SSOAR

Open Access Repository
www.ssoar.info

Xenotransplantation Policies: Italy and The Holy See

Grießler, Erich; Lang, Alexander; Metzler, Ingrid; Truttmann, Vera

Veröffentlichungsversion / Published Version
Forschungsbericht / research report

Empfohlene Zitierung / Suggested Citation:
Grießler, E., Lang, A., Metzler, I., & Truttmann, V. (2012). *Xenotransplantation Policies: Italy and The Holy See.* (Reihe Soziologie / Institut für Höhere Studien, Abt. Soziologie, 103). Wien: Institut für Höhere Studien (IHS), Wien. https://nbn-resolving.org/urn:nbn:de:0168-ssoar-312188

Nutzungsbedingungen:
Dieser Text wird unter einer Deposit-Lizenz (Keine Weiterverbreitung - keine Bearbeitung) zur Verfügung gestellt. Gewährt wird ein nicht exklusives, nicht übertragbares, persönliches und beschränktes Recht auf Nutzung dieses Dokuments. Dieses Dokument ist ausschließlich für den persönlichen, nicht-kommerziellen Gebrauch bestimmt. Auf sämtlichen Kopien dieses Dokuments müssen alle Urheberrechtshinweise und sonstigen Hinweise auf gesetzlichen Schutz beibehalten werden. Sie dürfen dieses Dokument nicht in irgendeiner Weise abändern, noch dürfen Sie dieses Dokument für öffentliche oder kommerzielle Zwecke vervielfältigen, öffentlich ausstellen, aufführen, vertreiben oder anderweitig nutzen.
Mit der Verwendung dieses Dokuments erkennen Sie die Nutzungsbedingungen an.

Terms of use:
This document is made available under Deposit Licence (No Redistribution - no modifications). We grant a non-exclusive, non-transferable, individual and limited right to using this document. This document is solely intended for your personal, non-commercial use. All of the copies of this documents must retain all copyright information and other information regarding legal protection. You are not allowed to alter this document in any way, to copy it for public or commercial purposes, to exhibit the document in public, to perform, distribute or otherwise use the document in public.
By using this particular document, you accept the above-stated conditions of use.

gesis Leibniz-Institut für Sozialwissenschaften

Mitglied der Leibniz-Gemeinschaft

103

Reihe Soziologie

Sociological Series

Xenotransplantation Policies: Italy and The Holy See

Erich Griessler, Alexander Lang,

Ingrid Metzler, Vera Truttmann

The project “Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field” (CIT-PART), Contract Number: SSH-CT-2008-225327, is funded by the European Commission within the 7th Framework Programme for Research – Socioeconomic Sciences and Humanities. We would like to thank the Commission for its contribution. The project is active from 2009 to 2012. For more details see: www.cit-part.at

INSTITUT FÜR HÖHERE STUDIEN
INSTITUTE FOR ADVANCED STUDIES
Vienna

103
Reihe Soziologie
Sociological Series

Xenotransplantation Policies: Italy and The Holy See

Erich Griessler, Alexander Lang,
Ingrid Metzler, Vera Truttmann

March, 2012

Institut für Höhere Studien (IHS), Wien
Institute for Advanced Studies, Vienna

Contact:

Author: Erich Griessler
☎:+43 1 59991 DW 170
email: erich.griessler@ihs.ac.at

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

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

Contents

1 Introduction

Citizens, policymakers and social scientists often call for citizen participation for reasons of democratic legitimacy and effectiveness. A field in which this has been vigorously claimed is science and technology policy. Thus, many countries witnessed the introduction of Participatory Technology Assessment (PTA). The "litmus test" of PTA and of citizen participation, however, is their impact on policy-making. But can PTA keep its promises and increase the influence of citizens' voices on decision-making? What in actual fact is the impact of PTA on decision-making? How can we increase it?

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

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

By adopting a theoretical approach of “social practices”, this project assumes that the impact of citizen participation on decision-making is not only dependent on the quality of the PTA process itself but also on practices of policymakers, in which PTA is embedded. From this theoretical approach, the project proceeds by applying qualitative methods of empirical research.

In this report, we explore the trajectory of xenotransplantation policies in Italy as well as the evolution of the position of the Holy See on xenotransplantation. In particular, we investigate the role that expert commissions and the public played in these processes.

