy-making.

### Research Questions:

- To what extent are citizen participation exercises actually applied?
- What are the furthering and hampering factors citizen participation is facing in complex decision-making processes? And to what effect do cultural differences have in this respect?
- What can we learn about the complex relation between lay-peoples' and experts' views and expertise in TA and PTA?
- What in actual fact is the impact of PTA on decision-making?
- How can PTA contribute to increase citizens' influence on decision-making?
- Does citizen involvement increase the democratic legitimacy of policy decisions?

The CIT-PART project studied the impact of PTA and expert based technology assessment comparatively in several EU member states (Austria, Denmark, Italy, Latvia, Netherlands, Sweden, United Kingdom), the European Commission, the OECD, Canada, Switzerland and the Holy See. From the findings of these case studies, the project drew conclusions about the potential impact of citizen participation in science and technology policy at the EU level. CIT-PART addressed these questions through an analysis of 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 help to remedy the shortage of human transplants. Its opponents insist that it involves too many risks, most prominently infection from animals to humans, and ethical questions.

The final CIT-PART workshop which took place at the Wien-Haus in Brussels on June 12<sup>th</sup>, 2012 aimed to stimulate a discussion about the particular challenges of citizen participation in complex and knowledge intensive policy fields. It addressed policy makers, NGO-

representatives, researchers, and practitioners in citizen participation and (participatory) technology assessment as well as in the area of bioethics and xenotransplantation research.

## 2 Welcome and Introduction

*Erich Griessler (Institute for Advanced Studies), Simon Schunz (European Commission)*

Erich Griessler, coordinator, and Simon Schunz, project officer of the European Commission responsible for the CIT-PART project, welcomed the participants. Mr. Schunz underlined the importance of citizen participation in policymaking and pointed to the CIT-PART project as a good example of dealing with this issue from a research perspective.

Mr. Griessler presented the main goals of the CIT-PART project<sup>1</sup> and indicated the objectives of Technology Assessment (TA) and participatory Technology Assessment (pTA), respectively. The objective of expert TA is to “speak truth to power”, whereas the goal of pTA is to tap citizens’ knowledge, enabling the public to (re-)frame a topic and to increase public involvement. A crucial problem of (p)TAs, however, is their actual impact on policy-making. However, it is difficult to clarify this question because existing studies only compare (p)TA exercises which were organized at different times and dealt with different technologies. CIT-PART did international comparative research on the use and impact of citizen participation in one and the same knowledge-intensive policy field. It compared the use of expert oriented TA and pTA as processes of investigating a new technology – xenotransplantation – in several European countries, Canada, and select international organizations. Moreover, it studied the impact of these processes on actual policy-making. The selected sample was comprised of Austria, Canada, Switzerland, Denmark, the European Commission, Great Britain, Latvia, Italy, Netherlands, the OECD, Sweden, and The Holy See. The sample was selected so as to provide diversity with regards to xenotransplantation policies (i.e. include permissive and restrictive policies), approaches to TA (expert oriented and pTA), as well as diverse political structures.

The topic of xenotransplantation<sup>2</sup> was chosen for several reasons. First, in the 1990s and early 2000s there was hype about xenotransplantation and hopes existed that clinical application would be just around the corner. At the same time, xenotransplantation shares traits with several modern technologies, in the sense that it entails risks and ethical problems, for example, the tension between the benefit for individual patients versus the collective risk for society as a result of possible infection or animal welfare. Governments in different countries and international organizations rushed to come up with xenotransplantation policies at the same time. The CIT-PART project looked (1) at the way in

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<sup>1</sup> For presentation slides go to <http://www.cit-part.at/CIT-PART%20Introduction%20-%20Griessler.pdf>. More information about the project and its results can be found at: <http://www.cit-part.at/>.

<sup>2</sup> Xenotransplantation is the transplantation of organs, tissues and/or cells across species.

which these policies were developed; (2) to what extent they were underpinned by experts and citizens TA and (3) the impact of expert TA and pTA on policy development.

CIT-PART broadened the knowledge about pTA in several ways. It showed:

- cultural contingencies in the way different countries dealt with the issue of xenotransplantation
- the importance of framing xenotransplantation as a policy problem
- the dominance of expert TA as a way of finding a position with regards to xenotransplantation; in international comparison pTA was marginal
- international forums - which turned out to be most influential - were mainly characterized by strict scientific framing and an expert approach that excluded the broader public
- although the direct impact of pTA was hard to establish - e.g. because political decisions were sometimes made before pTA was finished - it was possible to establish the wide-ranging and broader impact of pTA
- the cases of Canada and Switzerland showed that it is possible to include pTA as a routine practice

Mr. Griessler concluded his presentation by thanking the European Commission for funding, the Commission officers for their support, the invited experts for their contribution, all consortium members for excellent cooperation, the City of Vienna and the Wien-Haus for hosting the workshop, and, last but not least, all interviewees for their readiness to support the project.

### **3 Session 1: Xenotransplantation, democracy and participation<sup>3</sup>**

#### **3.1 Presentation**

*Anne Loeber (University of Amsterdam)*

A video clip on the general topic of xenotransplantation and citizen participation introduced the session.<sup>4</sup> *Anne Loeber* started her presentation with a short overview on the history of xenotransplantation. She highlighted two landmark experiments to illustrate the long history of xenotransplantation. In 1902, Emerich Ullman transplanted a kidney from a goat to a dog

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<sup>3</sup> Presentation slides can be found at the website

<http://www.cit-part.at/CIT-PART%20xenotransplantation%20Democracy%20Participation%20-%20Loeber.pdf>

<sup>4</sup> The project videos, produced by Christina Lammer, can be found at the website [http://www.cit-part.at/v\\_cit01.php](http://www.cit-part.at/v_cit01.php)

and a kidney from a pig to a human. In 1984, a newborn with a deadly heart condition, who later became famous by the name of Baby Fae, received a heart from a baboon. The latter experiment, which took place at a time when scientific progress in transplantation surgery had speeded up, caused public controversy about xenotransplantation for the first time. At that time, genetic engineering and immunosuppressant medications were at a point of development, which made xenotransplantation a hypothetical possibility. But the promise of xenotransplantation also came at a time of crisis. HIV/AIDS and BSE heightened scientific and public awareness of zoonotic risks and public trust in governmental regulation was shaken by scandals about contaminated donor blood. Overall, the belief in the benignity and “goodness” of science was shattered. In this context xenotransplantation experiments continued, e.g., in Poland, Sweden, and the UK (pre-clinical trials etc.).

In the early 2000s, the promises of xenotransplantation were eventually considered disappointing. The British animal activist group Uncaged, e.g., leaked papers documenting unsuccessful scientific pre-clinical experiments by one of the major private companies promoting xenotransplantation, the UK based firm Imutran. Later on, in the mid-2000s, xenotransplantation evaporated as a research topic in Europe to a considerable extent. Imutran was re-located to the US. Moreover, other research topics, such as stem cell research, which doesn't involve the same zoonosis risk as xenotransplantation, became important research topics in regenerative medicine. As a consequence, the UK regulatory body, which had to oversee xenotransplantation (UKXIRA), was dismantled. But research on xenotransplantation never really ceased to exist.

In the second part of her presentation, Mrs. Loeber focused on the regulation of xenotransplantation and the related policy process. The CIT-PART project showed that xenotransplantation was regulated very differently in the selected cases. Some countries, such as Switzerland, the UK, and the Holy See, developed permissive policies. In these countries, xenotransplantation research is permitted as long as formal consent and permits exist. Austria, another case, took a “wait and see” attitude and developed no specific regulation in the beginning of the 2000s. Other countries, e.g. the Netherlands and Sweden issued a formal or informal moratorium on clinical xenotransplantation research. Mrs. Loeber highlighted these two countries because, although the regulatory processes in both of them were quite different, their outcomes were rather similar.

One of the questions the CIT-PART project addressed was how to account for the differences and similarities between national xenotransplantation regulations. The project therefore looked at the entire regulatory process, applying a comparative and diachronic perspective. Hardly any regulatory activity existed before 1995. This situation changed from 1996 onwards, when regulatory efforts increased. At that time, a couple of early reports on xenotransplantation set the stage for further regulatory activities. These influential documents include the Nuffield Report in the UK, which set the ethical framing. Other important activities at the international level were the reports and workshops organized by

the OECD, which influenced the framing of the xenotransplantation in an economic perspective.

The international comparison of xenotransplantation policies shows that converging dynamics were at work in various countries. Among them is the influence of the agenda setting efforts on the supranational level (e.g. by the OECD), which had a strong impact on individual countries. The OECD put the topic on the agenda and served as clearinghouse for information, bringing together policymakers from national states, international organizations, academia, and industry. Traces of the impact of the work of the OECD can be found in each case study.

Another core question of the CIT-PART project that Mrs. Loeber addressed was how and to what extent the general public was actually involved in TA and regulatory processes. Was there any public engagement at all? CIT-PART showed that formally, the public only got involved in a few cases in a deliberative way of exchanging information. Public involvement occurred in countries where fully-fledged pTAs were carried out, i.e. Canada, the Netherlands, and Switzerland. However, the absence of formal pTA-arrangements does *not* necessarily imply that the public was not at all involved. In other countries, the public was involved in many, very different manners.

