**Research Report**

# CIT-PART:
# Report Case Study Denmark

**Janus Hansen**

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# Report Case Study Denmark

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# 1 Introduction

This paper reports the findings of the Danish case study on public debate, technology assessment and governance of xenotransplantation (XTP) conducted for the CIT-PART project (www.cit-part.at). The report is based on analysis of a range of different kinds of documents (newspaper reports, policy documents, research literature etc.) and 13 qualitative interviews conducted with persons engaged in different manners in the debates about XTP in Denmark such as scientists, regulators, politicians or technology assessment (TA) practitioners. The interviews were carried out in the period between November 2009 and September 2010. Furthermore, qualitative data material from an older study on public perceptions of biotechnology from 1999/2000 has briefly been revisited.

Xenotransplantation has experienced only a modest degree of public attention and policy activity in Denmark compared to other countries covered by the CIT-PART sample (full reports of all country case studies can be found at www.cit-part.at). Most of this activity was concentrated in the years 1998-2002. During that time XTP was the object of some attention and activities by the institutions in the Danish policy landscape, which are devoted to engaging "the public's" concerns in regard to new technology in various ways. However, XTP was never the topic of any genuine public participatory process or event in Denmark. In 2001 a non-statutory but *de facto* moratorium was issued on XTP, which has remained in force until now. The moratorium was suggested first by the Central Committee on Research Ethics and was later put into force administratively by the Board of Health, but it was never formally sanctioned in legislation. Since then, XTP has drawn little public and policy attention, given the focus of scientific research and expectations regarding future treatments largely have turned towards other technologies, notably those based on stem cell research. No renewed public or policy interest seems to be on the horizon in the foreseeable future, but of course this may change if new scientific developments should put XTP on the agenda internationally again.

This report seeks to map the trajectory of XTP as an object of scientific research, of public debate, of organised technology assessment and of political discussion and regulatory intervention. It also focuses on how these different trajectories interacted. More broadly it furthermore examines the context in which this played out. This mapping should serve to answer the following research question of the work package:

**Why did XTP experience relatively little attention from "the public" as well as the established TA system in Denmark in a context which 1) is otherwise very attentive to biotechnological innovation and 2) has a comparatively well established tradition of public debate and civic participation in the governance of science and technology?**

This report recounts how XTP was conceived and treated in four different social fields or institutional sectors of the Danish society. These are

- scientific research,
- media reports/public debate/public perceptions,
- the “Technology Assessment (TA) system” and
- the political/policy field.

Subsequent to this, the report takes a step back and attempts to answer the research question through an interpretation of the Danish experience in relation to XPT. It is suggested that the lack of public attention can be ascribed to a combination of the fact that the technology never had any strong promoters in the Danish context, scientific, commercial or otherwise, and the TA activities that did take place were initiated in a rather top-down fashion before the technology was mature enough to generate any genuine public engagement and/or mobilisation.

# 2 XTP and related research in Denmark

In Denmark no clinical trials with XTP have been conducted on human beings. Nor have any experiments been carried out on larger mammals (Genteknologiudvalget 2002: 71). One of the first medical textbooks on XTP was co-authored by a Danish transplantation surgeon, Ejvind Kemp (Cooper et al. 1991). Kemp followed the research field intensively and has been one of the most vocal proponents of XTP in the Danish context. However, when XTP research gained significant momentum in the wake of new possibilities of genetic modification of donor animals, and expectations rose that clinical trials were approaching, Kemp had retired. He continued to participate in discussions on the technology in various TA processes, but as far as the present research has been able to establish, no other scientists have shown the same kind of devotion to XTP. Unfortunately, Kemp was not available for an interview for the CIT-PART study.

For a while in the mid-1990s there was some optimism regarding XTP among Danish veterinarian researchers and medical doctors, who engaged with this field in response to international developments. The ultimate motive was the hope to alleviate the growing organ shortage for heart and kidney transplants in particular. This hope generated some research activity related to XTP in Denmark, but XTP research never grew to be very important in Denmark, neither in medical or commercial terms.

Denmark has a large agricultural sector and pig framing has traditionally accounted for a significant share of the overall economy. To accompany this production, the country has developed a comparatively strong knowledge base and veterinarian research capacity on pigs in general. As consensus stabilised in the international scientific discussion that pigs were the most suitable donor animal for XTP, veterinarian researchers in Denmark saw opportunities to apply their competences in the emerging research. This stimulated some shared interests and collaboration between veterinarians and medical researchers working in transplantation medicine. However, as far as the present research has been able to establish, XTP in itself was never the primary concern of most veterinarian researchers. XTP was rather seen as a field of research, where their existing knowledge of porcine genomics, embryonic development, etc. could be applied in an interesting manner, and which allowed them to tap into the new avenues of research funding accompanying the XTP field. However, as these sources dried up due to poor results and the withdrawal of the commercial actors from this field, so did the interest in XTP from veterinary researchers in Denmark (Interview *Professor of Veterinarian Embryology*).

At the height of the XTP research activity medical researchers in Denmark worked primarily in basic research, which was carried out on mice and rodents at several universities and research hospitals. None of these research groups were seriously approaching clinical applications. Rodents were considered convenient animals for basic research in terms of

costs and reproduction time. However, as it became clear that for clinical purposes, XTP had to rely on porcine material, new avenues for interdisciplinary collaboration were opened up.

In the hope to ensure Danish participation in this development a "Danish transgenic pig study group" was formed, involving researchers from several Danish universities. The Danish transgenic pig study group tried to raise funds for research on alpha-gal knock-out mechanisms in pigs.[1] The researchers proposed a partnership with a company specialised in pig breeding, which was supposed to put their practical expertise and physical facilities at the disposal for the breeding of transgenic pigs in a sterile environment. However, the group never managed to attract sufficient funding, and gradually the interest in XTP deteriorated (BIOSAM 2004: 4). Basic research on Alpha-gal knock-out problems was therefore subsequently continued on mice at much lower costs, and the most of the involved researchers focussed their attention on other issues, notably cloning and stem cell research, which generated both much more research interest and public controversy in Denmark. The transgenic pig study group still exists, but is now devoted to other questions (primarily examining pigs as "model animals" for medical research), and XTP related research activities are all but extinct in a Danish context (ibid.).

The waning interest can be attributed in part to the developments in the international scientific community around the millennium, which gradually moved its attention towards stem cell research, in part to more contingent factors in the Danish context. These have to do with the fact that XTP research was never fully institutionalised in research groups etc., but was mostly carried out by a few committed individuals in transplantation medicine. However, when they retired, the field was virtually abandoned and attracted virtually no attention from their successors. In short, there was never any sustained scientific interest in driving XTP beyond basic research in the Danish context, and the interest dwindled in a relatively short time as technical difficulties regarding rejection, combined with growing international concerns about the transmission of zoonotic diseases, proved more difficult to overcome than initially expected.

In fact, it seems that research interest in Denmark was already in decline once the first regulatory initiatives got under way. The political concerns about XTP thus seem to be driven primarily by international developments and were largely decoupled from domestic scientific activities.

[1] That is, it was hoped that by inserting a particular human gene into transgenic pigs, the rejection of transplanted organs, which normally occur in cross species transplantations, could be avoided.

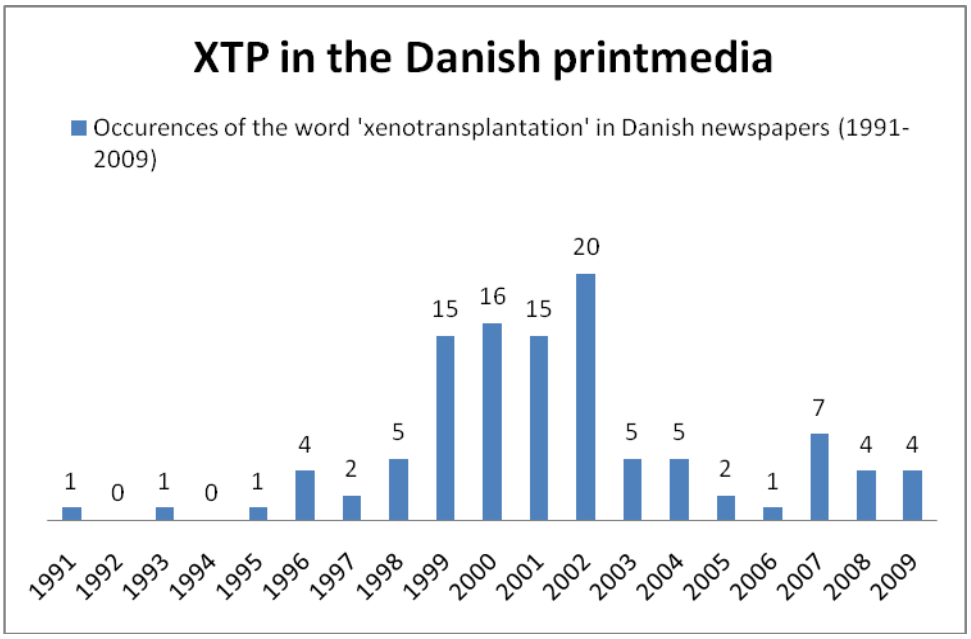
# 3 XTP in the public imagery and the media

The concept of a “public opinion” or a “public sphere” observing, discussing and in some cases passing judgement on contemporary affairs is not a unitary or well-defined phenomenon (Neidhardt 1993). It is therefore a matter of some discussion in the social sciences how “public opinions”, “public debate” – or whatever term is preferred – is best approached and registered (Bauer and Gaskell 2002). Yet, despite such conceptual intricacies some concept or image of the public debate cannot be avoided if we want to analyse the trajectory of novel technologies, which in some way or another are relevant to or attracts the attention of a significant segment of the population in a democratic country.