There are important differences between the two cases: Italian authorities are able to regulate xenotransplantation research on their territory, while the Holy See in principal lacks this ability but nevertheless had a significant voice in discussing the ethics of xenotransplantation. Despite these differences, we decided to include the two states in our country samples for various reasons: (1) Both belong to the group of countries that dealt with the problem of xenotransplantation. (2) Both relied on expert committees to investigate the regulation of xenotransplantation and did not involve the public into these debates. (3) Both

took a permissive stance towards xenotransplantation in their respective policies. Italy and the Holy See are therefore meaningful cases within the CIT-PART country sample. They also contribute to the variety of the study and thereby strengthen the international comparison.

1.1 Methods

The case study is based on an online search of xenotransplantation policies in the 1990s and early 2000s in Italy and the Holy See. The search resulted in a report, which identified the main xenotransplantation policies and the actors shaping them. Subsequently, the search was supplemented by an analysis of newspaper articles to construct a chronology of events and to detect dominant frames as well as shifts in these frames. In addition, published literature on Italian xenotransplantation policy (e.g., European Commission 2001, Mazzoni/Tallacchini 2008), work carried out within the CIT-PART project (Allansdottir 2010) as well as policy reports, documents and relevant websites were analyzed. Literature on Italian biotechnology policies (e.g. Allansdottir et al 1998, Testa 2011) and the role of public involvement in Italian science policy as well as the use of expert advice in the Italian political system (Glynn et al 2003) was taken into consideration. Finally, and this was a main source of information on xenotransplantation policies in Italy and the Holy See, a total of twelve interviews with experts, involved in the development of xenotransplantation policies, were conducted. Interviewees included officials, Academicians and Corresponding Members as well as external experts, who were involved in the Pontifical Academy for Life (*Pontificia Academia per la Vita*, PAV), the Italian National Bioethics Committee (*Comitato Nazionale per la Bioetica,* CNB) and the National Committee for Biosecurity and Biotechnology (*Comitato Nazionale per la Biosicurezza e Biotechnologie,* CNBB). The interviews lasted between 30 and 100 minutes; all but one were taped, fully transcribed and, using the software Atlas.ti, analyzed according to qualitative methods (thematic analysis). Two interviews were carried out with the help of an interpreter. In addition, one expert provided a written statement. References to interviews are indicated in the text with the first number indicating the interview and the following numbers referring to the line numbers in the text.

1.2 Acknowledgements

We gratefully acknowledge the funding by the European Commission within the 7th Framework Programme for Research – Socioeconomic Sciences and Humanities. We are particularly grateful to our interview partners. Without their readiness to answer our questions, this study would have been impossible. We also want to thank Isabella Reisenzaun and Roman Wegmann for transcribing the interviews and Andrea Haslinger for taking care of formatting this report.

1.3 Authorship

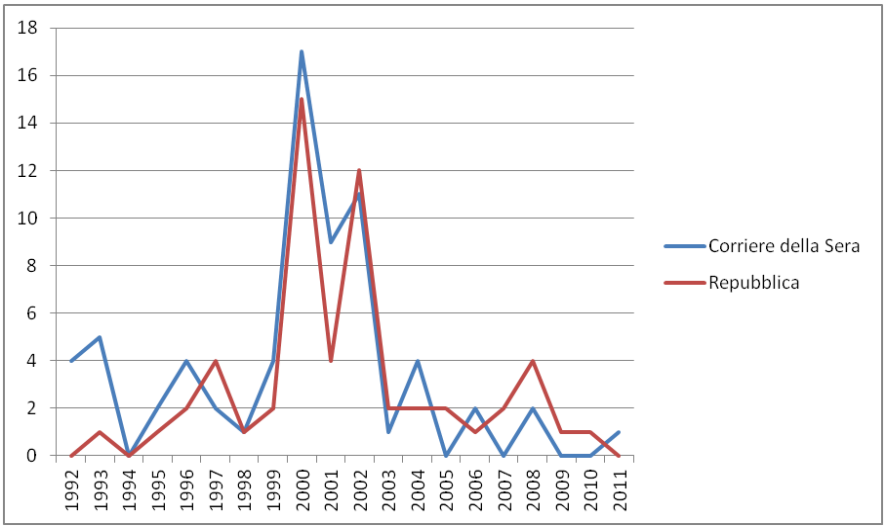
This report is the result of a team effort. Erich Griessler was responsible for coordinating the research, analyzing and carrying out most of the interviews, which were held in Italy and the Vatican State. He wrote the main part of this report. Alexander Lang contributed to the Italian case study. He authored the sections on the Italian political system, and on the public perception of xenotransplantation in Italy. Ingrid Metzler contributed to the Italian case study by analyzing newspaper articles and conducting and analyzing two interviews. She also put the case into the context of Italian policies on biomedicine and biotechnology. Vera Truttmann did preparatory work during her three-week internship at the IHS in summer 2011. She conducted Internet searches on xenotransplantation policies in Italy and the Holy See.