This observation led Mrs. Loeber to continue to highlight three general topics concerning public participation which in her view characterize the debates about public engagement triggered by the issue of xenotransplantation:

1. What is the nature of participatory arrangements? Are they set up to enable the public to voice their concerns and claims about some issue, or to inform and educate people about the issue in the first place?<sup>5</sup> The underlying issue here is the question whether it is at all possible to arrange for a pTA or other form of public deliberation, if there is no 'public concern' about some issue at all, possibly because information on a newly developing technology has not reached the general public yet. Does one need to inform 'the people' first in order to enable a public debate, and if so, what implications does that have for the way the pTA is organized?
2. Who has the right to speak? Who is considered a legitimate discussion partner in a debate about some issue?<sup>6</sup> This question is directly linked to the first discussion issue.

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<sup>5</sup> Mrs. Loeber showed, by way of illustration, a slide with a quote taken from the Dutch debate on organizing a pTA on xenotransplantation, which was frowned upon by some: "Is it possible to initiate a debate when any germ for such a debate is absent among the public? ... A public debate implies that a broad circle of people acknowledges that something bad is going on. ... The discussion about these themes searches a natural bed in society and ends in The Hague, where the decisions have to be taken." (Van Kleef, 1995)

<sup>6</sup> Again Mrs. Loeber illustrated the issue with a quote, here of the Dutch minister responsible at the time for organizing a pTA on xenotransplantation: "I find it more legitimate [compared to people that eat pork] that a vegetarian such as [a member of parliament, who was known to be a vegetarian] starts a disquisition about the

In a pTA that is set up initially to inform and educate a by and large uninformed public about some issue, the power to define 'legitimate participants' lies strongly in the hands of the initiating party. This was observed in the Dutch case where a small ad-hoc anti-xenotransplantation working party, which was genuinely engaged with the topic, found it very difficult to have their views acknowledged in the pTA. The way the Dutch pTA was set up to reach out to an 'innocent public' to inform them about xenotransplantation did not allow room for the voicing of alternative framing of the issue.

3. The discussion about the function of a pTA and the selection of legitimate discussion partners leads to a third, more fundamental question that deserves attention: Do formally arranged pTAs serve the need for expressing public concerns? Do they allow for sufficient opportunities to engage in debates? In some cases, where pTAs existed, particular groups (e.g. patient groups) deliberately stayed out of these formal arrangements. Furthermore, the fact that no public formal pTA arrangement existed, does not necessarily mean that the public was completely absent (see for instance the playful protest as shown in Channel Four's Mark Thomas Comedy Product Series)<sup>7</sup>.

Mrs. Loeber concluded her presentation by remarking, that some of the CIT-PART findings were "surprisingly unsurprising." Xenotransplantation carries with it the potential for public controversy: it includes ethical issues, and pertains to collective as well as individual risks. Furthermore, it has the potential to stimulate debate among a broad range of institutions, connecting actors who in another context would not normally meet (healthcare, animal welfare, etc.). But this potential hasn't been realized to the degree expected (regulatory efforts, public debate, etc.). The CIT-PART project showed why and how this was the case. At an early stage, regulatory actors, such as the OECD, framed the topic from an economic and medical perspective. Their early studies served the need for information of other institutions and nation states in search for a basis to discuss and regulate the issue. This early framing thus became and remained dominant, and was hardly challenged. Even formal participatory practices, such as pTAs, didn't challenge the dominant framing.

All in all, the limited extent to which xenotransplantation stirred controversy and discussion, according to Mrs. Loeber, results from a "double misfit", between scientific developments and established regulatory practices, on the one hand, and between regulatory practices and pTA, on the other hand. PTAs – the few that were organized – did not fit into, and thus did not impact, the established regulatory practices; they more or less were carried out parallel to the regular policy making process. Finally, she presented a number of recommendations for political practices drawn from the project:

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instrumental use of the pig as an organ donor and regard this as a big ethical problem, than all those Dutch people who are no vegetarians and still say: you cannot breed an animal to then use it as a donor. Apparently you can if you eat them" [Dutch Minister of Health, after agreeing to initiate a societal debate]

<sup>7</sup> See the still in the Power point presentation. Source: <https://www.youtube.com/watch?v=OqTVEzpUMgc>

- Possibly contrary to what one would expect on the basis of the modest impact of pTAs studied in the CIT-PART project, a clear recommendation to be drawn from the research is that PTAs are important. They are often a first occasion for the public to be introduced to a topic. Thus, they can initiate public engagement and political will formation. Given a proper embedding in the regulatory process, this can serve as an opportunity to widen initially narrow scientific and economic framings.
- International organizations and scientific advisory bodies should be aware of their role in initiating debates and the strong grip they have on how an issue gets framed. It is recommended that the initial framing should be deliberately broadened to include ethical issues. It should be acknowledged that an issue that is potentially controversial can and should be the topic of wider societal debate and political deliberation.
- Finally, in order to enable proper political will formation and deliberation in the public domain, regulation should not be done on a case-by-case basis, but the issue should rather be kept “public” (“res publica”) and discussed in general.

### 3.2 Panel Discussion

*Anne Loeber, Annika Tibell (Karolinska Institutet), Mariachiara Tallacchini (Università Cattolica del Sacro Cuore), Sergio Bellucci (TA-Swiss), Moderation: Erich Griessler*

The main objective of the workshop – as presented by Erich Griessler – was to get different perspectives on xenotransplantation and citizen participation. He therefore asked each panel member for a short introductory statement on the topic and the project.

*Mariachiara Tallacchini* took a legal perspective on xenotransplantation and focused particularly on the legal framework of xenotransplantation, as coproduced by science and law.<sup>8</sup> She distinguished three regulatory models (taking place at the beginning of the 21<sup>st</sup> century): (1) a science-based US policy model; (2) a policy-related science applied by the Council of Europe and the EU; (3) an extended participatory or peer review model used in Canada and Australia.

The US system can be categorized as individualistic and contract-based, in which the traditional clinical trial model applies, with an agreement between sponsor and patient, and the sponsor as the main responsible for the trial. The state becomes involved only in case of liability for unexpected events (if participants or third parties go to courts, according to the Common law system). In Europe, the EU and Council of Europe favoured a compulsory regulatory framework where patients could not withdraw consent after the procedure, and

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<sup>8</sup> For more details see the presentation slides to be downloaded at <http://www.cit-part.at/CIT%20PART%20XTP%20democracy%20and%20participation%20-%20Tallacchini.pdf>

their behaviour could be lawfully restricted according to public health needs;<sup>9</sup> whereas in Australia and Canada civil society and the state worked together to establish a fully legitimate regulation.

From Mrs. Tallacchini's point of view, US policies were very influential. In 1990, the Nobel Prize candidate for immunology, Fritz Bach, claimed that xenotransplantation researchers were ready for clinical trials, but no such trials happened until 1996 – as previous cases (such as the Baby Fae case) were seen as isolated experimentation undertaken by prominent surgeons pioneering the field. At that time, public agencies published a draft guideline for clinical experimentation. This guideline strongly framed xenotransplantation, from a scientific and policy point of view, along the existing guidelines of biomedical research.<sup>10</sup> The scientific background for the guideline was the assumption that AIDS could be used as the default infectious disease on which the guideline should be specified. However, as AIDS transmission can be controlled by adopting a responsible behaviour and its containment is compatible with a liberal society, the analogy with potentially unknown infections in xenotransplantation was imperfect. Unknown xeno-infections may include diseases such as SARS, Ebola, and similar airborne infectious diseases: all requiring compulsory measures for public health reasons. Instead, the basic assumption of the US guideline was that risk control was possible.

In 2001, two directives were published in the EU that left much room for national decision-making. The former, Directive 20/2001 on clinical trials, established that ethics committees have no deadline to provide their binding opinion on an experiment with xeno-cells. The latter was the GMOs directive (Directive 18/2001) asking for forms of public consultations to take place in Member States. Europe had the opportunity to frame the issue in two different ways: either according to the US biomedical research paradigm or to a broader environmental and public health impact assessment. In 1996, the British Nuffield Council for the first time suggested that the precautionary principle could apply not only to the environment, but to all biotechnology, including xenotransplantation, because of the risks involved in releasing genetically modified animals into the environment and the risk of spreading epidemics or pandemics. European science mostly focused on precaution. For example, the British researcher Robin Weiss was the first scientist who showed, that porcine retroviruses can infect human cells. In the same line, the Council of Europe called for a moratorium on xenotransplantation clinical trials in 1999.

Compared with the US and Europe, Canada and Australia took a radically different approach, seeking legitimization through democratic participatory procedures. Eventually, Australia called for a formal five-year moratorium. However, after the moratorium expired,

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<sup>9</sup> The EU (not the Council of Europe) regulatory framework was modified with the regulation on ATMP (Advanced Therapy Medicinal Products), but only in relation with cells and tissues.

<sup>10</sup> In 1995 the Office of Technology Assessment (OTA) was discontinued, which never gave an opinion on xenotransplantation because it was considered as an issue of individual risk.



Australia was ready to start again with xenotransplantation. In Canada, no formal moratorium was declared, but no proposals for clinical experimentation have been submitted since.

Mrs. Tallacchini also pointed out the phenomenon of “neo-colonialism” in research with regards to ethics. In 2001, in Mexico, type-1 diabetic children were enrolled in a clinical trial with pancreatic porcine cells without the possibility for the international community to intervene because the trial had been approved by the national ethics committee and national health authorities. More recently, New Zealand, in order to allow a private company to perform a trial with xeno-cells avoiding criticisms, launched a (quite controlled) public consultation; thus showing that the potential for normalizing the problem of xenotransplantation by means of using public consultation was very strong. According to Mrs. Tallacchini, public consultations have become a major way to normalize all controversial technologies in Europe as well, as in the case of Advanced Therapies (mixing human and non-human cells).