In the present case study XTP as a public topic was approached retrospectively via a mapping of media coverage. Media coverage provides a convenient way to capture at least some of the concerns about particular topics present in the public sphere, and a means to track these over time. This is so for two interrelated reasons: Many of these concerns originate from media coverage, which provides most of the knowledge contemporary citizens hold of the world (Luhmann 1991). And vice versa: the media make their livelihood from being sensitive to public concerns. For this reason, it also seems reasonable to assume that political decision makers take at least some of their cues on public preferences from the mass media. As such, the printed media leaves an impression of public concerns, which is still accessible ten years later when the issue of XTP has more or less disappeared from the public view. Towards the end of this section a brief look is also cast on two other sources of public perceptions of XTP at the time most policy making took place: the EuroBarometer surveys on biotechnology conducted in 1996 and 2002 and a focus group study on public perceptions on biotechnology conducted in 1999/2000.

For the present purpose a search was conducted in a database (InfoMedia) containing a complete, verbatim collection of all Danish newspapers in nation-wide circulation, regional newspapers and selected trade journal. The search covered the period from January 1$^{st}$ 1985 until October 2009. The word “xenotransplantation” returned a total of 108 journalistic articles, commentaries and letters to the editor (excluding non-editorial material such as birthdays and anniversaries of scientists etc.). Only three occurrences appear before 1996, with the very first appearance of the word in 1991 (a letter to the editor stating in a matter of fact manner that within 10 years, it will be possible to provide hearts and kidneys from pigs!). Figure 1 shows the distribution of the occurrences of XTP in media reports over time.

Figure 1




(Source: Infomedia database, accessed on October 20th, 2009)

As indicated by Figure 1, “xenotransplantation” as an object of media reports experienced most of visibility in the years 1999 – 2002, which coincides with most of the TA and policy activities in this area. After 2002, the appearance of the word becomes more infrequent again. Practically all reports appear in broadsheet papers and very few in the two leading tabloids. Practically all articles provide an explanation of the meaning of the word. Using alternative search words such as “pigs organs AND transplantation”, “animal organs AND transplantation” etc. does not add any significant additional articles. In most cases the technical term is either used or explained, and it is assessed that no significant number of articles pertaining to XTP has been missed.

All 108 articles have been read through at least once to conduct an initial screening of whether they were substantively related to XTP. Many of them make only superficial reference to XTP, but are primarily about other topics. It is assessed that XTP is the substantive focus (perhaps among several) of about half (55-60) of the articles. These articles have been read through more carefully and provide the material of the following attempt to extract the most important issues discussed in relation to XTP and the frames applied. The approach is by nature interpretive and aims to identify and analyse frames and relations without paying initial attention to the question of whether some issues or framings are more dominant than others.

The following topics were identified through a mapping of how XTP was framed and related to other topic. The framings will be elaborated in the following (numbers in brackets indicate number of articles classified in each category). Some articles pertain to several issues:

- Biotechnological progress and the potential of XTP to alleviate organ shortage (30)
- Technical challenges and physical risks associated with XTP (36)
- The ethics of XTP (24)
- Economic interests in relation to XTP (6)
- The status of Danish research and regulation of XTP (17)

## 3.1 Biotechnological progress

Research into public engagement with modern biotechnology repeatedly indicates that biotechnological innovations are a source of excitement and hope as well as concerns and fears about novel risks and transgressions of ethical limits (Bauer and Gaskell 2002). This ambivalence applies to the reporting on XTP in the Danish press as well, although the fears and concerns appear less outspoken than in relation to other biomedical applications, such as stem cell research and genetic testing. XTP is presented in most newspaper articles as a means to solve a specific problem; the shortage of organs for donation to patient suffering from kidney or heart conditions. This shortage is the state of affairs, on which all reporting and discussion is premised, and it is presented as an evident and significant challenge for health care. Hence, in practically all accounts XTP is framed as a technology with a specific and in principle acceptable purpose – to help alleviate suffering in patients. However, in addition to its relation to a specific medical capacity problem, XTP is also frequently mentioned as one among many applications of a “brave new world” of biotechnology, where various interventions at the genetic level are opening up a host of new possibilities for different kinds of treatment, which presents society with a host of challenges. As such, XTP is associated with the wider debates around modern biotechnology, including some of its more controversial aspects.

Although framed as a future technology, many accounts – whether primarily supportive or critical in their framing – seem to assume that XTP is likely to become reality in a “foreseeable” though not quite predictable future. Therefore, reporting raises various issues affiliated to the – more or less inevitable – introduction of XTP. In doing so general progress in genetic science and biotechnology is framed as a given, and virtually all reports seem to be based on the premise that eventually XTP will become technically possible unless it is deliberately banned.

However, during the period surveyed the balance in the articles gradually shifts between a primary focus on the potential for medical treatment to also include of focus primarily on the

potential problems with disease transmission. Simultaneously, the time horizon for actual treatments to materialise seems to get longer, rather than shorter as time passes. In the beginning of periods surveyed scientific experts are quoted for saying that it is a matter of a (relatively short) time before clinical trials will commence. Later on, experts are more hesitant to speculate about when this might happen. This "delay" in relation to previous hope is in some reports made a separate object of discussion. However, at some point (largely coinciding with the publication of the "Genetechnology Commission's" report, see below) XTP practically disappears from the media agenda. While there are continued reports of the difficulties encountered in controlling the risks from retro-viruses, there are no explicit indications that the technology has been abandoned. Rather than being reported as a failed technology, XTP just disappears from the repertoire of expected future treatments, to pop up only on a few occasions after 2002. When XTP is in fact mentioned after 2002, it is mostly framed as a technology, which may still have potential to alleviate organ shortages, but has experienced unexpected difficulties in being matured.

## 3.2 Technical challenges and physical risks

The overriding frame in the reporting and discussions about XTP concerns the technical challenges associated with carrying out XTP as well as the health risks associated with the technology. Neither the word "xenotransplantation" itself nor the process it describes has ever become part of the common stock of knowledge the average reader is expected to be familiar with, as for instance genetic modification or stem cell research, which are often reported about without any technical jargon or explanation. Therefore, most news reports as well as commentaries and letters to the editor make some effort to explain what XTP is and the problems associated with it. Two types of challenges dominate the reports and discussions. Many reports describe in more or less details the *rejection mechanisms* at work in transplantation and the challenges they raise for XTP. They often explain why the addition of human genes to the donor pigs may be a solution. However, in terms of difficulties most reports focus on the risk that *the organs may carry viruses*, which might produce zoonotic diseases. During the period surveyed, the problem regarding retro-viruses in the donor animals' genes is mentioned still more frequently as the major obstacle for the technology to actually be used in clinical practice. The potential that viruses may travel not only to the patient receiving an organ, but might potentially cause epidemics in the general population is repeatedly quoted as the primary concern among scientific experts and regulators. This risk is often likened to the "Spanish flu" pandemic of 1918, but the dangers from zoonotic infections are also repeatedly illustrated with reference to HIV/AIDS. Yet, although the reporting focuses on the potential dangers, these are mostly framed as challenges to be solved by scientific research before the technology will proceed to clinical application, not as a present or imminent threat to the general public. There are very few really alarmist reports or opinions regarding XTP.

## 3.3 The Ethics of XTP

While most of the media reports are concerned with the technical aspects of XTP, addressing the questions of whether it is possible and dangerous, some articles also address in various ways what they describe as “ethical” aspects. This framing of topics as “ethical” in facts covers a lot of different issues.

Most of the contributions claiming to deal with ethics address the question of whether it is morally permissible to undertake XTP. The question is mostly related to the potential disturbances it may produce for the recipient patient as well as the wider collective’s understanding of what it means to be a human being. This concern can be exemplified by letters to the editor, where the question is posed if “one can fall in love with a pig’s heart”? In this framing, “ethics” thus have to do with defining in what respect biotechnology encroach on our definitions of what it means to be ”genuinely human” – a state of affairs which is considered in need of protection. According to several articles, the question of what is permissible when the “genuinely human” characteristics are violated requires ethical clarification by society at large, it is not a question that can be legitimately left to the individual patients and their doctors.

Yet, despite raising the question of the ethical and/or emotional reaction to the xeno-aspect of transplantation, by far the most contributions introduce the ”ethical question” only to present authoritative voices (medical doctors, ethicists, theologicians) who claim that physical organs are immaterial to human identity or that the question is insignificant compared to the human lives that can potentially be prolonged or saved.

By far the majority of contributions present the technology as relatively unproblematic or benign from an ethical perspective, and variations of the argument that having a pig’s heart implanted is not worse than eating pork are much more frequent than concerned voices. Likewise, animal welfare is introduced as an ethical issue, but mostly dismissed as a problem by arguing that we already have an instrumental/exploitative relationship with pigs. For instance, the chair of the Council for Animal Ethics states that:

> “Therefore saving human lives cannot possible be more ethically objectionable than the already widely accepted breeding of pigs just for consumption – that is a normalisation by comparison to other, well known practices where animal welfare issues are settled. Secondly, it is argued that transgenic pigs bred for transplantation purposes are likely to be treated far better than pigs in industrial production." “The pigs that will be bred in the project will be treated better and have a better life than ordinary production pigs. Furthermore, I believe this will contribute to raise the general level in pig production. And if people know that pig organs are used to save human

> lives, it might contribute to raise people's respect of the pig as an animal" (quoted in Politiken, January 29th, 1999).