2 Italy

2.1 Italian xenotransplantation policies

Over the past twenty years, Italy has often witnessed intense debates on bio-technology and bio-medicine. For instance, in the 1990s, genetically modified organisms (GMOs) as well as in vitro fertilization (IVF) technologies occupied a prominent space in the news as well as in policy making. After the turn of the century, GMOs moved into the background, yet IVF technologies, now complemented with cloning technologies, continued to steer controversies, as did human embryonic stem cells (hESC), which somehow supplanted GMOs as publically contested objects (c.f. Testa 2011, Allansdottir et al 1998, Allansdottir/Veltri 2011). In comparison, xenotransplantation never gained such a salient place in the Italian public imaginary nor did it constitute a knotty object on the political stage. A brief reference to the number of articles in the two dailies *Corriere della Sera* and *Repubblica* supports this claim (see Figure 1).

Figure 1: Number of articles containing the word "xenotrapianti" in the two dailies "Corriere della Sera" and "Repubblica" in between 1992 and 2012.



In the electronic archive of the *Corriere della Sera*, the entry "xenotrapianti" (xenotransplants) produces a total of 69 hits in between 1992 and February 2012. This number is modest when compared to the number of articles covering other controversial issues. Indeed, the same archive produces 1,870 hits for "cellule staminali" (stem cells) in the same period and 1,134 for "OGM" (GMOs or genetically modified organisms).[1]

[1] http://sitesearch.corriere.it/archivioStoricoEngine; accessed: 13/2/2012.

A similar exercise in the more comprehensive archive of the daily *La Repubblica*, which goes back to 1984, produces a total of 58 hits for the entry “xenotrapianti”, 1,796 for “cellule staminali” and 1,634 for “OGM” (see Figure 1).[2]

The temporal distribution of these articles is equally telling. Indeed, the peak newspaper coverage of xenotransplantation at the turn of the century corresponds with the short time period in which regulatory authorities explored xenotransplantation and suggested ways to deal with it. In the early 21st century, however, xenotransplantation was no longer deemed a discipline in need of new regulatory settlements.

However, this silence is by no means representative of a complete absence of research activities in this area. On the contrary, research ranging from the breeding of trans-genic pigs as potential organ donation candidates, to clinical trials with bio-artificial liver systems, has taken place in Italy, and continues to do so. There is a small but lively scene of xenotransplantation research in Italy. An OECD survey in 2001 listed six centers that have been authorized to conduct research in xenografting.

Also the European Commission-funded research project XENOME involves a number of Italian partners (see Griessler 2012),[1] such as: Emanuele Cozzi (Azienda Ospedaliera Di Padova) as coordinator; Cesare Galli (Consorzio per L'incremento zootecnico SRL And Avantea SRL), a veterinarian, who produced the first cloned mammal in Italy (torre Galileo); Marialuisa Lavitrano (Universita degli Studi Di Milano-Bicocca), Ermanno Ancona (Consorzio per la Ricerca sul Trapianto D'organi', tessuti, cellule e Medicina rigenerativa), and Mariachiara Tallacchini (Universita Cattolica del Sacro Cuore), a jurist who works on the ethical, legal and social aspects of xenotransplantation. Additionally Fulvio Calise (Cardarelli Hospital Neapels) was active in the development of a bio-artificial liver (see 2.2.1).

However, the existence of these research activities has not generated new regulations which oversee such research. Instead they are governed by pre-existing regulations, such as the legislative that oversees research with animals.

In general, newspapers portrayed xenotransplantation as a promising bio-medical field, characterized by scientific uncertainties and risks. As a consequence, scientists and technical experts had a prominent standing in these debates, while “publics” had no role. After 2000, xenotransplantation did not disappear altogether, yet debates slowed down and took a more dispersed shape. The same seems true of policy-making and regulations. Indeed, after the early 21st century initiatives, no further attempts have been made to settle xenotransplantation in a comprehensive manner. Instead, research initiatives are tackled on an ad-hoc basis and in light of pre-existing regulations, such as on transgenic animals.

[2] http://ricerca.repubblica.it/repubblica?query=xenotrapianti&view=archivio; accessed: 13/2/2012.

Italian xenotransplantation policies can be divided into several stages, in which: xenotransplantation first appeared as a topic; subsequently became subject to regulatory activity and debate in different advisory bodies to the Italian Government; and finally became an issue with diminished interest in public debate and policy making. Table 1 provides an overview of landmark developments in the history of xenotransplantation policies in Italy, which are discussed in the following sections.