Mrs. Tallacchini didn't think that societies are necessarily going towards more democratic ways of dealing with issues like xenotransplantation just because of public consultation procedures. At the origins of biotechnology, ethics and ethics committees were supposed to represent citizens' values; instead, they have become a bureaucratic way to produce values and take them for granted.

Finally, Mrs. Tallacchini raised a number of open questions:

- What is the role of pTA regarding xenotransplantation today? Since TA is typically applied with emerging technologies, is TA only relevant for emerging and not for re-emerging technologies such as xenotransplantation?
- Are we still looking at national publics?
- How can the relevance of citizens in the international arena be increased?
- How can infectious diseases be managed in more participatory ways, minimizing the use of compulsory measures?

*Annika Tibell* was involved as a scientist (transplant surgeon) in xenotransplantation research and also participated in national and international policymaking processes. For her, the CIT-PART report was interesting because it provides an outside perspective on the work, which was done in political organisations that dealt with xenotransplantation. She identified a connection between the sense of urgency for regulation felt at that time and the actual existence and extent of experimental xenotransplantation research in a country. Critical questions that are discussed internationally are defined at an early stage.

Mrs. Tibell posed the question, why the scientific field at the moment is rather silent about xenotransplantation? She picked up the example from the research group that worked in Mexico, but then moved on to Russia, developing countries and New Zealand.

From her experience with working in the US, she reported a strong involvement of the public health service in regulation. The FDA had to approve procedures and set quite high thresholds to authorize research. Federal agencies had a strong involvement in the development of xenotransplantation. But in the US there is still a strong effort to do xenotransplantation. And there is a group with pretty good results. But altogether, for several reasons, there is not that much work on xenotransplantation anymore. First, research is also subject to trends and xenotransplantation isn't among them at present. The second reason is money. When Imutran moved to the US, it wasn't the same company anymore but only a small part of it. Xenotransplantation is an enormously costly enterprise, especially because of safety precautions and the use of non-human primates. Imutran, e.g., invested about 50 % of their funds into safety precautions regarding infectious diseases. It is impossible to finance these measures with small nationally granted funds only.

Mrs. Tibell believed that some applications of xenotransplantation might be biologically possible, but was unsure whether they will ever become reality. She presented a slide of a cover-picture of *Nature* from 22 January 1998 showing a small man riding on a giant pig. The headline to the caricature said: "Xenotransplant hopes and fears". The issue was published on the same day that the US public health service had a hearing on xenotransplantation directives. Annika Tibell participated in this hearing. Fritz Bach, one of the leading pro xenotransplantation researchers, was the one at the meeting who added his caution about the infectious risk. With this and the "Nature" issue the atmosphere about xenotransplantation changed.

*Sergio Bellucci* applauded the CIT-PART report and started his input with the topic of technology assessment (TA), its methods, role and impact. TA-Swiss contracted three studies, two on xenotransplantation – first on organ and later cellular xenotransplantation - and one pTA, the so called "PubliForum Transplantationsmedizin".

Mr. Bellucci was critical of the notion, made by Mr. Griessler's in his introductory remarks, that increasing public acceptance of new technologies is one of several goals of pTA. The role of TA is rather to evaluate public acceptance of a new technology, to identify controversial aspects of technology and to analyse patterns of pro and con arguments. TA-Swiss carries the mandate from the Swiss Parliament to carry out studies on new technologies in this way. These studies are interdisciplinary and include ethical, legal, medical and social aspects of the issue concerned.

Typically, TA-Swiss starts with an expert study and try to evaluate the public opinion on a certain topic later on. In 1998, TA-Swiss started with the first study on transplantation (one

aspect of this was xenotransplantation) and it took about ten years until a law finally came into force. A major problem of TA, identified by Mr. Bellucci, was the timeliness of such an endeavour, i.e. neither to start too early, because then no political discussion will occur, nor too late, because TA will then probably have no impact.

According to Mr. Bellucci, it is important to recognize that TA-organisations do not have the task of quantifying the impact of a TA procedure but rather to advise members of Parliament on certain topics. Finally, it is up to politicians to decide. The impact that the Swiss pTA had on transplantation had can be seen from the parliamentary discussion and statements during the law-making process. Both frequently refer to the TA-paper drawn up by TA-Swiss. Another way TA-Swiss can yield an impact is through direct communication with policy-makers. The authors of a study are often invited to hearings with Members of Parliament to provide direct advice. Overall, Mr. Bellucci was sceptical about the possibility to measure the impact of (p)TAs, simply because it is not the role of TA to produce decisions.

Mr. Bellucci emphasized the importance of an interdisciplinary approach, where TAs involve politicians, government staff (e.g. the minister of health), (critical) NGOs and scientists. Switzerland has a very particular political system, in which direct democracy forms an integral part. Within this particular context, Mr. Bellucci identified the general public as being overwhelmed to a certain extent by the opportunity to vote on complex technological issues like xenotransplantation. Besides, the Swiss Parliament is not a professional but a “Milizparlament” (“militia-parliament”) that meets four times a year for two weeks. Members of Parliament have other professions as well and are not experts in new technologies. Therefore, it is important to provide them with objective information. It is the founding idea of TA-Swiss, as an autonomous organisation, to provide this information to Members of Parliament.

In the subsequent discussion, *Mrs. Tibell* raised the question of how to transport neutral information on a particular topic to the public. *Mr. Bellucci* replied that TA-Swiss prepares its projects (including TA projects) over a one-year period and that for each project they put together an advisory group. These groups consist of people from different interest groups (e.g. industry, patient organisations, politics, etc.). In these groups, TA-Swiss prepares an information brochure about the topic, with an attempt to reach consensus on the content within the group. There are also introduction lectures on the respective issue under discussion. Mr. Bellucci pointed out, that this process might be difficult but very important nevertheless.

*Mrs. Einsiedel* asked *Mrs. Tibell* whether the increasing research in human stem cells is connected to the demise of xenotransplantation. She also wondered whether and how international ethics guidelines would be worked out in developing countries, where xenotransplantation research is now increasingly carried out.

*Mrs. Tallacchini* stated that the International Xenotransplantation Association (IXA), together with the WHO, is trying to find out what ethical means can be used in the difficult relationship between the international scientific community and the national sovereignties, but that this was identified as a complex problem with a variety of aspects to be considered and assessed. In her point of view, the xenotransplantation community ended up by performing not only science, but also ethics, sociology, and regulation. Moreover, an ongoing discussion within the xenotransplantation community concerns the ethical acceptability of exploiting (and publishing) medical results obtained from non-ethical practices.

*Mrs. Tibell* commented that transplant-surgeons' attitude towards society is special, since they depend on donor organs to help their patients. This attitude also influences the role of IXA. IXA and the Transplantation Society can put professional pressure on e.g. governments. They could, for example, approach individual governments and inform them about their view of the "state of art". Mr. Tibell commented on stem cells, saying that ten years ago people would also have believed - like with xenotransplantation some years before - that this technology was just "around the corner", which has turned out not to be the case.

*Mrs. Wolfslehner* asked whether the lack of money was solely responsible for the decline in xenotransplantation research efforts. Mrs. Tibell replied that there were indeed financial issues, but trends in the scientific community played a role as well. Xenotransplantation became controversial the moment the retrovirus-discussion started. Then, many researchers stopped their research to wait and see how much risk there actually was.

## 4 Session 2: (Participatory) Technology Assessment and Politics

The session started with a video about the relationship between TA and politics.<sup>11</sup>

### 4.1 Presentation

*Janus Hansen* (Copenhagen Business School)

*Mr. Hansen* presented results of the CIT-PART project on the role of TA and pTA in their relationship to politics and policy-making.<sup>12</sup> The questions addressed included:

- What functions do (p)TAs serve?
- When are (p)TAs used?

<sup>11</sup> The video clip, produced by Christina Lammer, can be viewed at [http://www.cit-part.at/v\\_cit03.php](http://www.cit-part.at/v_cit03.php)

<sup>12</sup> For presentation slides go to: <http://www.cit-part.at/CIT-PART%20pTA%20and%20Politics%20-%20Hansen.pdf>; last accessed: 02. January 2013.

- What is their democratic potential? They are promoted as a mean to strengthen democracy, so what is their outcome in this regard?
- When do (p)TAs achieve impacts and what actually counts as impact?
- Which factors facilitate and constrain the use and effects of (p)TAs?

Mr. Hansen emphasized that since both have different goals; TA and pTA should be separately discussed with regards to their political function.

- TA aims at supporting political decision-making through expert input. Originally TA was conceived to prepare society for technological innovation, including negative side effects. Technological innovation at that time was understood as a linear process, society had to be prepared for. TA tries to serve this purpose by using scientific expertise in order to forecast future developments. Within this framework, TA's legitimacy lies within its scientific competence.
- pTA was introduced as a response to criticism raised against conventional expert TA. pTA should facilitate decision-making through deliberation and participation of ordinary citizens or various stakeholders with different interests in the issues being discussed. pTA is about adjusting technological innovation and regulation to societal needs. These processes receive legitimacy through inclusion, by having the right composition of participants (citizens, stakeholders). However, there are also concerns that pTAs might generate public acceptance of technologies through token inclusion: they only create discussions about topics which are anyway decided in different forums.