Two additional issues, which can be labelled "ethical" and are discussed thoroughly in some of the TA activities reported below, only find their way into just a few media reports. One is the question of how to weight the (potentially huge) benefits for the individual patient, whose life may be prolonged with a pig's organ, against the (unknown) risks of transmitting diseases to the population at large. Nor is the expected need for continued monitoring of patients that has received animal organs to contain the risk of contamination really touched upon as an ethical question. In media reports, the question of contamination is dealt with almost exclusively as a question of adequate controls of risks, which is framed as an issue that requires more knowledge and better regulation, not as a question of weighing different values against each other. One explanation for this could be that it is taken for granted that no treatment should be allowed if it exposes anybody else to a risk. Many articles mention there is a risk of transmission of diseases, but the problem is consistently framed as a need for more knowledge, adequate risk assessment and a precautionary regulatory approach. Only very few articles presents this as an ethical issue, as a value based trade-off between different goods.

The second question regards the costs of XTP, should it become a more common procedure, and its effects on public health care spending. This issue was raised in the public debate as early as 1991 in a book by a science journalist, Gitte Meyer, debating different challenges arising from novel biotechnologies (Meyer 1991). However, according to Meyer, this – potentially extremely important – question never found any resonance with the medical science establishment (Interview *Science journalist*). In any case, the question of the potential costs of XTP is virtually absent from media reports – possibly because the technology was never close enough to clinical application to actually generate any public interest in the potential costs.

## 3.4 Economic interests in XTP

While the potential cost of XTP and the burdens it might place on the public health care system is absent in the media reports, another economic issue is repeatedly brought up, namely the question of the economic incentives driving modern medicine and biotechnology. While most reports dealing specifically with XTP make reference to the organ shortage problem, but rarely touch on the financial burdens this may place on the public health care system, XTP is often mentioned in passing in relation to other biotechnologies such as cloning and stem cell research, which have raised much more public concern and controversy. In these contexts addressing biotechnology more broadly, a more critical stance can be observed in many reports focussing on the profit motives driving the technological development. In this manner, some media reports associate XTP to technologies that are attracting more adverse publicity. However, in these cases XTP is mostly mentioned in

passing, not given any individual treatment. It is not reported anywhere that much of the work on XTP was carried out by pharmaceutical companies looking to sell organs along with immunosuppressive medicine. Therefore, no linkage appears to exist between the public imagery of XTP and the profit-motives driving biomedical research, as for instance in the debate on GMOs. That industry interests may be a driving force in the development of XTP was not really treated in the public sphere.

## 3.5 The status of regulation and the need for public debate

While XTP in most media reports is framed as a technology that is likely to be introduced in a few years – though the time perspective tend to get longer rather than shorter during the period surveyed, only for the topic to practically disappear from media reports – some contributions raise the issue that the regulatory framework is not up to date and risk being taken by surprise by rapid technological developments. Concerned politicians and scientific experts are quoted for claiming that the area is wholly unregulated in Denmark. Especially the risk of transmitting diseases across species barriers is described as a problem that requires novel regulation. Therefore, several calls are made from medical doctors as well as politicians that it is important that Denmark has a public debate about the risks involved and how they can be properly regulated in a precautionary manner. Eventually, this perception that regulation was insufficient led to the political initiatives recounted in the following – though likely more a result of concerns articulated in expert circles and reported in the media than the outcome of any genuine public concern manifested in the public sphere.

This summary interpretation of the framing of XTP in the Danish print media obviously does not give a precise picture of what the population in Denmark thought of XTP. However, it gives a picture of the kind of framings available to participants in the public debate at the time when technology assessment and policy making activities were taking place. This said, it should be noted that XTP as such has not received much media attention at any point in time and has largely remained an elite concern.

## 3.6 Existing data on public perceptions

In the 2002 EuroBarometer survey more than 80% of the Danish population report that they have heard about the concept of XTP (the word itself is not used in the survey, which speak of “introduction of human genes into animals (eg pigs) to produce organs (eg hearts) for human transplants). At this point in time public opinion was divided between approximately 25% of what the EuroBarometer analysts call “supporters”, approximately 50% “risk tolerant supporters” and approximately 25% “opponents”. This was a significant growth in public support compared to a similar measurement done 6 years earlier in 1996, where especially the moral reservations to XTP appears to have to have subdued – possibly in the light of other, even more transgressing novel technologies appearing in the public sphere in the

meantime, such as cloning and embryonic stem cell research (all numbers drawn from Allansdottir 2010).

In complement to the EuroBarometer surveys qualitative studies on public perceptions of biotechnology were carried out in a number of European countries including Denmark (reported in Wagner et al 2001). In the fall of 1999 and the spring of 2000 a series of six focus groups interviews were conducted, which investigated the nature of public perceptions of biotechnology (reported in Wagner et al 2001). The transcripts of those focus groups have briefly been re-examined for the present report.[2]

The focus group interviews focus on a broad range of issues in relation to biotechnology, such as the acceptability and desirability of different applications of modern biotechnology in both agriculture and medicine, whether such applications ought to be assessed according to criteria of risk or ethics, perceptions of the role and responsibility of different social actors such as scientists, regulators, politicians and NGOs etc.

When re-analysing the transcripts with a particular focus on xenotransplantation, two issues emerges as particularly noteworthy. First, XTP is not a very pertinent issue in the discussion compared to other technologies, which strengthens the conclusion above that XTP was largely an elite concern. Second, there is a significant ambivalence in the assessment of XTP.

Although XTP was one of the (potential) technologies mentioned on cue-cards handed out by the interviewers, it did not attract much attention among the participants compared to other topics, which clearly triggered more responses. This pertains in particular to cloning of animals and the prospect that this technology might be used on human beings, and genetically modified food. Both of these topics had been intensely covered by the media following the announcement of Dolly and the Europe-wide contestation of GMO products. As a consequence, these applications triggered most recognition among the focus group participants. There was some confusion among the participants as to whether XTP had actually been carried out between animals and human beings, as some participants had heard “rumours” that this had indeed happened, either from pigs or primates.

As reported in the general conclusions from the project (Wagner et al 2001) there was significant ambivalence regarding many applications of modern biotechnology. This pertained in particular to XTP, which generated a number of comments on the “unnaturalness” of crossing species barriers, which were intuitively rejected as an undesirable development. Comments were also made regarding the heart as the seat of

[2] The interviews were conducted by as part of the EU project ‘Life Sciences in the European Public’. The Danish team consisted of Professor Arne Thing Mortensen (Roskilde University), Assistant professor Erling Jelsøe (Rosklide University), Mercy Wambui Kamara and Assistant professor Jesper Lassen (The Royal Veterinary and Agricultural University, Denmark). I am grateful to the authors for kindly putting their data at my disposal.

emotions, and consequently as something one should be careful tinkering with. One group touched upon the question of whether one could continue to consume pork form pigs with human genes added, though without the term cannibalism being used. The overall picture emerging from the focus groups is one of significant moral reservations against XTP.

On the other hand, many interviewees also expressed a more utilitarian stance that if XTP offered the possibility to save the life of people, possible themselves or someone next of kin, it would be cruel and impermissible to reject the technology out of hand.

Most comments were critical of XTP on ethical grounds or as “gut reactions” against something considered unnatural. None of the participants seemed aware of the discussions regarding the risk of transmission of zoonotic diseases, and the question regarding to potential costs of XTP were touch upon only very superficially.

# 4 XTP in the Danish TA Field

The concerns about different potential consequences of XTP, which were articulated in the scientific community and also to some degree found their way into the public sphere, led to some specific policy initiatives in Denmark. However, to understand these specific initiatives it may be helpful to first say something about the context in which they took place. In particular it is pertinent to try to explicate some characteristics of the interplay between the public sphere, the political level and selected "debate-institutions", which are central players in the governance of modern biotechnology in Denmark.

In the international literature on public engagement with science and technology, Denmark is often pointed out as a front runner and role model, which might be a source of inspiration or even imitation (e.g. Joss and Durant 1995). This is so for several reasons. Some of the back ground conditions have to do with the country's relatively high degree of cultural homogeneity, an egalitarian political culture and a tradition for public and popular education (*Folkeoplysning*, people's enlightenment) dating back more than a hundred years (Cronberg 1995). However, there is also a particular institutional locus for public engagement with science and technology, the Danish Board of Technology (DBT), which has emphasised participatory modes of technology assessment in a particular manner since its founding in 1985. The Board was an attempt from (parts of) the parliamentary system to give an institutional locus and channel to the grass root activities that had emerged in relation to (nuclear) energy policy and biotechnology in the preceding 15-20 years and bridge a perceived gap between experts, politicians and the public. The DBT has attracted significant international attention for its particular approach to public involvement with technology assessment (Klüver 1995). The Board has arguably been an important vehicle for the understanding and acceptance among elite decision makers that ordinary citizens can be both sufficiently competent and interested in novel technologies to have a say in their governance.

However, when it comes to the regulation of biomedical technologies, there is another institution, which is equally important in regard to addressing public concerns over new technologies, the Council of Ethics (CoE). The Council was established by Parliament in 1987 to provide advice to the legislature on ethically sensitive issues in the life sciences and to stimulate public debate on such issues. It is not obligatory for legislators to hear or heed the advice on the Council, but the parliament nonetheless frequently solicits advice and often follows the recommendations. The Council is also free to take up issues on its own initiative and thus serves an early warning function. The CoE does not apply participatory methods when producing policy advice, but it has played a significant role in Danish governance of biomedicine as a moderating force in the face of the rapid technological innovations. Although the CoE is compiled of biomedical experts, ethicists, theologians and a few "lay people" (usually individuals originating from the cultural sphere such as writers, journalists

etc.), the Council understands itself as a guardian of the public interest, which is often equated with being a modifying force in the face of rapid biomedical developments. One interviewee, for instance, described the role of the Council as exercising the privilege to expend the time necessary for reflection, which is rarely available to political decision makers.