Table 1 Overview of landmark developments and timeline

30 September 1998	*Consiglio Superiore di Sanità* (CSS): guidelines on the use of the bioartificial support system incorporating porcine hepatocytes ("Linee guida per la sperimentazione clinica del fegato bio-artificiale").
29 January 1999	Council of Europe Recommendation 1399 invites Member States to establish a moratorium on xenotransplantation.
18 November 1999	*Comitato Nazionale per la Bioetica* (CNB) opinion on the moratorium on xenotransplantation.
December 2000	*Comitato Nazionale per la Biosicurezza e Biotechnologie* (CNBB) guidelines *("Linee giuda per la sperimentazione clinica degli xenotrapianti").*

2.1 First Period (1994-1999): xenotransplantation starts to percolate into the news

News on xenotransplantation started to percolate into Italian media in the early 1990s, reaching a peak at the turn of the century. Most of these articles reported that animals, or more precisely pigs, could provide an unlimited organ supply, thereby providing a solution to the shortage of organs. They reported about studies from abroad as well as those conducted in Italy. Xenotransplantation was framed in these articles as a cutting-edge scientific field that had to overcome a number of hurdles, such as the barrier between humans and animals, and that was still highly promising. For instance, in November 1995, the daily *Corriere della Sera* featured a small report on an event celebrating the anniversary of the

first heart transplantation in Italy, with the headline: “Transplants, transgenic animals are the new frontier” (Montefiori 1995). The article quoted Mario Viganò, who back in 1985 had conducted the first heart transplant at the *Policlinico di Pavia*. He emphasised that animals represented the future for the human organ economy. “In England”, Viganò was quoted, “research in this area is crazy”. There, “the prospect to implant organs from transgenic animals (that is genetically modified [animals] in order to make them ‘closer’ to the human species, editor’s comment ndr) into human[s] is explored at large scale, in particular [with organs] from pigs. This is a perspective that is still distant, but once the difficulties will be overcome, we will have an almost unlimited ‘reservoir’. And then the problem of the scarcity of organs will be resolved” (Montefiori 1995).[3]

Most of these newspaper articles gave scientists a voice. They portrayed xenotransplantation as a field of science with a high potential whose major problems were related to risks of rejection or infection. Ethical concerns were not voiced loudly. This pattern also emerges when reviewing the actions of the bodies that tackled xenotransplantation at the turn of the century. And, indeed, the actions of regulatory authorities on xenotransplantation did not gauge much attention.

2.2 Second Period (1999-2002): xenotransplantation on the political stage

In this stage several advisory bodies to the Italian Government successively tackled the issue of xenotransplantation.

2.2.1 Consiglio Superiore di Sanità (CSS)

On 30 September 1998 the Higher Council of Health (*Consiglio Superiore della Sanità,* CSS) issued “guidelines for clinical trials on the use of bioartificial liver” (*Linee-guida per la sperimentazione clinca del fegato bio-artificiale*) (c.f. Mazzoni/Tallacchini 2008: 49ff.), responding to a particular application for the authorization of clinical trials. The CSS is an advisory body with a long tradition, which reports to the Ministry of Health (7: 262-264).

Mazzoni and Tallacchini note that the document laid down “suitable behavior aimed at guaranteeing the safety and respect for patients undergoing treatment with the bioreactor incorporating porcine hepatocytes – the bio-artificial liver” (2008: 50). After proper information patients must give written consent to the following rules:

- “that they may have to undergo 15 years of clinical and laboratory investigations;

[3] "In Inghilterra le ricerche in questo senso sono forsennate . ha detto il cardiochirurgo. Si studia la possibilita' di impiantare nell' uomo, su larga scala, organi di animali transgenici (ossia modificati geneticamente per renderli piu' "vicini" alla specie umana, ndr), soprattutto di maiale. E una prospettiva ancora lontana, ma quando le difficolta' saranno superate avremo un "serbatoio" pressoche' infinito. E sara' risolto il problema della scarsita' di organi".

- that for 15 years they may have to comply with 'measures capable of reducing the potential risk of transmitting infective agents to the population, even through reproduction;

- that the treatment may be discontinued" (ibid.). Informed consent, in particular conditions may be granted also by the nearest relative" (ibid.).