The case studies of the CIT-PART showed that most countries introduced elements of expert TA in some way or another as soon as xenotransplantation reached the political agenda. CIT-PART showed that policy ideas and framings circulated internationally to a significant degree. First movers, such as the UK and the OECD, were able to successfully set the agenda. PTAs, in contrast were much more infrequent than expert TA. In global comparison, only three countries used pTA. The causes why these pTAs were organized were contingent on country specific circumstances; they were incorporated in different existing discussions (blood contamination, genetic modified animals, transplantation). In addition, all these three countries had some previous experiences with participatory procedures. The pTAs carried out were in general considered procedurally robust and legitimate. The CIT-PART project again showed that the link to policy-making is central for both TAs and pTAs. Comparison showed the importance of the fact that the institution that organizes a pTA has proper institutional standing and is able to tap connections with the political system. TA-Swiss, for example, is very closely connected to the Swiss political system. In the other two cases of pTA, the respective organizations were more marginal and it was less easy to gain an impact on policymaking.

Mr. Hansen asked, under which circumstances pTAs were adopted. In the CIT-PART cases, pTA was carried out when xenotransplantation was controversial in public or it was anticipated that it might turn into a controversy. But public concern was a necessary, but not sufficient, precondition. Other factors played an important role as well. The political system has to be to some extent open (for agenda setting, etc.). Moreover, there is a certain kind of path dependency, since previous experiences with TA existed in all cases of participatory processes.

Another topic of the CIT-PART project was the democratizing potential of (p)TAs. Mr. Hansen emphasized that democracy is an utterly contested concept. There is no clear and consensual definition of democracy and it means different things to different people in different institutions. Therefore, any statement on the democratizing potential of pTA depends on the model of democracy used.

Two main ideals of democracy exist within democratic theory. First, there is a liberal or representative ideal, which forms the institutions or ideas of most representative democracies. Most CIT-PART cases belong to this category. Second, a direct, participatory or deliberative ideal exists. The liberal ideal matches with expert TA. It draws a clear distinction between facts and values and is uncomfortable with pTA because it holds that the latter creates a platform that would not represent the general electorate. PTA, on the other hand, matches with the deliberative ideal of democracy, which takes up the position that everything is political and that it is impossible to draw a clear line between facts and values. The deliberative form of democracy is more uncomfortable with expert TA because it tends towards technocratic forms of governments.

In the CIT-PART project, the country cases were assessed within this theoretical framework: When evaluating TA/pTA from a perspective informed by *liberal ideals of democracy* three issues are central:

- Equal weight to all citizens
- Decisions should be informed. Citizens should get adequate and unbiased information.
- Decision makers should be accountable. Decision-making process should therefore be transparent.

In the CIT-PART sample, Canada, Denmark, Netherlands, Switzerland, Sweden and the UK performed relatively well according to these ideals emphasized in representative democracy.

The *deliberative ideal* has slightly different concerns:

- It is concerned with inclusion of all people that could be affected by a decision; every person with a legitimate interest should have a voice.
- The participants frame the issue by themselves; they must be enabled to bring up the issues they deem relevant.
- The procedures are deliberative. The procedure should not involve deliberation through power struggle but through debate and bringing forth different perspectives.

Only three cases in CIT-PART had pTAs and not all the criteria were fulfilled in these cases.

The case studies can be ranked qualitatively according to the degree of implementation of TA and pTA in the regulatory process.

Rank	Country
1	Switzerland (expert TA, pTA)
2	Canada, Netherlands (expert TA, pTA)
3	UK (expert TA, public communication)
4	Denmark (expert TA)
5	Sweden (expert TA)
6	Italy (some expert TA at regional level)
7	Austria, Latvia (no policy debate, no targeted regulatory activities)

Mr. Hansen continued with drawing several conclusions from the analysis of the different cases. Different approaches exist to determine to what extent procedures are democratic; however, they are not mutually exclusive but rather correlate. Countries, which performed well according to the representative ideal, can also perform well according to the deliberative ideal. Not all pTA or TA instruments fit well in all contexts; there are different institutional setups and political cultures. Mr. Hansen pointed out, that it is important to be aware of the normative basis of the assessment of the democratizing potential of procedures. Scientists have to be conscious of the democratic model they use and should focus on the specific cultural and historical contexts they are working in.

The question of impact was central in the CIT-PART project. Mr. Hansen responded to Mr. Bellucci's earlier concern about measuring the impact of pTA. Mr. Hansen pointed out, that it would be necessary to assess and demonstrate the impact of participatory procedures to motivate citizens to participate. On the other hand, these procedures have to be perceived as "making a difference", otherwise there would no reason to carry them out. This creates a dilemma for organizers of pTA. On the one hand, pTA should make a difference and add to "politics as usual", but, on the other hand, the more different and distant they are from conventional politics, the harder it is to get them integrated into the political decision-making.

According to Mr. Hansen, there were different ways to talk about impacts. One of the articles produced in the CIT-PART project speaks about three waves of evaluations of pTAs:

1. Directly observable impacts on policy. In the project this was studied with qualitative comparative analysis to see if it is possible to assess the impact on politics. However, it turned out to be impossible to ascertain such an impact.
2. Impacts can also be seen in a broader sense. In the CIT-PART project the concept of resonance was used to study whether and how participatory procedures were taken up in other contexts.
3. Impact of participatory procedures of participatory processes can also be discerned by the way they reconfigure the policy field.

Mr. Hansen went on explaining some of the facilitating and constraining factors of pTAs:

A first prerequisite was that an issue is politicized. It must become a matter of public concern and not just a private issue. Second, the political system needs some degree of openness to more alternative ways of getting information and making decisions. Third, there need to be actors ("policy entrepreneurs") who pursue pTA. Finally, it matters whether pTA has been done before, and whether previous (positive) experiences exist. When pTA is conducted for the first time, there is a certain barrier to start.

An important constraining factor is how narrowly an issue is framed. The political system will be hesitant or even aversive to getting lay people involved in complex policy issues. Moreover, it might be that policy makers and stakeholders have preconceived agendas and therefore might not want to get outsiders involved (avoid wider discussion). Sometimes policy makers might not be attentive enough to hear what is being articulated in the wider public. Finally, there is also a temporal mismatch between slow moving participatory procedures and politics, which at times is fast moving.



## 4.2 Panel Discussion

*Janus Hansen (Copenhagen Business School), Robby Berloznik (Institute Society and Technology, Flemish Parliament<sup>13</sup>), Doris Wolfslehner (Austrian Bioethics Commission), Peter Biegelbauer (Institute for Advanced Studies), Moderation: Mavis Jones (University of Calgary).*

*Robby Berloznik* started with commenting on the project and citizen participation in general. He was positive about the CIT-PART approach, the research design, its scope and structure. He pointed out that TA is today practiced in a much broader sense than defined by CIT-PART. Nowadays practitioners of TA have a “toolbox” of methods. In each TA project the method has to be a function of the problem and not the other way around. PTA, in his perspective, is not only defined from the citizens’ side. Experts and stakeholders are “participants” as well. The Institute Society and Technology in their last project, e.g., combined expert and citizen participation. From this perspective, expert TAs and pTA don’t exclude but actually complement one another.

Technologies, in Mr. Berloznik’s experience, were not often topical in parliamentary discussion. Parliamentary work is problem driven. They deal with problems caused by technologies, but not with technologies per se. For example, the Flemish Parliament, when discussing information and communication technologies (ICT), dealt with problems of inclusion and exclusion.

Mr. Berloznik commended the fact that the CIT-PART consortium did not include any TA-organization, because this would allow for a different perspective than past research projects on pTA. Compared with other projects, which looked into pTA from an academic perspective, CIT-PART was not only interesting, but useful for practitioners as well.

However, pTA in his view is not only about regulatory issues. Therefore the definition adopted by the CIT-PART project was too narrow. Hence, Mr. Berloznik raised the question whether the project results could be transferred to the entire field of pTA.

Furthermore, according to his experience, the first order impact of TA occurs on the level of agenda setting and TA influences don’t necessarily directly impact the complex policymaking process. There are also other TA practices that are situated in the field of precautionary governance regarding emerging technologies. In these practices it is scientists who participate.

Mr. Berloznik mentioned the example of a TA project, which did not deal with science and technology or a particular new technology per se but rather with agenda setting in research.

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<sup>13</sup> At the moment, R. Berloznik is working at the Flemish Institute for Technological Research (VITO).

Citizens assessed what priorities they would have for future research. Later on, experts reflected on citizens' recommendations. This exercise would be a "new kind" of TA.

Mr. Berloznik mentioned another way of looking at the objectives of these processes, which he called "large scale awareness TA". These TA processes create platforms to raise acceptance within society (participatory science communication). They are created to inform politicians and stakeholders and create an opportunity for discussion. The Flemish Parliament, for example, organized a large-scale nano-festival, the purpose of which was not to gain particular results but to inform politicians and to make them aware of possible problems. Later on, politicians produced a paper on important topics to be considered in the research and development of nanotechnology.