In Denmark public concerns over and debates about new biotechnology proliferated during the 1990s, in particular in relation to two technological trajectories: the introduction of GMOs in the agro-food sector and new reproduction technologies. Biotechnology became particularly politicised through the combined effects of the introduction of GMO, which coincided closely with the revelation of a link between BSE and nvCJD (i.e. admitting that "mad cow disease" could spread to human beings), followed quickly by the arrival on the world scene of Dolly the cloned sheep. These events in combination raised public concerns about the safety of new products and the ability of scientific experts to control the risks affiliated with them. It also placed "ethical" questions concerning the motives behind and moral acceptability of these new technologies on the public agenda. This resulted both in a surge in NGO mobilisation and activity, increased media coverage and public debate as well as a number of policy initiatives aimed at addressing some of these concerns in various ways (Jelsøe et al 2001).

In the autumn of 1997 the ministry of trade and industry, on request of trade organisations in the food sector – which demanded some clearer political signals regarding the use of biotechnology – compiled a commission to unravel the reasons behind the continued public concerns regarding in particular GMOs and provide the basis for more inclusive public debate on how to apply the novel genetic technologies. This committee, called BioTIK (a verbal contraction of "biotechnology" and "ethics" in Danish) presented a report in the summer of 1999, which formulated a set of ethical guidelines to direct the governance of biotechnology across all domains of application (Hansen 2010). It also produced a number of recommendations on how to ensure a continued public debate on these issues and make sure the ethical principles would be taken into consideration in the drafting of relevant novel legislation. One of these recommendations was that a better coordination should be ensured between the different advisory bodies that deal with biotechnology.

However, at the time of publication of the BioTIK report collaboration had already been initiated between various public bodies working on issues related to the assessment and governance of biotechnology. This was instigated following a parliamentary debate on cloning in the wake of the announcement of Dolly. An umbrella organisation consisting of the Danish Board of Technology, the Council of Ethics, the Council on Animal Ethics, the Danish National Committee on Biomedical Research Ethics and the Inspectorate on Animal Experiments was launched in 1998 under the name BIOSAM. According to some interviewees there was really no strong desire for this umbrella among the involved organisations. It happened on the request of the government, which wanted a stronger and

more unanimous base of advice on how to govern the novel biotechnologies through synergies in the advisory system. In the view of some of my interviewees the desire for this collaboration originated in a political compromise to accommodate two smaller centrist party (Centrumdemokraterne and Kristeligt Folkepart), which took a particular interest in biotechnology. As a result, funds were made available for collaboration, and the involved organisations started to look for topics, on which it would be relevant to collaborate. At this time XTP was rising on the horizon internationally. Interviews with people centrally placed within the BIOSAM collaboration has not been able to establish more specifically exactly why XTP was selected for attention (Interviews *Bioethics professor, Former Chair of CoE, Member of CoE Staff*). However, the topic was well suited to the institutional purpose of BIOSAM. It bundled together issues regarding physical risks from an emerging technology, ethical issues pertaining to both the human and the animal domain as well as questions concerning priorities in health care expenditure.

In retrospect, some interviewees indicated that the selection of XTP was as much a matter of finding a suitable topic for the BIOSAM collaboration, which was relevant for all the involved organisations, as it was an expression of a pressing need for either ethical or regulatory clarification. However, other interviewees did not quite agree with this cynical reading of the process. While not denying the topic was well-suited to facilitate collaboration in the organisational constellation of BIOSAM, they insist that XTP raised some genuine concerns at the time, and it is only in retrospect that concerns over XTP can be deemed premature and perhaps even unfounded. The selection of XTP for closer examination followed relatively closely upon the much more controversial discussions regarding GMOs and animal cloning. Some members of the organisations in BIOSAM foresaw that XTP might generate similar public concerns in the future and suggested that BIOSAM should try to deal with this prospectively and proactively. As such, XTP indeed fitted the BIOSAM collaboration well, as it pertained to all the involved organisations different mandates. Therefore, most of the policy activities regarding XTP in the following years were initiated by or at least affiliated with BIOSAM.

The Council of Ethics was a central organisation in BIOSAM. However, former members of the Council differ in their assessment of how important XTP was considered to be at the time. One interviewee recalls that XTP never generated much interest in the council (Interview *Former Chair of CoE*). In the assessment of the Council, XTP does not involve “identity carrying organs”, which makes it less challenging and controversial from the kind of ethical perspectives occupying the CoE. By “identity carrying organs” the CoE understand primarily the brain as the seat of consciousness, visible features of the physical appearance and the genetic code amendable to intergenerational transmission. Consequently the primary concerns are about the control of physical risks, which the Council considers a more technical aspect and hence at the fringes of its remit (Interview *Member of CoE Staff*). However, another former member of the Council recalls that the ”yak-factor” – the immediate repulsion by the transgression of species barriers and the idea of having an animal organ in

your body – was discussed by the Council, but was "overruled" by more "rational" arguments, suggesting that fatality is worse and that most people have no reservations against eating pork (Interview *Former Member of CoE*).

Although several of the organisations involved in the BIOSAM collaboration have as a central task to address the concerns of the public in relation to (bio)technology and convey this to policy makers, the activities related to XTP were not participatory in nature. The guiding idea was, it the words of one interviewee, to "generate a broader discussion than had been common practice until this point in time" (Interview *Bioethics professor*). In comparison to the public debates on other technologies (e.g. GMO, cloning and stem cell research) several interviewees involved with the XTP activities in BIOSAM recall that the topic was remarkably uncontroversial. Some of them suggest that there was a strong desire among policy makers and scientists to avoid a repetition of the controversies regarding GMOs and cloning. In regard to GMOs several of the interviewees articulate a shared assumption that the general public was somehow unprepared for the novel GM technology, and that a more thorough public debate about the purposes and regulation of the technology at an earlier stage could have eased its introduction into society and onto the markets.

As a consequence of this diagnosis, which appears to have been shared among the organisations involved in BIOSAM, it was seen as desirable to have a broad debate and initiate regulation of XTP before scientific developments progressed anywhere near clinical applications. However, several interviewees suggested in retrospect that the desire to initiate debate may in fact have been premature in two respects; 1) XTP never (at least not so far) reached a stage of clinical maturity that made it necessary to legitimate its application beyond the confines of basic research laboratories. 2) XTP did not seem to generate any particular potential for controversy. Following the announcement of Dolly the cloned sheep, the Danish Parliament passed a resolution that the cloning of animals should be prohibited in Denmark until further notice. This type of resolution is an instruction from Parliament to the Government to prepare legislation, which Parliament can then subsequently pass. However, the resolution was never turned into proper legislation and consequently lost legal force when Parliament was dissolved for a general election. The subsequent Parliament never actually passed any legislation. Therefore, researchers kept pressing the minister of science for legal clarification by repeatedly producing cloned bovine embryos and bringing them still closer to delivery. This was disputed in the Danish media at the time and animal cloning was strongly criticised by animal welfare groups. However, nothing similar in terms of public attention was ever seen in relation to XTP. In fact, one interviewee working in the biosciences suggested that XTP was always seen as "the benign biotechnology", one where the benefits were so obvious and the ethical problems insignificant, that he and his colleagues tended to use XTP as a "lubricant" to make other biotechnologies more palatable in the wider public (Interview *Professor of Veterinarian Embryology*). XTP was used to symbolise (potential) applications of genetic engineering, which were unequivocally beneficial.

A similar comparison can be made with the debates on GMOs. Where GMOs generated a lot of concern and hostility among especially environmental NGOs, there was never any similar adverse attention to medical research on XTP from animal protection organisations. As one interviewee expressed it, animal protection organisations do not wish or need to engage with complex problems pertaining to the welfare of human beings, there are plenty of other, more pressing animal welfare issues, were there are no immediate counterweighing interests (Interview *Bioethics professor*). Hence, compared to agricultural biotechnology no mobilisation potential has been generated by XTP in Denmark. There may have been a certain "yak-factor" – the crossing of species boundaries were seen by some people as repugnant – but given that it is framed as something that might save lives and nobody ever would be treated against their will, the prospect of the procedure itself never generated any noteworthy public resistance. Likewise it seems that the prospect of a transfer of viruses between animals and human beings remained too distant to generate any genuine public concern, most likely very few members of the public were aware of this risk.

However, even if it seems in retrospect that XTP did not generate the kind of concerns or controversies in public, which is often motivating more elaborate, perhaps participatory, technology assessments, it did generate some TA activity, as will be described in the following.

In March 1999 BIOSAM (with the DBT as the executing organisation) together with the University of Copenhagen organised an expert hearing with four researchers from Denmark, Sweden, the US and the UK. These were all biomedical experts, who were invited to talk about prospects and challenges affiliated with the potential use of XTP. The minutes from the meeting reveal a high degree of optimism among the experts regarding the technical prospects for XTP aided by genetic modification of the donor animals, but a more hesitant and divided attitude towards the possibilities of managing the accompanying risks of infections through retro-viruses. The meeting did not produce a shared conclusion or recommendation, but it transpires from the minutes that the experts agreed that a cautious step-by-step approach, where gradually more and more steps towards clinical applications is accompanied by a close monitoring of risk, would be the best way to proceed. The participants stated that it is important that developments in XTP are not forced by renegade scientists or commercial pressures. If progress is forced prematurely, problems that are unavoidable in developing a technology such as XTP might create backlashes for this otherwise promising technology. At this point the experts summoned by the TA system thus still consider XTP as a promising technology, although concerns about unwanted side-effects are beginning to overshadow the positive expectations. Yet, the issues are being discussed in rather linear terms, as a given trajectory, which can be followed "step-by-step", whereby only the pace of progress may need to be moderated. The chair concluded that there had been less disagreement among the experts than he had expected, but that BIOSAM now had a good case to present to the public.