Safety measures concerning xenotransplantation mentioned in the document apply to the husbandry of the source animals and the surveillance of patients. "Patients must be subjected to precautionary measures during hospitalization and must be monitored by means of a 15-year follow-up (every 6 months during the first 3 years), in particular to detect the onset of pathologies and the presence of PERV A and PERV B retroviruses in their blood" (ibid. 51).

The guideline permits experimenting with xenogeneic cells. Mazzoni and Tallacchini criticized that the guidelines would "impinge on fundamental constitutional rights that may be not too easily limited without a legislative act" (2008: 61). An interviewee criticized that the guidelines, which addressed only one single application for clinical trial, would not only violate fundamental human rights as regards the restriction of informed consent and civic liberties, but also that they were developed without the involvement of parliament and any public discussion (1: 271-278). However, an interviewed natural scientist and a physician refuted this critique, pointing out that the patients in these clinical trials were in life threatening conditions, and also that liver perfusion had been permitted previously in other countries 7: 273-275).

2.2.2 Comitato Nazionale per la Bioetica (1999)

2.2.2.1 Organization

The CNB is an advisory body to the Presidency of the Council of Ministers and was created by decree of the President of the Council of Ministers on 28 March 1990 (Fuchs 2005: 35).[4] It has *inter alia* the task to advise Government, Parliament and other institutions. It issues general guidelines on ethical problems (Glynn et al 2003: 264). With more than 40 members the CNB is a rather large body.[5]

[4] http://www.governo.it/bioetica/eng/index.html, accessed: 10/2/2012.
[5] http://www.governo.it/bioetica/eng/composition.html, accessed: 10/2/2012.

2.2.2.2 Getting on the Agenda

On 29 January 1999 the Parliamentary Assembly of the Council of Europe unanimously adopted Recommendation No. 1399(1999)[6], which recommended that the Committee of Ministers

(i.) "work for the rapid introduction in all member states of a legally-binding moratorium on all clinical xenotransplantation",

(ii.) "take steps to make this moratorium a worldwide legal agreement";

(iii.) "ask its European Health Committee and Steering Committee on Bioethics to work out, in cooperation with the World Health Organization, a strategy for balancing the ethical, medical, scientific, legal, social and public health aspects of xenotransplantation, before the scientific and medical establishment is permitted to proceed with clinical trials on humans" (Council of Europe 1999).

In response to this Recommendation (7: 721-730), the CNB presented an opinion (*parere*) on 19 November 1999.[7]

2.2.2.3 Content

Embracing the Parliamentary Assembly's recommendation for a moratorium, the CNB issued a brief statement of two pages on xenotransplantation (Comitato Nazionale per la Bioetica 1999).[8]

The opinion starts by affirming the CNB's hopes that scientific progress would help reduce the risks as well as future risk-related anxieties. For the time being, however, it admitted that there were a number of questions as well as practical problems that needed to be settled.

"As things stand at present, no safe scientific conclusions have been reached, particularly with regard to the rejection of such organs and to the transmissible pathologies, giving rise to doubts and concerns that cannot be considered to be entirely without foundation. In particular, it is not yet possible accurately to identify the risks relating to the transmissibility of transgenetic infections, and particularly in terms of the effects of the relationship between genetic recombination and viral recombination" (Comitato Nazionale per la Bioetica 1999).

[6] For an overview of the Council of Europe's xenotransplantation policies see Griessler 2010.

[7] President at that time was Prof. Giovanni Berlinguer (1999-2001) (http://www.governo.it/bioetica/composizione.html, accessed: 27/2/2012).

[8] http://www.governo.it/bioetica/eng/opinions/xeno.html, accessed 5/2/2012.

Moreover, the CNB argued that xenotransplantation had to be framed in terms of a conflict between an individual interest and the protection of collective health (*tutela della salute collettiva*). “The direct benefits to individual transplanted patients cannot be considered separately from the, admittedly less likely, risk of spreading infectious diseases among humans” (Comitato Nazionale per la Bioetica 1999).

Due to scientific uncertainty, the CNB suggested adopting a precautionary approach and embracing the Parliamentary Assembly’s recommendation for a moratorium. This did not imply that xenotransplantation be dismissed altogether. Rather the CNB recommended to “intensify the scientific research” in order to overcome those knowledge gaps that rendered xenotransplantation both uncertain and risky for the time being. Moreover, the CNB underlined the “need to encourage every opportunity to hold a public debate to disseminate knowledge of these issues and promote an ethical awareness on the part of everyone concerned, in order to be able to appraise the true level of social consensus on the issue” (Comitato Nazionale per la Bioetica 1999). However such a national debate was never organized.