Mr. Berloznik also remarked on the role of the citizen in, and perception of TA processes. He thought that the CIT-PART project in this respect missed one important aspect. The impact of pTA on citizens themselves should be assessed as well because citizens are not just objects, but people with values and expectations. Citizens and their perspective on PTA should therefore be considered as well. Much of the democratic deficit in the field of R&D was caused by the perceived cleavage between experts/politicians, on the one side, and citizens, on the other side. However, people would want to participate, because they would think that they could make a difference. Participatory projects must meet this attitude. However, in the end, politicians are the ones who decide – independent from which democratic theory applied. These aspects should be taken into account when organizing participatory processes. For example, by coupling the political discourse with the citizen's discourse and vice versa. It is impossible to force politicians to do what people want; however, it would be possible for experts/politicians to connect with people by speaking their language.

Well-organized participatory processes help to avoid the "participation dilemma". On the one hand, people would want to participate because they would want to influence things but, on the other hand, they would not have anything to say in politics because it would be politicians who decide. So after a participatory exercise, when people realize that their expectations were not met, the cleavage might be even bigger than before. In his own work, Mr. Berloznik stated that he aims to integrate citizens as much as possible in different ways to circumvent this problem. However, this is very difficult in practice.

Mr. Berloznik concluded that projects such as CIT-PART should focus more on the role of and impact on citizens. For him as a practitioner, the CIT-PART report is useful to optimize processes and doing ex-ante evaluations because it raised awareness about the entire process and the frame in which (p)TA procedures are organized.

*Doris Wolfslehner* emphasized that in most countries the profession of "ethicist" does not exist. Ethics commissions (basic level and national level) consist of experts from different

professions, such as legal advisors, people from the medical field, philosophy, and social scientists. Looking from an ethical perspective at the xenotransplantation discussion, she perceived two central issues: animal and human welfare. In relation to animal welfare, the number of animals involved, animal suffering, potential pain, distress produced by experiments and the question of the earliest point to stop in-vivo experimentation are important issues. Research ethics committees (the clinical trials committees) look at matters of informed consent, the scientific quality – in her experience, the scientific advisors have the strongest influence on decisions – and the legal framework (e.g., data-protection issues). National bioethics committees, however, look at issues on a meta-level, at questions such as the precautionary principles, autonomy, justice and beneficence/maleficence for the public.

Regarding timing, Mrs. Wolfslehner pointed out that it is extremely difficult to find the right moment to start a pTA process. If pTA starts too early, it will be difficult to know what the field is about. Some countries started a discussion about synthetic biology at a very early point in time without being able to truly assess the technology, as too little scientific knowledge on the technology was available.

Mrs. Wolfslehner then discussed whom to involve in TA and regulatory processes. She had a broad view of the TA process. In her opinion, it is an interchanging process between expert committees, the public and stakeholders. Although politicians finally have to decide, everybody should be involved. In her opinion, it is important for experts to know what citizens think about a topic and how they frame the discussion. It is impossible to draw a line between different social fields, such as experts, citizens, stakeholders, and politics. On the contrary, the process as a whole has to be perceived as national discussion of an important issue.

Mrs. Wolfslehner stated that it is difficult to measure the impact of pTA, because the discussion always feed into a political process and it is impossible to ascertain at what point of time a politician's opinion was or was not influenced by external factors.

Mrs. Wolfslehner finally suggested some reasons why Austria is very low in the CIT-PART participation country ranking. Austria does not have a strong tradition of pTA and involving citizens because a lot of institutionalized processes exist, which involve different stakeholders but not citizens. Besides, xenotransplantation was not regarded as such a pressing issue in Austria. The problem of organ shortage is not as imminent in Austria as in other countries due to the fact that explicit consent for organ donation is not needed (system of presumed consent). The question of xenotransplantation is therefore not high on the agenda and thus no TA process was started.

The last speaker on this panel, *Peter Biegelbauer*, attempted to widen the perspective through taking up and discussing preceding comments. Mr. Biegelbauer described historic progress as a "tale of crisis and response". It has been normal in OECD countries for the last

40 years to talk about crisis; there were constant crises of some sort, such as energy, social, environmental crises. And in the beginning of the 1980s a crisis in trust and perception of science occurred, as mentioned in Anne Loeber's presentation, which led to a broad de-legitimization of the political system in terms of decision-making on new technologies. In the late 1990s, xenotransplantation entered the scene.

There was a response of politicians and policymakers to this crisis. There were efforts to amend the input side, to raise input legitimacy through asking for input from voters by means of instruments such as TA, pTA and instruments of direct democracy. There were all sorts of grassroots efforts, which have been promoted by ICTs (foremost Internet, mobile phone). Mr. Biegelbauer referred to Janus Hansen's remarks on the institutionalization of pTAs in several political systems.

Mr. Biegelbauer continued by talking about the issue of output legitimacy. Output legitimacy correlates with the functionality of regulations of new technologies (or other issues e.g. welfare state). For example, because of output legitimacy, evidence based policymaking was introduced in many countries and regulation practices were changed (especially in EU and OECD countries). There were attempts to reform the way in which laws are formulated, in which they are explained to the public and how they can react to them ("new public management").

In general, Mr. Biegelbauer identified a move from "government" to "governance", from "state" to network type of decision-making. This shift can be seen on the input and output legitimacy side. This process already occurred before 2008 but accelerated with the financial crisis. In many countries a de-legitimization of the political and administrative systems can be observed. This process can be measured by looking at surveys, by counting demonstrations, etc.

One response to this trend was to open up governments on some levels, issues and policy fields, in order to promote transparency and elements of direct democracy (on the national, European and international level). These measures had been discussed for much longer but in the wake of de-legitimization, this process accelerated. There are also grassroots-movements, which argue that the gap between citizens and politicians, who decide in the name of citizens, as mentioned by Mrs. Wolfslehner, does not work properly. The introduction of elements of direct democracy into the political systems can be interpreted as a reaction to these criticisms of the representative political system.

Mr. Biegelbauer continued by pointing out that political and economic crises in the last 100 years were always accompanied by a strengthening of the executive branch of government. This trend can be identified in the current crisis as well. Whereas governments and the European Council become more powerful, national and European parliaments are losing power. In order to deal with the economic crisis, executive forces and powers are getting

stronger and technocratic governments sprout. At the same time, efforts exist to make political decision-making more democratic. Mr. Biegelbauer claimed that while this partly contradictory process might make governments more efficient in dealing with the financial crisis, it doesn't raise input and output legitimacy.

Mr. Biegelbauer asked whether the different forms of TA discussed could help to reverse these de-legitimization processes, at least regarding issues connected with new technologies. There is hope that they can and some of the CIT-PART results point in this direction. In some cases, pTA processes opened the frame in which an issue was discussed, they changed the political debate, and they have played a role in dealing with the de-legitimization of the administrative political system.

Regardless of the form of government – non-professional (e.g. in the case of Switzerland) or professional politics – most politicians are laypeople when it comes to new technologies. In his opinion, most of the Austrian politicians, e.g., do not fully understand the financial crisis. Therefore, it is important to funnel knowledge in an understandable form. In terms of input legitimacy, pTAs could provide knowledge, which could form the basis of decision-making. Regarding output legitimacy, there could be a lot of involvement of different stakeholders and citizens.

The most interesting cases studied in CIT-PART were those in which a multitude of sources of information had been used for policymaking, e.g. in Canada, the Netherlands and Switzerland. In cases that had a lot of instruments to funnel knowledge and to serve the two forms of legitimacy, there was a greater resistance to the crisis. Mr. Biegelbauer concluded that it would always be better to have multiple options and political "tools" to answer a crisis than to have only one rigid response.

After this presentation, Mavis Jones opened up the discussion for remarks and questions.

*Mr. Berloznik* remarked that it should be clear that pTA is not an answer to all the problems of democratic systems. The pTA community should stay modest because the problems are big and the tools of pTA organizations are small; they are only one part of the solution. He estimated the role of pTA as rather small in the context of citizen participation in general. Therefore it is crucial to find a specific role for pTA through robustness of methods, the quality of methods and procedures, built on 20 years of experience. In the Netherlands there are a lot of initiatives for citizen participation established in a legitimate context – at the local and macro level. But there are big movements, where pTA organizations would not play any role at all. Mr. Berloznik argued in favor of strengthening the very specific role of pTA organizations.

*Mr. Hansen* responded to Mr. Berloznik's statement about the unfeasibility of impact measurement. To some extent, he shared Mr. Berloznik's skepticism, however, as a social

scientist, it is important to raise this question and, moreover, methods to detect impacts exist. The CIT-PART project explored different ways of understanding impacts. It is possible to see impacts on political decision-making, but there are also other concepts of impact to discuss. Especially in time of fiscal austerity, it is also essential for pTA practitioners to deal with this problem.

*Mr. Berloznik* replied, that the way scientists define impact would be totally different from the way politicians did. *Mr. Hansen* replied, that negotiating the meaning of “impact” would be a good thing. He pointed out, that politicians would want to know as well what they spend money on.

*Mr. Bellucci* said that he appreciates the way *Mr. Berloznik* coined impact as “impact to competence”. For him impact of pTA means making the results visible to politicians and enabling them to arrive at their own conclusions. There would also be the question of empowerment of citizens by these procedures. It would be important to make clear to citizen participants, that pTA is only one part of a much larger political process and to be modest about its impact on political decision-making. Finally, *Mr. Bellucci* was surprised that Denmark scored only fifth on the country ranking. He claimed to know Danish TA-organizations and wondered why they only took the fifth position.

*Mr. Hansen* replied, that CIT-PART focused on citizen participation in xenotransplantation. This technology, however, was not a big topic in Denmark. He reported that the Danish Board of Technology was to be shut down by Parliament, because of fiscal austerity measures. In his view, this would illustrate that pTA organizations have to justify themselves to protect themselves against being dismantled.