A summary of the conference with the politically most pertinent issues was then presented to the public in the form of two newsletters from BIOSAM (BIOSAM 2000, 2004). As part of its introduction, the first newsletter stated that: “In Denmark, there is currently no particular legislation regulating xenotransplantation. There is thus a need for a debate and political clarification about whether we wish xenotransplantation to be introduced in Denmark, and, if so, a debate about what demands should be made to experiments with and use of xenotransplantation.” (BIOSAM informerer 1999, 2000). It was, however, also lamented that “Denmark is practically void of research in this field and the government does not possess the competences to follow the international development” (BIOSAM 2000).

Following upon this, in February 2000, the DBT and the Council of Ethics organised a one day hearing on XTP at the request of the standing committees on health and research in the Danish Parliament. At this meeting the scope of the agenda is somewhat broader, going beyond the strictly scientific issues. This is reflected in the composition of the panel of invited experts, which includes natural scientists, ethicists, a lawyer and an economist specialised in health care economics. The themes elaborated in the hearing were compiled under the following headings: “Organ transplantation”, “Xenotransplantation”, “Risks of transfer of virus”, “Health economic considerations”, “Regulatory considerations”, “Ethical implications in relation to humans”, “Ethical implications in relation to animals” and “International experiences in regulation”. As can be seen a broad range of themes were elaborated through expert presentations and Questions & Answers sessions between experts and parliamentarians (Danish Board of Technology 2000).

One theme, which proved to be significant for the subsequent political treatment, was the fact that XTP was practically unregulated by law in Denmark. It was made clear that experiments with XTP would have to be approved by research ethics committees at a regional level, as is standard practice that medical research is approved by regional research ethics committee. However, these committees serve to protect the patients participating in medical experiments from unethical treatment and nothing in Danish legislation would prevent a doctor from treating a patient with an animal organ as a last resort and outside formalised experiments. In this case, the doctor would only be obliged to think of the welfare of the patient, not about the risks of transmission of viruses or other diseases. In this case the patient would have to give his or her informed consent, but this could not obligate the patient to take part in any subsequent monitoring schemes. This state of affairs raised some concerns regarding whether existing legislation was suitable and sufficient to handle XTP in a responsible fashion.

This lack of regulation was to some extent rectified in January 2001. The Council of Ethics and the Danish National Committee on Biomedical Research Ethics issued a joint statement to the regional scientific ethics committees. This stated that all clinical trials with XTP raise fundamental question of a broader character regarding their acceptability in the light of uncertainties and possible risks. Therefore, all such experiments must be deferred to the

National Committee on Research Ethics. As far as the present research has been able to establish, the initiative for the moratorium came from lawyers in the Committee on Research Ethics, who were concerned with the fact that the risks of zoonotic diseases was a genuine threat to public health, but in fact the Committee had not statutory basis to prevent such experiments, as their jurisdiction pertained only to the welfare of the patients that might participate in experiments. Therefore, they suggested a moratorium until the issue could be legally regulated. They did so in collaboration with the Council of Ethics (with which close ties existed due to the movement of central staff between the two organisations) in order to underline the ethical importance of this precautionary approach. The moratorium did not completely do away with the possibility that individual doctors in principle could carry out xenotransplantation outside of controlled experiments. In practice, however, it meant that no experiments would take place without centralised approval. Yet, this did not quite entirely satisfy the more concerned politicians, who felt that formalised legislation was required in this domain. At this point in time, the governance of XTP therefore briefly becomes the object of direct political attention and intervention.

However, before describing this process in more details, one further finding of the Danish TA system's dealings with XTP must be mentioned. When regulating such areas in Denmark, there is a long tradition of hearing actors with a stake in the development in various ways. In a case like xenotransplantation this would include for instance patient organisations. This did not happen in any of the activities recounted above. In Denmark there is an organisation for patients with kidney diseases (Nyreforeningen), which organises and represents patients in dialysis treatment and kidney transplanted. When interviewed about their views on XTP, the (recently appointed) director explained that the organisations had no interest whatsoever in supporting or furthering the technology. The organisation does not see XTP as a feasible, potential source of treatment. In their view, the lack of organ donors is an organisational issue, which should be solved through a better system to motivate and organise potential human donors. Furthermore, the organisation feels that the ability to maintain and raise the level of organ donation will not benefit in any way by the organisation participating in public debates on the prospects of xenotransplantation. In short, they did not wish to engage with the issue at all (Interview *Patient organisation*).

Although patient organisations – especially for more rare diseases – can be idiosyncratic and shaped by a very few, vocal activists, it does seem remarkable that in this case a significant sum of money have been spent in the hope to develop a medical technology for which the potential beneficiaries show no interest whatsoever, rather to the contrary. Furthermore, patient organisations have not participated in any of the technology assessment exercises recounted above. It seems that all initiatives have been generated by professional scientists, either concerned with the public legitimacy of their work or the kind of risks entailed in it.

# 5 XTP in the field of policy making

A few days later after the *de facto* moratorium on XTP was announced by the CoE and the Committee on Research Ethics in January 2001, a debate was held in the Danish Parliament, initiated by the Christian Democratic Party. There was no immediate link between the issuing of the moratorium and the debate in Parliament, as the debate was scheduled much earlier as a follow up to the hearing held the year before. Rather, both the moratorium and the parliamentary debate can be said to be occasioned by the previous hearings and the kind of concerns that were raised. The Christian Democratic Party, which initiated the debate, was a small a centrist party with only four MPs, which often sought to profile itself on "ethical issues", such as a restrictive attitude to abortion, animal welfare and a cautious attitude towards novel biotechnologies such as cloning, stem cell research etc. According to their spokesperson, concerns about XTP were a "natural" subject for them to address, as "everyone expected for us to take up things like this. If we had not taken up the issue, probably nobody would, back then. Today, luckily, this has changed" (Interview *Parliamentarian*). The Christian Democrats were mostly concerned about the unchecked risks that might be affiliated with XTP, but also felt that the ethical aspects deserved to be explored thoroughly by political decision-makers, like "… how many animal organs can you put in a human being and still call it a human being?" (Interview *Parliamentarian*). The party therefore raised an inquiry ("forespørgselsdebat") in the Parliament. This is format of debate where the minister(s) responsible for a given area has to give an account of the status of the legislation, policies and potential problems to the Parliament, which can then decide to request ministers to do something, for instance prepare a particular piece of legislation.[3]

The Christian Democrats posed the following question to the ministers of research, health and justice: "How will the government ensure that research into and experiments with xenotransplantation only takes place with due consideration for the necessary safety, that possible trials only happen in controlled and contained circumstances, and that the welfare of the donor and experimental animals are carefully considered?"

The responsible ministers informed the Parliament that 1) with the recent announcements from the Central Committee on Research Ethics and the Council of Ethics, all research should be approved by the Central Committee on Research Ethics, 2) that public hospitals and universities will be instructed not to carry out any experiments until the risks and regulation is further clarified[4] and that 3) research on xenotransplantation was unlikely to

[3] This was the format of debate in which a previous Parliament request the Government to ban cloning, which, however, never actually made it to a bill – see above.

[4] In principle, the government cannot instruct universities in Denmark about what they can and cannot do experiments on (outside proper legislation) as there is freedom for research. However, the medical faculties of the universities are so closely integrated with the public hospitals in regard to clinical research that in practice such political instructions will be heeded.

induce any particular animal welfare problems, which were not covered by the existing legislation and monitoring.

In the issuing debate the Christian Democrats proposed that Parliament should decide to ban xenotransplantation in Denmark until further notice, such that the decision to resume such research would demand by a renewed parliamentary decision. However, practically all other parties in the parliament considered this as excessive, and proposed an alternative that foresaw a *de facto* moratorium but no legislation. They suggested that 1) experiments with XTP should be approved by the scientific research ethics committee system (and not by Parliament), but 2) the minister of research should form a committee to undertake a review of the prospects and risks presented by a number of new biotechnologies, not just XTP, in order to clarify the need for new legal and/or regulatory measures.

This motion was carried by the Parliament, and this was the occasion for the formation of the "Genetechnology Commission". This Commission was subsequently compiled with a number of scientific experts, ethicists and ministerial representatives. Their mandate was to elucidate the possibilities and challenges affiliated with four emerging technologies (XTP, gene-therapy, stem cell research and genetic diagnosis) in order to stimulate public and political debate on an informed basis and make suggestions for necessary legislative initiatives. The commission was compiled by the Ministries of Research and Health and included active scientists from the respective fields, representatives from the ministries and from the Council of Ethics, the Council of Animal Ethics and the Danish Board of Technology. This kind of committee is standard practice in policy formation in the Danish political system.

About the time this commission initiated its work, in May 2001, the National Board of Health (highest medical authority in Denmark) issued an instruction to all Danish hospitals that no XTPs should be carried out in Danish hospitals outside controlled experiments approved by the Danish National Committee on Biomedical Research Ethics until the question of risks involved in such research had be further clarified and further regulation was put in place. This turned the principled decision in Parliament regarding a moratorium into actual policy. Although no legislation was issued, in practice such an instruction from the National Board of Health meant that a moratorium was *de facto* in force.

Several members of the Committee have been interviewed for the present inquiry. None of them were able to recount why precisely those four technologies were included for examination. The Christian Democratic parliamentarian, who raised the debate initially, suggested that there was an "economy of scale" involved; if the government had to compile a commission, they might as well add more topics, on which it thought legislation might be necessary in the future. The chair of the committee, a professor of clinical biochemistry, suggested that substantively it made sense to elucidate challenges affiliated with several technologies, which might potentially serve equivalent purposes in medical treatment. In

particular XTP and stem cell research were seen as different approaches, which might potentially deliver treatments for the same diseases through different means.