2.2.2.4 Working Process

The development of the opinion resulted from the involvement of the Italian representative in the Council of Europe’s recommendation for a moratorium (see 2.2.2.2). As he was very familiar with the topic already, the opinion was written in a comparatively short time. One CNB member wrote a draft which, after discussion at a one day panel of the CNB involving almost all the members, was redrafted and finally accepted (7: 693-699; 706-720).

2.2.2.5 Impact

The CNB’s influence on national legislation varies according to the issues at hand. In a small number of cases the CNB’s influence was clearly evident, “however”, as Fuchs pointed out, “such influence is by no means the rule” (Fuchs 2005: 35). Interviewees agreed with the assessment of the CNB’s low impact on policy making, which was also clear in the case of xenotransplantation (9: 400, 407-408). Different factors are responsible for this state of affairs:

Firstly, the CNB is not an indisputable, but a politically contested organization. This weakens its position. Drawing on the Italian cloning debate, Testa observes a principal division in Italian biopolitics by two lines of severe conflict. He argues that “Italian political culture appears to be structured around two rigid dichotomies: the secular/religious and the natural/artificial, which refer to the two main sources of certified authority (science and the Catholic Church) and the historical divide along which they strive to maintain their separate spaces” (Testa 2011: 95).

As interviews showed, the conflict between secular and religious, conservative and liberal, is also manifest in the CNB, particularly in the way its members are appointed. This conflict turns the CNB into a contested organization. A secularist interviewee criticized the CNB for being "dominated by Catholics" in the sense "that almost all the presidencies were given to Catholics" (5: 46-47). Another respondent, who was involved in the PAV, referred to this criticism, pointing out that the establishment of the CNB was unfortunate, because it was "accused of (being) a committee of bishops (…) So there are different parties that sustained that this committee was not composed (…) in a good way" and appointment was based on political considerations (9: 403-407). Another interviewee confirmed "fairly strong political component in (the) choice" of CNB members (7: 433), which is within the competence of the President of the Council of Ministers (Fuchs 2005: 35 ff.). Although scientific merits would play a certain role in the selection of members, the choice would also be very complicated, recognizing, e.g., the interests of ministries and regions, and would therefore be "inspired by politics" (7: 442).

2.2.3 Comitato Nazionale per la Biosicurezza e Biotecnologie Guidelines

Shortly after the CNB had presented its opinion, the National Committee for Biosecurity and Biotechnologies (*Comitato Nazionale per la Biosicurezza e le Biotecnologie*, CNBB) started to work on a document on xenotransplantation.

2.2.3.1 Organization

The CNBB was established in 1992 to oversee the implementation of the EC Directives on Genetically Modified Organisms (GMOs).[9] However, the committee soon expanded the scope of its action from a narrowly defined overview of the release of GMOs, to the development of concepts as well as strategies to enhance the place of the biotechnologies and life sciences in Italy. This expansion of the competences of this committee is reflected in the evolution of its name. Initially called "Scientific Committee on the Risks Deriving from the Usage of Biological Agents" (*Comitato Scientific per I rischi derivanti dall'impiego di agenti biologici*), the committee was first renamed "National Committee for Biosecurity and Biotechnologies", and, at a later stage, "National Committee for Biosecurity, Biotechnologies and the Life Sciences (*Comitato Nazionale per la Biosicurezza, le Biotechnologie e le Scienze della Vita*).

In contrast to the CNB's mandate, which "covers the ethical and moral issues surrounding biomedicine and life sciences", the CNBB "has a clear mandate in terms of a scientific expert-led approach to risk" (Allansdottir 2010: 76).[10] Indeed, whereas there are some issues that have been tackled by both committees in joint efforts of governance, generally there is a

[9] http://www.governo.it/biotecnologie/eng/, accessed: 10/2/2012.

[10] http://www.governo.it/biotecnologie/eng/Institutional_responsibilities.html, accessed 10/2/2012.

clear division of labor, with the CNB tackling issues that are deemed ethical, and the CNBB dealing with issues deemed more technical. This is mirrored in the subjects seen as being able to provide knowledge for these committees. The CNB consists of a range of external experts, whereas the CNBB comprises delegates from ministries and research- and health-related entities.

2.2.3.2 Getting on the Agenda

An interviewee involved in the CNBB at this time noted that the CNBB decided to tackle the issue of xenotransplantation because "it seemed to be a problem with a big impact" (notes from interview 4), adding that "it was our choice [to deal with these issues]". The CNBB established a Working Group on xenotransplantation, which was chaired by Leonardo Santi, the president of the CNBB. The decision to put xenotransplantation on the agenda seems to have been made by the CNBB on its own initiative.