*Mrs. Wolfslehner* commented on the problem to communicate politics. In her opinion, the EU has problems to communicate their discussions to the public. Furthermore, people do not trust in politicians’ decisions anymore. This distrust is also a basis of TA, since people are thought to not trust in science and politicians. How to organize a national debate is a relevant issue. In Austria, it is not yet the government, which is trying to establish the dialogue with the people, but the parties. They are trying to establish participatory systems and to go outside the area of stakeholders or interested citizens in order to formulate the party’s position. Austria hasn’t gone so far that the government, or even the Parliament, tries to start a participatory discussion. But eventually – even in a time of austerity – they will go into this direction.

*Mrs. Tallacchini* was wondering, whether CIT-PART was able to confirm *Ulrike Felt’s* notion, that people are tired of participatory exercises. *Mr. Berloznik* pointed at the concept of *participation fatigue*, but said that he never experienced it in his work. *Mrs. Tallacchini* added that such a fatigue might occur amongst expert participants. *Mr. Berloznik* shared her view and added that *participation fatigue* is futile when a broader perspective is taken. People are

eager to have a say and this desire is increasing because of frustration with the political system. *Mrs. Tallacchini* remarked, that in some cases, though people are willing to have a say, they do not want to be responsible for the decisions made (as it happened with Canadian citizens). *Mr. Berloznik* raised the question about the representativeness of pTA. How representative are samples in those procedures for the entire society? Politicians and scientists who oppose pTA always raise this issue first in discussions about participatory procedures.

## 5 Cultural framing in the context of xenotransplantation and citizen participation

After lunch, the Workshop continued with a panel about the *cultural framing in the context of xenotransplantation and citizen participation*. Again, a video clip was shown as part of the introduction ([http://www.cit-part.at/v\\_cit04.php](http://www.cit-part.at/v_cit04.php)).

### 5.1 Presentation<sup>14</sup>

*Nik Brown (University of York)*

Mr. Brown presented the cultural context in which policymaking, regulation and citizen participation evolve. In particular, he talked about a topic that he and his colleague at the University of York, Sian Beynon-Jones, worked on: reflex regulation. This is a way of expressing enduring features of regulatory policymaking in the biosciences that has determining implications for citizen participation.

He indicated two intellectual drivers for his work in this project, the two Italian philosophers Roberto Esposito and Giorgio Agamben. Esposito worked on the relationship between science and politics and that “the role of science (but especially of politics) is that of impeding the opening of too broad a gap between nature and history; making our nature, in the final analysis, our only history” (Enigma of Biopolitics). With regard to the relationship between humans and animals, or non-humans, Mr. Brown referred to Giorgio Agamben: “We must learn ... to investigate [to historically analyze and understand] ... the practical and political mystery of separation. What is man (sic), if he is always the place – and, at the same time, the result-of ceaseless divisions and caesurae?”

Mr. Brown then picked up one of Brian Wynne’s ideas when he talked about technocratic reflexes, about “an established set of institutional reflexes and habits”. Wynne also writes about institutional body language, things that just become part of the features of the approached policymaking. They are driven by a normative technocratic underlying register or

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<sup>14</sup> For presentation slides go to: <http://www.cit-part.at/CIT-PART%20Reflex%20regulation%20-%20Brown.pdf>; last accessed: 20. January 2013.

agenda. The scientific agenda or substrate seems to be the basis of regulatory policymaking in science. You see the science first before anything else follows. Wider involvement or consultations usually come after that. Wynne questions this seemingly linear sequential order. Fundamental to these reflexes is a temporal attribute. Wynne expresses this as a temptation to neglect the upstream, the political starting point of science. What are the driving human vision, interests and purposes of science itself?

According to Mr. Brown, other aspects of the temporal reflexes are often hastiness and urgency, i.e. to get in motion rapidly, to try to get on top of the sciences and to facilitate and make them safe at the same time. Policy communities also tend to be quite vulnerable to promissory entrepreneurs, narratives and discourses. The research on the sociology of expectations done by Mr. Brown and others suggests that there is a reason for that: policy communities are often removed from the messy contingencies of laboratory science.

To illustrate those conclusions, Mr. Brown elaborated on the UK case and the enterprise Imutran. In 1995, Imutran announced its readiness to move to clinical trials very rapidly (within 12 months). This was an agenda setting move, because it forced policymakers to act really fast. It triggered serious policy undertakings: first, the Nuffield Council Report and then the Animals into Humans Advisory Report (Department of Health). Both reports repeatedly restated and went back to the 1995 Imutran announcement as the validation and legitimisation for undertaking their work. Mr. Brown quoted one of their interviewees: “there’d been a lot of press articles where biotech industry were saying that they were ready to transplant a pig’s organ, a pig’s heart within six months, which turned out of course not to be true. And government really didn’t have a view, nobody in the department really knew much. The industry was making the running and governments across the world were sort of struggling to catch up.”

According to Mr. Brown, there was the tendency not to question the necessity or urgency associated with the developments claimed by the entrepreneurs. There wasn’t much of a deconstruction of the meaning of organ shortage or of xenotransplantation as a solution to the organ shortage. It was an appraisal of xenotransplantation and its own merits rather than assessing it in a broader context. Both reports tended to concentrate on managing the impacts of this new technology and its facilitation rather than questioning it (or the claims of the entrepreneurs). There was also a prioritization of the near-term, which itself imposes institutional and regulatory risks. In the UK there was the requirement to produce a protocol for clinical trials; it was in place very rapidly in 1998. In 1999, the UKXIRA annual meeting was held with a sense of momentum and an optimistic spirit regarding the development of xenotransplantation. But within 12 months the whole “show” collapsed. Already in 2000, the UKXIRA report put it like this: “...the evidence of efficacy has not advanced at the rate predicted when the UKXIRA was established some three years ago”. The Roslin Institute terminated its xenotransplantation program and Novartis winded-up Imutran. And then there were huge events around the publications of *Diaries of Despair* (Uncaged).



Mr. Brown identified this whole process as an example of an attribute of reflex regulation; when an innovation or technology is threatened by potential problems, there is a need to overcompensate by selling it even more strongly. But it doesn't take much for the underlying vulnerabilities to become more transparent and suddenly the policy expectations collapse.

The disbandment of UKXIRAS resulted in a weaker regulatory apparatus in the UK despite global ongoing work in this field. Bibliometric research shows a clear trajectory that is still going up in terms of interest and activity. For Mr. Brown, this is an additional feature of reflex regulation: it demonstrates the absence of a persistent, longer-term policy engagement. He referred to McLean and Williamsons, who described the closure of UKXIRA as something highly negative, which would show the loss of important institutional memory in this context of regulation.

One other feature of interest for Mr. Brown in the UK case was a frequent default return to established institutional mechanisms. UKXIRA was originally established for a certain purpose: "the authority's role as a focal point is important given the number of interests which xenotransplantation brings together – animal and human welfare and ethics, industry, public health, and other regulatory systems which exist for medicines and medical devices." It tried to be articulated as a hybrid institutional body, which was just as hybrid as the physical bodies that it was supposed to offer advice and regulate on.

For Mr. Brown and his colleagues, it was surprising that this hybrid institution had been dominated by the old institutional architectures. UKXIRA was largely located within the Department of Health (Human Health). The Home Office or the Animal Procedures Committee (APC) dealt with questions regarding animal welfare or preclinical issues. There were major institutional divisions with hybrid innovations falling between the gaps even where there had been an innovative institutional apparatus like UKXIRA established to fill this vacuum. A member of UKXIRA and the APC commented on the issue: "the APC is all tied up with confidentiality. So when you get a situation where somebody applies to the APC to do a project involving primates the logical thing to do would be to refer back to UKXIRA", but that wasn't happening.

Mr. Brown pointed out, that reflex regulation or reflex policymaking was not about singular events but would be a persistent institutional feature of regulation. Looking at the UK debate on trans-species embryo, e.g., similar features become apparent: there are promises associated with this new technology, there is incredible motivation by policymakers responding to threats to UK competitiveness, the threats to patients who need treatment. But lobbying and public media debates are much more professionalized in the UK than they were at the time of the xenotransplantation debates. Williams and colleagues (2011) looked at the role of the media in this debate. But again, there is a division between the human and the non-human, the tendency to downplay the novel innovative non-human, animal based attribute of the technologies. Trans-species embryos, e.g., were constantly presented as

99.9% human, so that any kind of animal attribute would be just residual. The Department of Health changed its language: they moved from talking about “transpecies’ embryos to “human admixed embryos”. Some stem cell scientists stopped talking about “enucleation” – i.e. the process of extracting the nucleus from an animal egg – and started talking about “despeciation”, i.e. taking away the species or animal attributes of these entities. All these processes were rarely contested. Public consultations on this topics came after the policy decisions (the before mentioned topic of timing!).

Mr. Brown raised the question of the implications of a regulatory policy context, a cultural context and its impact on the potential for citizen participation.

The technocratic and temporal reflexes are pressing and significant: the susceptibility to entrepreneurial demands for urgent regulatory action, the difficulty politicians have to do anything that would be seen to undermine clinical or economic prosperity. Moreover, there are institutional reflexes: the tendency to recycle institutional routines, to reproduce routines that already have been established.