In the report from the Committee, which was published in the fall of 2002, the development of XTP is motivated in the large gap between supply and demand of organs for transplantation. However, it also notes that "The overall hope is that xenotransplantation in time may become a routine treatment. There are, however, a number of both technical, biological and ethical problems concerning xenotransplantation, which makes it difficult to decide whether the technology will be feasible as a form of treatment within a foreseeable future" (Genteknologiudvalget 2002: 67). The report goes on to elaborate these problems. Especially the problems related to the transmission of viruses from donor animals to human being are quoted as a reason why XTP is not expected to become a clinical reality for a foreseeable future.

All the members of the committee interviewed for this inquiry recollect that XTP was not a very big or controversial part of the work of the committee, and was largely overshadowed by the other topics. One member suggested that the assessment at the time was that XTP was rather unlikely to actually happen in a foreseeable future. According to the interviewed members and the Commission's secretary there were significant debates in the commission about stem cell research, where in particular members from the research community and the representative from the Council of Ethics engaged in elaborate debates about how to regulate the use of human embryos. Nothing similar took place in relation to XTP on which all members concurred that the crucial issue (apart from the technical issue regarding rejection of the organs) was whether the risks of contamination could be dealt with in a satisfactory manner.

In October 2002 the commission delivered its report, which concluded that no further legislation or regulation was required for XTP for the time being. It was assessed that clinical applications of XTP has been pushed off into the future on account of the risk of transmission of viruses. Consequently, the existing *de facto* moratorium was a sensible and sufficient regulatory tool, which only would require review in the case of significant international breakthroughs in XTP research. The commission makes a number of recommendations regarding the other technologies involved in its mandate, and it was the immediate occasion for a change of the law on assisted reproduction (pertaining to the use of "surplus" embryos for stem cell research, see e.g. Horst 2008).

Since then there has been no further policy activity or measures concerning XTP in Denmark.

# 6 XTP Timeline in Denmark

| Date | Central policy events | Other events and developments |
|---|---|---|
| 11.1991 | | The word “xenotransplantation” appears for the first time in a Danish newspaper as well as a book debating novel biotechnologies (Meyer 1991) |
| 12.1995 | | The first letter to the editor containing the word “Xenotransplantation” occurs in a Danish newspaper |
| 1998 | BIOSAM is formed as a collaboration between The Danish Board of Technology (DBT), The Council of Ethics (CE), The National Danish Committee on Biomedical Research Ethics (CVK), the Inspectorate for Animal Experiments and The Council of Animal Ethics (CAE). BIOSAM takes up XTP as one of its central areas of interest | |
| 3.1999 | DBT, BIOSAM and University of Copenhagen organize an expert hearing with 4 natural science experts from DK, S, USA, UK | |
| 2.2000 | DBT organizes a hearing for the Danish parliament with 8 Danish and 2 Swedish experts, including natural scientists, ethicists, one lawyer, one economist (Sweden had had a XTP Committee) | |
| 1.2001 | CE and CVK make a joint announcement to the regional scientific ethics committees that all XTP trials or preparations thereof raises fundamental questions and must be presented to the CVK | |
| 1.2001 | Questions/Debate in the Danish parliament, resulting in<br>1) A de facto moratorium on XTP<br>2) The formation of a “Genetechnology Commission”, examining four different new medical technologies (XTP, gene therapy, stem cell research, genetic diagnosis) in order to support decision making and public debate | |
| 5.2001 | The National Board of Health (highest authority in DK) issues an instruction to the county authorities (in charge of hospitals) that no XPTs should be carried out in Danish hospitals outside controlled experiments approved by the CVK until further regulation is in place | |
| 10.2002 | The Genetechnology Commission delivers its report, concluding that at present no further legislation or regulation is required in the XTP domain | |

# 7 Interpreting the Danish case

When compared to a number of other modern biotechnological applications, which were debated around the same time, e.g. cloning, stem cell research, GMOs, it is safe to say that XTP has drawn relatively little public or policy interest in Denmark. This can probably be ascribed to two factors in particular:

1. There was never any really strong interest in XTP from the scientific community or commercial operators. Apart from a few dedicated transplantation surgeons (who went into retirement as the international developments really took off), nobody seriously promoted a move towards clinical applications. Ever since, XTP appears to have been a rather dormant field within the scientific community in Denmark, where international developments are monitored, but no researchers engage actively with the field

2. Simultaneously, XTP was framed in the public as a relatively benign application of genetic engineering with a well-defined and uncontroversial objective. Although some concerns were raised regarding the ethical acceptability of the crossing of species-barriers, the public debate generally took a pragmatic and utilitarian view on XTP, based on the assumption that any transplantation would be voluntary and only affect the receiving patient. As a consequence, there was virtually no NGO mobilisation or critical interest in XTP. As explained, the most likely group of patients to benefit from whole organ XTP – kidney patients – expressed an outspoken dismay for the idea and did not engage in the debate at all.

Yet some TA activities were initiated to clarify and debate a number of issues in relation to XTP. However, rather than being a response to any pressing need felt by any particular actor or actor coalition in the larger society, the activities seemingly arose out of the need of the TA systems itself. At least according to some interviewees the selection of XTP as a topic of debate had as much to with the need of TA organisations to find an issue on which to collaborate in a reasonably meaningful manner, though not all participants are willing to accept this cynical reading.

This initiative followed close on the heels of other – much more prolific – controversies over especially GMOs and cloning techniques. XTP appeared at the time as an approaching technology, which shared many of the same characteristics and potential for controversy. This view of things embody a very linear conception of the trajectory of a technology, which in principles leaves only a rather passive role for TA activities – something that should prepare society for the oncoming technology, which will in any case arrive at some point in time. This linear thinking is quite common in the framing of modern biotechnology. Hence, it appears there was broad agreement in TA circles that it might be a good idea to raise some

of the potentially controversial issues in a prospective fashion. It was hoped and expected that experiences could be drawn from past controversies and prevent similar levels of fear and hostility, which some actors felt had befallen GMOs and cloning techniques. However, in hindsight the TA activities related to XTP are considered by several of the involved TA practitioners as premature (as the technology never reached clinical application) and too "top down" as popular concerns never really manifested themselves and central potential stakeholders, e.g. patient organisations, did not wish to engage in the debates or were not invited to do so. Somehow, the patients' view seem to have been filtered out of the TA processes, possibly – as suggested by one interviewee – because the field had a ring of science fiction about it and nobody seriously imagined that it would progress towards clinical applications in a feasible future. At least, the patients' view of the prospect of XTP appear to be wholly absent from the recorded discussions among policy makers. In the end, assessing XTP remained an elitist undertaking restricted to some rather narrow and – to some extent – closely intertwined expert circles in Denmark.

Yet, some of the same practitioners also pointed out that XTP exemplified how TA activities inevitably are very sensitive to the temporal developments of events. Had the technology in fact matured to a level of clinical applications, the appraisal might have been both pertinent and appropriate. If nothing else, the case demonstrated some of the difficulties involved in designating the appropriate and timely measures for a democratic appraisal of novel technologies. If instigated "too early" – in phases where technological trajectories are not yet solidified – they may end up addressing irrelevant issues. However, if instigated "too late" technologies – or social appraisals – may be hardened to a degree where TA processes no longer can make a difference. In the case of XTP the Danish TA system (which has matured significantly in parallel to development to the life sciences) may simultaneously have been both overtly sensitive to developments still only on the horizon and strangely insensitive to the concerns of the potential beneficiaries of the technology in question.

# 8 The Danish Political System – Background information for comparison

This section contains information on the background variables required for WP 4

## 8.1 General features

### 8.1.1 Cabinets

Denmark last had a single party government in 1982. Since then all cabinets have built on coalitions of at least two parties.

1981-1992 lead by the Conservatives, including the Liberals and different constellations of other, smaller parties

1992-2001 lead by the Social Democrats, including different constellations of smaller parties

2001- present lead by the Liberals, including the Conservatives

### 8.1.2 Legislature

Denmark has only one chamber in parliament (Folketinget).

The parliament has few organisational means of information provision. Parliamentarians from the governing parties are to some extend able to rely on the services of the central administration (ministries and government agencies). Parliamentarians from the opposition rely on information provided to the standing committees by the central administration, but also frequently use the possibility of asking questions of ministers, who are obliged to answer (truthfully) to the parliament. However, this often seems to serve a function in the political game rather than as a source of information provision.

Interest organisations play a key role in providing information for parliamentarians.

The Danish Board of Technology is a rather unique organisational invention, as it is in direct service to the Parliament, providing knowledge and recommendations on novel technology and socio-economic impacts of technological innovation. Most expert commissions etc. report to the Government rather than the Parliament. This information is obviously passed on to the parliament, but the parliament can only initiate such information provision indirectly (as was seen regarding the Genetechnology Commission)

### 8.1.3 Executive-legislative relationship

Some observers talk about a long tradition of a “cooperative democracy”, where most wide-ranging, important decisions are based on compromises including all the major (old) parties in parliament. However, since 2001, the liberal government has found its parliamentarian basis in the Danish Peoples Party (rightwing populist party) and has been criticised for pursuing a more divisive strategy on many issues. This has lead to a situation where the executive has a more dominant position vis-à-vis the parliament than was traditionally the case, as many important issues are negotiated among the government and its parliamentarian support party prior to negotiations in parliament. Formally it is the role of the parliament to legislate, in practise by far the most legislative initiatives come from the government, prepared by the ministries. However, the parliament can take initiatives that instruct the government to prepare legislation (e.g. the cloning issue in 1997, although this was not implemented due a general election) or to compile commissions to provide knowledge and recommendations (e.g. the Genetechnology Commission).