2.2.3.3 Content

The CNBB issued its guidelines in December 2000.[11] In contrast to the brief CNB paper, the CNBB document consists of 30 densely written pages. Starting with general assumptions, it then provides detailed scientific and technical guidelines, before suggesting a normative framework, as well as the setting up of authorities that should oversee xenotransplantation.

The document starts from the assumption that, whereas the boundary between humans and animals had seemed to be "insurmountable", "today the considerable progresses in the understanding of the molecular foundation and the mechanisms involved in the rejection of xenotransplants, allow assuming to apply this technique that would provide an almost unlimited supply of organs" (CNBB 2000: 5). Nevertheless, the document states, "it is (…) important to keep in mind that the xenotransplantation of organs and the implantation of non-human cells and tissues violate the barriers which have developed between different species over thousands of years. [H]ence, even if on the one hand [xenotransplants] can, no doubt, produce individual benefits, on the other hand they might produce potential risks for the community" (ibid. 5).

The document cites pathogens and retroviruses as examples of such risks for the community, noting that these might also include "clinical syndromes that can hardly be diagnosed, given that for many micro-organisms of animal origin there are no specific laboratory tests" (ibid.). New pathogens might not only diffuse "silently in the human population, but also in animals" (ibid.).

---

[11] http://governo.it/biotecnologie/documenti/Linee_guida_per_la_sperimentazione_clinica_degli_xenotrapianti.pdf, accessed: 5/2/2012, translated by Ingrid Metzler.

Hence, the report allows ample room for the discussion of these risks, and also admits that alongside the known risks there might also be unknown ones. These are not only related to the bodies and lives of patients, but also to the "population" in general. Nonetheless, the paper does not suggest that, as a result, xenotransplantation should be abandoned altogether. Rather a considerable portion of the document comprises the mapping of strategies to tackle these risks, such as: detailed conditions in which trans-genic animals should be raised and cared for; conditions in which xenotransplantation should be conducted; and a series of measures to monitor and oversee those animals, patients and their families as well as the health-care personal that conducts such transplants.

The document does make room for the consideration of bioethics, noting that such considerations, however, were neither irresolvable nor altogether new. While it explains that for ethically speaking pigs rather than non-human primates would be the best source animals, it also notes that "it does not seem to be logical to make a difference between sacrificing these animals because they serve as food for humans and sacrificing them in order to provide a therapy that might save a human life. It is known that a small part of the population contests the legitimacy of killing animals, even as a source of food. But the bigger part of the population eats meat and there is no reason to believe that it does not agree with using animals as organ donors. The loss of a human life is more important than the loss of the life of an animal. Hence the necessity to save a human life can justify the sacrifice of an animal for a xenotransplantation" (ibid. 7).

The document also considers the "psychological acceptability" of xenotransplantation for patients, noting that if xenotransplantation was performed at present "the current lack of knowledge on the transmission of infections would oblige [us] tightly to control transplanted patients for very long periods: for years, or even for the entire life. It would also be necessary to impose limits on them that allow minimizing the risk of a transmission of a pathogenic agent. This would be hard to support for the subject, and it would also pose the problem of the ethical legitimacy of such limits on personal freedom" (ibid. 9).

In addition to individual patients and their families, the document also addresses the topic of public opinion. It notes that while it would be difficult to predict how the public would react on clinical studies, the controversies on transgenic food had shown that "not everything that advanced technology proposes is deemed acceptable" (ibid. 9). From this, the Working Group drew the "lesson" that it would be appropriate to "inform the public on this research, its objectives and progresses, and to be open to debates to clarify controversial aspects" (ibid.). However, no initiative was taken to substantiate this claim.

The document concludes with the recommendation of a normative framework for the oversight of clinical studies. It suggests establishing (ibid. 29):

1. A central commission on xenotransplantation, which: licenses all centers involved in research, including those that breed animals; authorizes protocols; oversees the results; and controls registers and biobanks.

2. A centralized registry as well as local registers, which collect and examine data on animals and humans involved in xenotransplantation studies.

3. A centralized biobank and local biobanks which store biological samples of animals, patients and their cohabitants, and the staff that is involved in clinical studies.

4. The monitoring of the “professionally exposed personal”;

5. A training program for the personal involved in clinical studies;

6. The updating of guidelines n light of the results of scientific progress.

2.2.3.4 Impact

The work of the CNBB was supposed, according to interviews, to be a background document for the CSS to guide decisions for applications on trials on xenotransplantation (5: 105-108). However, the document had not been publicly available for a long time (5: 134-135), and the actions suggested by the CNBB were never implemented. Indeed, after December 2000, xenotransplantation disappears as a topic of discussion for political authorities. However, this does not imply that no xenotransplantation-related research is conducted in Italy, but that the research is conducted in a disorganized way that is neither centrally steered controlled, nor regulated systematically.