## **5.2 Panel Discussion**

*Frans van Dam (CSG Centre for Society and the Life Sciences, Netherlands), Pēteris Zilgalvis (European Commission), Aivita Putnina (University of Latvia), Kristofer Hansson (University of Lund), Moderation: Meaghan Brierley*

*Mr. van Dam* started his comment with an anecdote. In 1999 he worked for a consumer organization in the Netherlands, the “Foundation for Consumers and Biotechnology”. He was a consumer lobbyist and a contract researcher for the government. He wanted to do a small project on stem cell research; however, after asking the Ministry of Health for funding he ended up with another project: facilitating a nationwide public debate on xenotransplantation. The whole project process took about two years: first an information phase, followed by a debating phase, which ended in 2001. Crucial for its success was that the Ministry of Health created room for decision- and policymaking by putting a moratorium in place, so that the participants felt that they have a say on the topic. Secondly, the facilitating organization, being a consumer organization, was more trustworthy than the government, according to the Ministry. They tried to not only involve the public but all relevant stakeholders, experts and politicians.

First, stakeholders and experts decided on the content and framing of the topic. Then citizens were asked in local meetings about their associations and framings of the subject. There wasn’t much experience with this kind of broad scale debate so they had to think of methods themselves. They wanted to use qualitative and quantitative methods.

Mr. van Dam pointed out, that at the same time a similar debate was orchestrated: the debate on organ shortage/donation. This was more of a TA related debate set up by the Dutch TA board, the Rathenau Institute.

After two years, a report was published; the debate on xenotransplantation had no first order impact because the moratorium was already in place. It showed that the Dutch public and most of the stakeholders were very much against xenotransplantation. Mr. van Dam, however, noted that he is not sure whether the debate had any impact at all. If the public had been in favor of xenotransplantation, then there would have been changes. In the case at hand, it confirmed existing policies.

Mr. van Dam summarized his learning experiences from the debate. Today, in order to have a more ideal frame as a starting point, he would involve citizens at an earlier stage of the process. He acknowledged that the Rathenau Institute chose a better framing of the topic. Most of the time public discussions on xenotransplantation started with organ donation as an issue because people were interested in this topic. He now would also put more focus on the second and third order impact, like the CIT-PART project did.

*Mr. Zilgalvis* started his presentation with a short account of his personal history. Before he took his current position he was working in the Social Science and Humanities program. In 1998/99 he was responsible for the dossier on xenotransplantation, which was proposed as an additional protocol to the convention on human rights and biomedicine.

One lesson he learned from his work is that useful and proactive debates are possible and that it is possible to do something before a technology arrives on the market. When they got first signals from researchers that xenotransplantation is ready to start off in several months and that they need a legal framework, Zilgalvis was sceptical: on the one hand, about the timeframe, on the other hand, because of problematic issues (immunosuppression). There was the promise of solving the organ shortage and several countries were eager to support this new technology because of its humanitarian and economic benefits. As in other topics – e.g., e-health – there was a sort of hype. In his opinion, there was a lot of good-will from many actors (e.g. Nuffield Council), but it was also possible to see the euphoria slowing down.

For him, this was a lesson in healthy scepticism and the process showed some basic rules of the democratic process and the sovereignty and subsidiarity of the EU member states. He then pointed to a similar challenge in relation to the policy area and public debate: e-health (e-prescription across borders, tele-medicine etc.). There are a number of issues around this topic (e.g. privacy, remote monitoring, etc.) that have to be discussed and there is a need for guidance and a legal framework. In the shorter or longer-term, the issue of the “digital me” will also become a pressing topic. Again, there is the question of when to start the discussion and to include stakeholders or the public in the debate.

He pointed out, that the legislation and policy adopted at a time shouldn't presuppose a technology in the future. The goal is to enable something that is safe and possible, but at the same time making sure that there isn't a framework that neither prevents innovation nor falls to the hype.

He proceeded to talk about public consultations as one of the European Commissions' tools for public engagement. In a public consultation of the "European Innovation Partnership on Active and Healthy Ageing" the number one barrier for e-health identified has been "non-involvement of end users". So it would be crucial to get the healthy citizen, the patient and the doctor on board at an early stage of the development. Again, the timing would be important: you have to assess if the new technology is already online or not and what the timeframe is. Then it is crucial to reflect on the influence of the biotechnology companies (and their promises).

Many of the participants of the e-Health Action Plans public consultation agreed, that the lack of users' awareness and confidence is one of the main barriers. Mr. Zilgalvis concluded that people have to be addressed at an early stage and the technologies have to fit their means and have to be ethically and politically acceptable.

*Mrs. Putnina* reported from the CIT-PART projects' perspective. She identified two ways of measuring impact: quantitative and qualitative. One result of the projects' research is that universal tools don't suit every situation. Participants, as well as framing, varied among the cases. On the other hand, participation also has the power to change the cultural context (political field, science). She referred to the notion of xenotransplantation research moving to other countries mentioned before but also to a statement made by Mrs. Tibell in the first panel that she, as a transplant surgeon, has to communicate with society. Mrs. Putnina commented, that this shouldn't be taken for granted. Because this attitude contains a certain framing of science and certain traditions; it involves a tradition of decision-making (open science) and resources for mobilizing opinions.

During the 70s and 80s there was much research on xenotransplantation in the Soviet Union and Latvia as well. Working on the CIT-PART case study on Latvia, Putnina and colleagues found two people who had been involved in xenotransplantation research. Soviet science was "silent"; it was state funded, didn't have ethical implications and scientists had free access to materials and resources. But when the state collapsed, this pretty closed science system collapsed as well. The lack of debate helped to kill research. According to Mrs. Putnina, the landscape has been changing and participation helps science to move forward.

*Mr. Hansson* looked at the topic from a more theoretical, culture-analytical perspective. Referring to Sherry Turkle, he described xenotransplantation in the 1990s as an evocative object. It was a technology, which produced new cultural symbols in a short period of time. Xenotransplantation reconfigured the view on both the human and animal bodies. Regarding

evocative objects, there is a time of transition where some sort of “crystallization” takes place – again it is also about agenda setting and timing: who is allowed to be part of the process and has the right of producing the frame? PTA can be an essential part of this process.

Mrs. Brierley perceived the panel as a good combination of theoretical concepts, empirical research and actual practice in the context of public participation and xenotransplantation. She then opened the floor for discussion.

*Mrs. Tallacchini* asked *Mr. Brown* how the UK policy approach succeeded in keeping the chimera discourse completely separated from the controversies about xenotransplantation, and in framing it within the Embryos Bill as “admixed embryos”.

*Mr. Brown* explained that the determination of entities as either human or animal is based on percentages. In other words, if an entity is considered less than 50 % animal, it is within the competence of a different regulatory committee. But if it's more than 50 % human, it falls under the competence of a human regulatory committee. This form of assessment is still instituted in law. He remarked that it is a complete institutional failure to accommodate the trans-species' novelties to these kinds of entities.

*Mrs. Wolfslehner* remarked, that the ethical question dealing with human, animals or trans-species entities are different ones, so it's crucial to not mix them up.

*Mr. Hansen* posed a question to *Mr. Brown* and *Mr. Zilgalvis*. For him, the case of xenotransplantation was science driven. Scientists came up with a possible solution to the organ shortage problem. But patients were very little or not at all involved. Some patient organisations didn't want to be involved in the topic because they thought there were better solutions to the organ shortage problem. In the wake of the process, he came to a similar conclusion as *Mr. Zilgalvis*: that end users have to be integrated at an earlier stage. But how can consultations of end users be enhanced? What should policy makers do to moderate these processes?

*Mr. Zilgalvis* responded that there is a tendency of seeing the technological development as a fast solution to many of the problems at hand (“white heat of technology”). But in most cases it's a more mundane process: from science and from politics. But in his view, in the past, the patients were quite receptive. Nonetheless, there is a place for healthy scepticism on what is on the forefront of the political agenda or public debate. Most of the time there are mundane (minor) things (on different levels and from different people) to do that have a bigger impact than a new technological development.

*Mr. Brown* described patient groups (e.g. for chronic diseases) as being highly pragmatic; they have been through times of hype and promises before. They are aware of what they really want and can expect. It is important to distinguish between patient advocacy

organizations and patient representations, which have undergone a serious professionalization in the last decades. They are professional media organizations that are able to frame certain topics in a certain way. Now they have a huge impact on the debate and thus on politics.

*Mr. van Dam* added that there are some similarities between xenotransplantation discussion and the GMO debates in the Netherlands. The ministry wanted a debate about GMOs organized but van Dams' organization, the Consumentenbond, challenged this order. They wanted to discuss the basic orientation of agriculture first, so that constructing the frame was part of the process. Hence, it would have been possible to discuss the issue in a broader frame (food quality, environment, etc.). But this concept was never realized and therefore the debate failed like the one on xenotransplantation.

*Mr. Griessler* addressed *Mr. Zilgalvis*. He was interested in the trajectory of ICTs in Health as planned by the EU, because there is resistance against ICTs in Health in Austria. The Austrian government tried to make a bill on this topic (electronic patient data) but there were horror scenarios, like the complete transparent patient ("gläserner Patient"), and resistance from doctors and patients. *Mr. Griessler* wondered how the EC is trying to tackle the problem of resistance by different stakeholders (doctors, patients)? And how the EC involves the public when there is such a controversy?