### 8.1.4 Bureaucracy

The central administration is politically neutral, only very few “special advisors” to the ministers are replaced when government changes. Except for the central bank, most government agencies are under direct political control of the government, but most day-to-day operations are left to the bureaucracy. Denmark has a very large public sector, accounting for more than half of the GDP. Of this, the state accounts for about one third, municipalities and regions for the rest. Consequently, the state bureaucracy is relatively large.

### 8.1.5 Judicial review

Judicial review plays only a minor role for political decision-making. Denmark neither has a constitutional court, nor specialised administrative courts. Labour unions and industry associations run their own judicial systems for arbitration and adjudication in industrial relations.

### 8.1.6 Party system

There are currently nine parties represented in the Danish parliament. Due to a low entry threshold (2%) and proportional representation, this is not unusual. The dominant parties – i.e. those that realistically can be expected to provide the prime minister – are the Liberal Party (currently in power) and the Social Democrats (in power 1992-2001 and considered the opposition leader).

### 8.1.7 Interest group system

Denmark is traditionally a corporatist country, where the influence of trade unions and industry associations on politics has been very strong. Furthermore, the labour market is self governing through collective bargaining between unions and employer associations, usually with little political interference. This corporatism is currently under pressure from declining union memberships, decoupling of occupation and electoral preferences, diversification of political interests to incorporate non-economic issues, Europeanization of regulation, etc., but in certain respects the political system actually seems keen to maintain this particular "Danish model" rather than succumb to a more pluralist system.

Political scientists thus refer to Denmark as an "negotiated economy", "… a structuring of society whereby an essential part of the allocation of resources is conducted through organized negotiations between independent decision-making centres in the public sector, private interest organisations, and financial institutions" (Pedersen 2006: 246), meaning that representatives of major societal interests are virtually always invited to the table, when important issues are being considered.

### 8.1.8 Direct democracy

Direct democratic instruments have primarily been employed on European issues, which have been somewhat disconnected from domestic politics, as cleavages in voter preferences on European issues often cut right through the constituencies of the main parties. Denmark has had five referendums on European issues (Accession to the EC 1973, Accession to the Common Market Act 1986, Ratification of the Maastricht Treaty 1992, Ratification of the Edinburgh Treaty 1993, Inclusion in the Eurozone 2000).

Other than that, constitutional changes need to be accepted by a referendum. This last happened in 1953. There are no provisions for popular initiatives to initiate referenda.

### 8.1.9 Political culture

Denmark is considered to have a thriving political culture with comparatively high numbers of participation in various kinds of associations, political parties (though declining) and public debate. Also there is a tradition in Denmark to consider "public debate" a prerequisite for competent and legitimate policy making. This means that prior to decision making, important issues are debated in the public sphere. The biotechnological domain is somewhat atypical in this respect, as the domain has experienced many more organised and formalised debates, for instance instigated by the Danish Board of Technology or the Council of Ethics. Furthermore, all legislation is passed through a hearing phase, where interested parties are notified and asked to submit comments.

### 8.1.10 Science-Society relations

The question about science-society relations is quite difficult to answer in general, as there are significant differences between sectors. For instance, in infrastructural planning, expert advice often succumb to political expediency - when motorways are located to contend regional interests rather than where most needed, or expanded despite expert recommendations that this will only increase traffic and not solve any problems in the longer run. Likewise, crime prevention is an area where experts have little influence on policies. In other sectors, experts govern without much political intervention or public attention at all, such as construction safety.

A number of domains such as environmental protection or biomedicine are intermediate in terms of expert influence. Expertise is obviously required and the state devotes significant sums of money to such areas. However, the role of scientific experts working in such fields are tempered by 1) an increasing dominance of economic incentives (e.g. economists replacing medical doctors as administrators in the health care sector) and 2) the need for public justification, which often mean that experts are required to participate in the public debate, serve on commissions with other kinds of expertise and sometimes organised interests or lay people.

Comparatively, Denmark is characterised by an anti-authoritarian and egalitarian culture. One implication of this is that experts are required to justify their judgements (often in public). In the interviews conducted for this study, it transpires that scientists generally accept that some political restrictions and regulatory oversight is beneficial as it helps to ensure their social legitimacy, and they find that the political system (including its bureaucrats) are generally willing to find compromises that balance this need for public legitimacy with conditions that do not inhibit the research, they wish to conduct.

### 8.1.11 Constitutional division of territorial power

Formally, public administration is divided between three levels in Denmark, the state, the regions (of which there are 5 after the system being overhauled in 2007) and the municipalities (of which there are 98 as of 2007). The regions administer the health care system and practically have no other significant functions. The municipalities provide social service, primary school education etc. The municipalities have taxation rights, but their freedom to act independently is rather circumscribed in most respects. Hence, all political power except in local affairs is located at the state level.

### 8.1.12 Electoral system

The electoral system is proportional with a 2% entry barrier. In principle, this should give easy access to new parties. It is relatively easy to be admitted to run in elections. However,

in practice it has proven quite difficult for novel parties to consolidate themselves in the political landscape. There was a major reshuffling of the party landscape in the 1973 election. Since then, there have only been minor adjustments with smaller parties entering for one or two election terms. This stability is partly due to the ability of existing parties to include novel themes. For instance, environmental problems have been admitted to the agenda of first the leftists parties, since then being variously adopted by other parties, thus not leaving space for a Green Party to gain representation.

## 8.2 The field of biomedicine/innovation policy

Relative to its size, Denmark has a strong position in biotechnology, in industry, agriculture and biomedicine alike. This is visible for instance in some major Danish companies like NovoNordisk (world leader in insulin-production), Novozymes (world leader in enzyme-production and biofuels), Danisco (world second in enzyme production), Chr. Hansen (food additives), Carlsberg (beer production) etc, most of which have a long history.

This history is mirrored in and facilitated by research activities in universities and public research institutes. During the 1990s and 2000s, the Danish government launched several strategic research programmes in biotechnology, seeking to foster cooperation between universities and industry to turn biotechnology into a strategic asset for the Danish economy and society in the future. Significant efforts are also involved in developing a “Medicon Valley”, a cluster of research and industry in the greater Copenhagen (DK) / Malmö(S) area around Øresund.

While most policy initiatives in this area concentrate on stimulating research and innovation, the Danish political system has also devoted attention to the various ethical and socio-economic controversies, which accompany some of these developments. This has lead to the institutionalisation of public debate on biotechnology through such organs as the Danish Board of Technology and the Council of Ethics, as well as other more temporary initiatives, seeking to stimulated public awareness and debate as well as safeguarding the societal legitimacy of these developments.

The shifting governments (primarily the ministry of science in various configurations) have obviously played a strong role in this but, reflecting the Danish tradition of a “negotiated economy”, most of the policies have be formulated in dialogue with industry and the research communities. This applies to all governments over the past 20 years, independently of their political ideology. Apart from disagreements about how to handle the issues regarding GM food, most of these issues have been managed without significant party political strife.

In several instances, contentious issues have been delegated to commissions, which were broadly constitutes in terms of expertise and societal interests. Among these are the “BioTIK Commission” on the ethics of biotechnology, the “Genetechnology Commission” on

regulatory needs in regard to four medical biotechnologies (incl. XTP) and the “Commission on Transgenic and Cloned Animals”. Interviews with different members of these committees suggest that apart from some interventions from the responsible ministries to safeguard their operational interests, politicians were mostly grateful when commissions could agree on quite specific regulatory recommendations, which left little room (or need) for political decision making on many of the more (ethically) awkward issues raised by the novel biotechnologies.

### 8.2.1 Cabinets

Innovation policy is a major concern for the cabinets, but the more (ethically and socially) contentions issues regarding biotechnology has not been an issue for the cabinets. They have been dealt with primarily by the bureaucracy, but with the involvement of responsible ministers from time to time.

### 8.2.2 Legislature

Biotechnology has been debated on repeated occasions in the Danish parliament. Some particularly contentious issues have been dealt with through legislation (cloning, embryonic research, release of GMOs etc), but in practice most regulation is delegated to the bureaucracy.

### 8.2.3 Executive-legislative relationship

Is not contentious – when disagreements occur, they tend to be articulated between the Government and the opposition, not between parliament and the government.

### 8.2.4 Bureaucracy

The bureaucracy runs most of the day-to-day operations in this field. At some point a special bureaucratic unit was formed to coordinate biotechnology policies across the government (the BioTIK secretariat, see e.g. Hansen 2010), but was dissolved, when the government changed in 2001. The relevant ministries are all represented in the commissions described above, but mostly play the role as connecting point to the ministries.

### 8.2.5 Judicial review

Courts play virtually no role in this field. There are regulatory oversight of research activities through the “Rådet for Dyreforsøg” (chaired by a judge) and the Central committee on research ethics (including a lawyer).

### 8.2.6 Party system

There is no green party in Denmark, as most of the environmental movement's issues have been appropriated by the existing parties, initially predominantly the two left wing parties, but increasing across the political spectrum. While represented in parliament, the Christian Democrats found a niche in addressing ethical issues related to biotechnology. The left-wing opposition has been critical of GMOs as representing too large risks only to serve agro-business interests, but in general biotech innovation has not been party political strife. Especially in the biomedical domain it is more accurate to say that ethical issues have been the source of political confusion and a desire to delegate decisions to advisory bodies such as the Council of Ethics and the Genetechnology Commission.