*Mr. Zilgalvis* replied that the European Commission would organize public discussions and the public consultation/debate on a European level. On a national level it can be easier or more difficult depending on the country. There is a strong Austrian engagement on the European level but there is a debate that has to happen nationally. The EC engages with the responsible institutions; in many countries they are on a lower level than the government. There is a huge take up in Sweden, Denmark, Finland, Estonia, Spain, Scotland and Northern Ireland. One of the lessons they heard of was that it is important to start with the users: the patients and the doctors. Whereas top-down approaches – e.g. a company wins a tender and starts implementing a concept – are likely to fail. Then there is also the issue of reimbursement; anytime doctors aren't reimbursed for a task done digitally, in contrast to the same task being done physically, there is resistance.

In *Mr. Zilgalvis'* opinion, implementation of such technologies (e.g. e-health) should start with the users. He also added that such a technology isn't negative overall, but also gives the patients the opportunity to monitor who is accessing their health-record.

*Mr. Griessler* asked *Mr. van Dam* if they gave feedback to policy makers (ministers). *Mr. van Dam* replied that they had a press conference without much impact because the hype on xenotransplantation had already been over. Before the publication of the report, they also had a final debate with all spokespersons from the political parties to get feedback from them.

## 6 Conclusion

*Panel: Erich Griessler, Edna Einsiedel*

*Mrs. Einsiedel and Mr. Griessler* summarized the workshop discussion. Mrs. Einsiedel noted that it was difficult to recapitulate such a variety of opinions and facts. She highlighted some of the key topics and issues that came up during the discussion:

- Social learning: project members learned a lot about citizen participation, its impact and framework conditions.
- Impact: on institutions, on involved citizens and society.
- Gaps and Mismatches
- Reflex thinking
- New institutions and institutional designs in this area

*Mr. Griessler* pointed at issues that are important especially for the project members to consider:

- The interconnectedness of developments in the U.S. and Europe.
- The role of IXA in regulating xenotransplantation.
- The connection between the scientific community that does research on regulatory issues and the regulators.
- Different regulatory approaches to deal with matters like xenotransplantation (broaden the frame).
- Caution whether and in what way to use the term “impact” (especially emphasized by pTA practitioners); clarifying the meaning of “impact” (and its implications).
- TA/pTA in relation to policymaking.
- Examples beyond xenotransplantation.
- The role of Bioethics Committees.
- Connection between the Dutch public consultation and policymaking.
- Consequences of excluding the public from the regulatory process.

In the following discussion the audience emphasized some issues/aspects as well.

*Mrs. Loeber* pointed to the temporal aspect that had been present in the accounts of different speakers although they had divergent views on the topic (e.g. in speaking of moratorium as a means to create room for discussion).

*Mr. Biegelbauer* stressed the fact, that the technology of xenotransplantation is not out of date. When the project started, he had the impression that xenotransplantation was not that relevant anymore but looking at other countries and levels, it is possible to see that it is still an existing and pressing issue. Furthermore, there are other stories that are quite similar e.g. regarding their problems.

*Mrs. Wolfslehner* emphasized that it would be crucial to reflect on the involvement of end-users. It depends on the state of the art if it is useful or not to include different stakeholders. She referred to the notion that it is important to start talking about the problems (e.g. organ shortage) that are going to be solved with a technology and not about discussing the technology itself.

*Mrs. Einsiedel* referred to the situation of Canada, where a patient organization (mainly represented by one person) had been involved in the policy discussion. In the US, patient groups had also been prominent in policy discussions. She identified patient organizations and animal welfare and rights organizations as two stakeholder groups that are prominent in the xenotransplantation debate.

*Mrs. Jones* wondered if there were also patient groups that transported industry interests (e.g. like in pharmaceutical patient organizations).

*Mrs. Einsiedel* mentioned that researchers from the US and UK who were doing work in this area would have been forerunners in the field and pushed the topic forward. She had an exchange with *Mr. Brown* about entrepreneurship in the field. Finally, she pointed to an underlying question: is an understanding of public participation too limited that focuses on formal public participation (pTA processes)?

*Mrs. Loeber* underlined *Mrs. Einsiedel's* concern by picking up the question on how to conceptualize this type of processes and where to draw the line between acting political and not acting political. *Mr. Griessler* also thought that this question was important and that it had been a crucial one for a long time. In the CIT-PART project, however, it was a deliberate choice to look at formal processes of citizen participation only.

*Mrs. Wolfslehner* then asked the project members what they would advise for a successful pTA. *Mr. Griessler* answered that it would depend on the political and cultural circumstances and the pursued strategies. But in general, he would recommend doing a pTA together with an expert TA, it should be embedded in the organization, using a variety of methods (qualitative/quantitative) and strategies (like in Canada/Denmark).

*Mr. Hansen* recommended not being fatalistic about scientific developments; scientists' predictions shouldn't be taken for granted. Awareness of the non-linearity of scientific developments and that there are different ways of dealing with them are also important. He



highlighted the power of the political system in changing the paths of scientific developments: they can set the agenda and priorities. Commenting on this notion, *Mr. Griessler* observed a problem in several case studies: politicians got information from scientists and then they had to deal with the development under time pressure. Often, it was hard for them to resist this pressure.

*Mr. Brown* interposed that policymaking can adopt mechanisms for screening the “good” from the “bad”, “hot-air” from “real stuff”, e.g. through organized skepticism and institutionalized peer-review (*Mr. Einsiedel*: “extended peer review”).

*Mr. Biegelbauer* responded to *Mrs. Einsiedel*’s question on how to conceptualize “public participation”. He indicated that there is an empirical way of answering this question that the project already followed: several adaptations and variations of institutional answers to these problems can be seen.

*Mrs. Einsiedel* paraphrased this as *institutional learning* and referred to the work of Chris Argyris about *single loop learning* and *double loop learning*. There are hardly any cases of the latter; the institutional memory is very short lived and not widely shared. There are elements in the structure of organizations that work against longer-term double loop learning.

*Mr. Biegelbauer* explained this with the necessity to have to some degree of stability of norms. However, double loop learning can be applied at an early stage of the existence of an organization or at a time of severe crisis (and this rarely happens).

*Mr. Griessler* thanked the audience and especially the panel members for attending and their interesting contributions.

## 7 Annex

### 7.1 List of abbreviations

<b>AIDS</b>	Acquired Immune Deficiency Syndrome
<b>BSE</b>	Bovine spongiform encephalopathy (“mad cow disease”)
<b>EC</b>	European Commission
<b>FDA</b>	Food and Drug Administration (US Department of Health)
<b>HIV</b>	Human immunodeficiency virus

**IXA** International xenotransplantation Association

**NGO** Non-Governmental Organization

**pTA** Participatory Technology Assessment

**TA** Technology Assessment

**WHO** World Health Organization

## **7.2 List of participants (in alphabetical order)**

<b>Name</b>	<b>Institution</b>	<b>Country</b>
Bellucci, Sergio	TA-Swiss	CH
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Brown, Nik	University of York	UK
Einsiedel, Edna	University of Calgary	CA
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Hanson, Kristoffer	University of Lund	SE
Hoitsch, Karin	European Commission DG IPOL STOA	
Kaleja, Jekaterina	University of Latvia	LAT
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Le Borgne, Hélène	European Commission - DG SANCO	
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Mavis, Jones	University of Calgary	CAN
N KADUHA, Elam		
Noort, Sam van	University of Amsterdam	NL
Putnina, Aivita	University of Latvia	LAT
Schiffino, Natalie	Université catholique de Louvain	BE
Schunz, Simon	European Commission – DG Research	
Tallacchini, Mariachiara	Università Cattolica del Sacro Cuore	IT
Tibell, Annika	Karolinska Institutet	SE
van Dam, Frans	CSG Centre for Society and the Life Sciences	NL
Wolfslehner, Doris	Austrian Bioethics Commission	AT
Zilgalvis, Peteris	European Commission - DG Connect	

### 7.3 Agenda

**9.00-9.15      Registration and Welcome Coffee**

**9.15-9.45      Welcome & Introduction**

*Simon Schunz (European Commission)*

*Erich Griessler (Institute for Advanced Studies)*

**9.45-11.15      Xenotransplantation, democracy and participation**

*Anne Loeber (University of Amsterdam)*

*Annika Tibell (Karolinska Institutet)*

*Mariachiara Tallacchini (Università Cattolica del Sacro Cuore)*

*Sergio Bellucci (TA-Swiss)*

**11.15-11.30      Coffee Break**

**11.30-13.00      (Participatory) technology assessment and politics**

*Janus Hansen (Copenhagen Business School)*

*Robby Berloznik (Institute Society and Technology, Flemish Parliament<sup>15</sup>)*

*Doris Wolfslehner (Austrian Bioethics Commission)*

*Peter Biegelbauer (Institute for Advanced Studies)*

**13.00-14.00      Lunch Break**

**14.00-15.30      Cultural framing in the context of xenotransplantation and citizen participation**

*Nik Brown (University of York)*

*Frans van Dam (CSG Centre for Society and the Life Sciences, Netherlands)*

*Pēteris Zilgalvis (European Commission)*

*Aivita Putnina (University of Latvia)*

*Kristofer Hansson (University of Lund)*

**15.30-16.00      Coffee Break**

**16.00-17.00      Summing Up**

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<sup>15</sup> Mr. Berloznik is not working for the Flemish Parliament anymore, but at the moment working at the Flemish Institute for Technological Research (VITO).

*Edna Einsiedel (University of Calgary)*

*Erich Griessler*



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