### 8.2.7 Interest group system

In general, interest groups have played a significant role in the biotech policy field. For instance, the BioTIK commission was founded in response to the request for regulatory clarification from the biotech industry. However, the XTP debates seem to be driven primarily by the scientific community and perhaps even more the TA community. Apart from a company interested in breeding transgenic pigs for experimental use, there has been no commercial interest in this area. Nor has there been any involvement by patients association.

### 8.2.8 Political culture

There has been quite a bit of civil society involvement with biotech innovation. Some of which has been stimulated through the activities of the Danish Board of Technology, which has organised several participatory assessment exercises in regard to biotechnology. As part of the "negotiated economy", decision making in this area is thus quite open to inputs from outside bureaucratic and expert circles. This, however, does not seem to have applied to any significant extend in regard to XTP – or at least the subject does not appear to have attracted much attention from outside expert circles.

### 8.2.9 Science-society relations

Some ministries have some in-house expertise on biotechnology, but mostly they rely on experts drawn from research institutes and universities. Scientists are often called to serve on commissions, where they are joined by civil servants and in some case representatives of the business sector and civil society. These commissions work out the state of knowledge in a commonly comprehensive language and usually provide recommendations for policy decisions (e.g. the BioTIK Commission, the Genetechnology Commission and the Commission on Transgenic and Cloned Animals). To a large extent, these recommendations are followed by the political system.

### 8.2.10 Direct democracy

Direct democratic measures have played no role in this domain in Denmark

### 8.2.11 Constitutional division of territorial power

Plays no role in Denmark

## 8.3 Social practices in biomedical policy making

This section contains step by step answers to the questions on social practices posed in the "Guidelines Research Methods and Research Questions" – some of the answers refer back to the case narrative.

### 8.3.1 Policy making

XTP was framed first and foremost as an emerging technology, which was likely to hit Denmark from the outside, and for which the regulatory system needed to be prepared. It was expected and accepted that Denmark would assume a reactive stance on XTP rather than an active, contributing role in the development of the clinical applications.

As the discussion on XTP gained (a little) momentum in the wake of the controversies on GM food and the announcement of Dolly the cloned sheep, XTP was framed as something that might potentially raise ethically sensitive issues and possibly generate public concern. However, the by far dominant framing in the policy making field had to do with the health risks for the general population associated with XTP experimentation. This framing was adopted from international discussions on the issue, translated – as far as this research has been able to establish – primarily though the activities of the TA community.

Policy practices included a *hearing at the parliament*, where interested parliamentarians debated with a panel of experts. This was organised by the DBT, which is standard practices on issues involving debate about novel technology. Subsequent to this, a debate in parliament including questions to and prepared accounts from responsible ministers ("forespørgselsdebat") was called for by the Christian Democrats. This debate had two outcomes: 1) The parliament instructed the responsible minister to ensure that a moratorium on XTP was issued. 2) It was agreed that the minister of science should convene a committee to scrutinise the problem and if necessary recommend policy revisions. This was the "Genetechnology Commission", the terms of reference was subsequently broadened to include a range of novel biotechnologies.

The by far dominant artefact related to this policy process is *written reports*, which are drafted, circulated and translated.

The TA activities consisted primarily in two hearings. One exclusively for scientists working in the field in order for BioSAM to gather knowledge to inform the policy system and the wider public, the other organised for the benefit of parliamentarians. The parliamentary hearing was the occasion for the Christian Democrats to bring up the issue in a parliamentary debate, which lead to the moratorium being adapted as official policy and the formation of the Genetechnology Commission. The Commission in turn assessed that the moratorium was a suitable regulatory measure and recommended no further initiatives in regard to XTP.

The Christian Democrat MP interviewed for this inquiry generally praised the DBT as a valuable support in the parliamentary work on technological issues, but did not seem to differentiate between different kinds of policy advice as TA, PTA or any other categories.

There was no institutionalised PTA on this matter – but otherwise PTAs are regularly organised as part of Danish policy making – although their actual impact is a contested issue (e.g. Hansen 2010)

The resulting policy is a moratorium on all clinical experimentation with XTP. Research on cloned and transgenic animals is permitted, but under licensing in regard to animal welfare. However, no research is carried out on XTP.

### 8.3.2 Citizen Participation

In the public debate (media coverage) XTP was framed in different ways

1. as an example of the marvels of modern biotechnology, which could make age-old science fictions come true

2. as a means to remedy the shortage of donor organs

3. as a potential source of risks to the individual recipients of organs as well as to the population at large

4. as a potential source of ethical concern and disturbance of our image of humanness – though this concern was mostly dismissed by utilitarian arguments

There was practically no involvement of “ordinary citizens” in policy making. Citizens were framed as members of the public in need of protection from reckless technological progress. Perhaps more surprisingly, nor was there any involvement of patient associations in any of the discussions, which would be standard practice in Danish policy making.

As there was no citizen participation, it is hard to discern any artefacts involved here – perhaps apart from news paper articles. Some newspaper articles carried images relating to research or pictures of the transgenic pigs that were designated to be donors.

Citizens were largely defined as a “public at risk”, as potential victims if something should go awry in the development process towards clinical application. Citizens were defined as “abstract patients” that might respond in various (emotional) manners to being confronted with the possibility of having an animal organ transplanted into their body. However, not a single media report has been found that confronts patients that have actually undergone organ transplantation with the idea of transplanting animal organs into human beings.

### 8.3.3 TA and PTA

The following TA tools were used:

- One-day seminar for invited scientific experts, organised by BioSAM, hosted by the University of Copenhagen
- An expert hearing at the parliament, facilitating discussion between experts and parliamentarians
- The Genetechnology Commission requested to assess if there was a need for new/further regulation of the field.

No PTAs were involved

The two hearings preceded a parliamentary debate on XTP, and their outcomes fed into the parliamentary debate. An outcome of the debate was that the Genetechnology Commission was organised. The debate requested a moratorium, and the work of the commission suggested to alterations to that.

The seminar at the University of Copenhagen involved only scientific experts, some from abroad.

The hearing at the parliament involved scientists, ethicists and economists, as well as members of the Swedish XTP commission – as well as parliamentarians.

The Genetechnology commission involved scientists, ethicists, staff from the DBT and civil servants, all appointed by the Ministry of Science.

Both the seminar and the hearing proceeded by means of experts' presentations and Questions & Answers sessions with the participants. They were moderated (and documented) but did not result in any concrete outputs and decisions. The most material outcomes were written resumes and a verbatim transcript from the hearing at the parliament. In addition, both events were reported in the newsletter series from BIOSAM.

The Genetechnology Commission produced a report with an overview of state-of-the-art in research written in an accessible language, discussion of various ethical issues and policy recommendations.

The aim of the initial seminar was to create an overview of the field for those involved with various aspects, such that BioSAM could present an overview of the field and potentially contentious issues to decision-makers and the larger public.

The aim of the parliamentary hearing was to inform parliamentarians through discussion with experts

The aim of the Genetechnology Commission was to create an overview of the field in terms of knowledge, possibilities and challenges to inform public debate and political decision making.

Power asymmetries do not seem to have been an issue that was explicitly reflected upon. The "lay people" involved were parliamentarians (which may be lay, but not exactly powerless, as the hearing was organised for their benefit). Gender issues do not appear to have been a theme at all.

One peculiarity seems to be the fact that at no point in time was there any attempts made to involve patient interests groups.

No particular problems have been identified

## 8.4 Gender issues

No gender issues are immediately discernable in the XTP debates. The two expert hearing organised by BioSAM had a clear male bias in terms of the scientists involved. However, there are no indications this has been made a theme in the debates.

The two commissions discussed in this report (the Genetechnology Commission and the Commission on Cloned and Transgenic Animals) both had a more or less equal distribution of male and female members. However, it has not been possible to establish whether this is coincidental or a deliberate move by the ministry commissioning the work.

# 9 List of Interviewees

Peter Sandøe, Professor of Bioethics, Chair of the Council of Animal Ethics (13.11.2009)

Johannes L. Brockdorff, Civil Servant, Secretary to the "Genetechnology Commission" (09.12.2009)

Torben Greve, Professor of Veterinarian Embryology, member of the "Genetechnology Commission" (11.12.2009)

Ebba Nexø, Chair of the "Genetechnology Commission" (08.01.2010)

Linda Nielsen, Professor of Law, former chair of the Council of Ethics (12.01.2010)

Anne Lykkeskov, Academic officer at the Council of Ethics (14.01.2010)

Lene Koch, Historian of Science, former member of the Council of Ethics (26.01.2010)

Tove Videbæk, former MP, Christian Democrats (12.02.2010)

Axel Kornerup Hansen, Professor of Veterinary Disease Biology, Chair of the "Commission on Cloned and Transgenic Animals" (13.08.2010)

Sven Gerner Nielsen, Director of "Nyreforeningen" (Patient organisation for kindney transplanted) (17.08.2010)

Gitte Meyer, Science Journalist, (18.08.2010)

Berit Faber Nielsen, former chief of secretariat at the Council of Ethics (20.08.2010)

Lars Klüver, Director, Danish Board of Technology (9.9.2010)

# 10 List of abbreviations

BIOSAM: Umbrella organization of TA organizations formed to promote TA and public debate on biotechnology

BioTIK: Government initiative to clarify ethical challenges of novel biotechnologies, consisting of an expert commission producing a report with ethical principles, which where subsequently handed over to an interdepartmental task force commissioned to ensure its implementation in legislation as well as stimulating public debate on the ethics of biotechnology

BSE: Bovine spongiform encephalopathy, also known as “mad cow disease”

CoE: Council of Ethics

DBT: Danish Board of Technology

GMO: Genetically modified organisms

NGO: Non-governmental organisations

nvCJD: new version Creutzfeld-Jacobs, also known as the human version of “mad cow disease”

TA: Technology Assessment

XTP: Xenotransplantation

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