During the third period of Italian xenotransplantation policies, xenotransplantation has disappeared from the political stage as well as from the public imaginary. Narratives of hope shift from the fixing of human bodies with the help of fully formed organs, to therapies on a cellular level.

2.3 Impact

There is an important distinction to be made between the impact of the documents developed by the CSS on the one hand, and the CNB and the CNBB on the other. The opinions of the CNB and the CNBB were recommendations to the President of the Council of Ministers. Neither recommendation had any impact on law-making at the parliamentary level (7:325-326). The reasons for that were:

- Clinical trials of xenotransplantation were stopped due to the self-imposed moratorium of xenotransplantation researchers, which was supported by many Italian researchers (8: 326-334).

- Xenotransplantation regulations came into being in other countries, and on an international level (8: 468-476).

- The CNB does not have the power to impose its recommendations: "the power of the moral and of persuasion and also to raise problems, you know, to present problems to the public and to the parliament, this is the real task of this committee and they not impose the opinion" (8: 479-481). Because the opinions of the CNB are not binding, they can seldom influence actual policy making (7: 508-514).

- The Italian Parliament tends to avoid engaging with ethics. As an interviewee put it, the state "usually refuse(s) to enter the ethical topics, (…) in order not to be accused to propose an ethics of the state" (7: 583-584).

While so far no general kind of governance was established, in contrast the CSS issued a binding document relating to a clinical trial of the application of bioartificial livers for a small number of patients.

2.4 Public perception of xenotransplantation in Italy

One way to assess the public perception of xenotransplantation is by reviewing the topic's coverage in the newspapers. Providing anecdotal evidence by listing a selection of headlines of Italian newspapers dealing with xenotransplantation in 2000, Mazzoni and Tallacchini are critical of the way in which Italian newspapers dealt with the topic. They observe "that generally newspapers do not inform and do not give precise and scientific information on any new practice or experiment. They simply give suggestions to readers about ethical and social problems generated by new technologies. It is easy to conclude that, on the basis of this kind of information, people are puzzled, vacillating between confidence and a vague suspicion about science and technology" (2008: 78ff). However, these observations tell us little about the acceptance of xenotransplantation by the Italian public.

Several studies addressing this question have been carried out, which give some insight into the Italian public perception of xenotransplantation.

In 2001, Frati et al conducted a survey on the acceptance of xenotransplantation. They asked 190 respondents from various groups[12], ranging from ordinary citizens to patients who

[12] The sample included (1) people from Rome or other cities of the Latium region (68); (2) law students from the University of Macerata (32); (3) medical students from the University of Rome "La Sapienza" (27); (4) patients affected by diseases not requiring transplantation but admitted to the University Hospital Policlinico Umberto I of

underwent transplantation, whether they would accept donor organs in general, and xenotransplantation specifically. Their results showed that:

- The group of respondents who already had had transplantation, or were currently on a waiting list, accepted xenotransplantation unanimously (100%).

- Patients who did not urgently need a transplant, accepted xenotransplantation more readily (69%) than the control group of ordinary citizens from Rome and other cities of the Latium region (34%);

- Medical students were more approving of xenotransplantation (59%) than either law students (39%) or the control group (34%).

Frati et al conclude from their study that "the clinical use of xeno-organs or tissues is not presently favoured by members of Italian public" (2001: 1885), and they advocate an "educational campaign and a public debate" to "inform the public about benefits and risks and to put the patients in a clear and informed position to express their possible consent" (ibid.).

Frati et al imply the validity of their research, but the significance of their study is limited. Although no evidence on statistical significance through key figures is given, the total survey sample size of 190 as well as the sizes of the various subgroups (27 to 68 members) is rather small. Furthermore, there is no information on sampling and whether or not it was randomized.

De Bona et al (2004, 2006) studied the attitude of Italian students towards xenotransplantation at an Italian University. They particularly focussed on the influence of socio-demographic characteristics such as religion and educational background. They conducted two subsequent surveys, asking students from the University of Padua in their first year, and, after three years, in their fourth year.

- Their findings suggest[13] that a majority of students knew about xenotransplantation (88% resp. 85%**)[14] and were positive about this technology (78% resp. 82%**).

- Students in science courses were significantly more positive about xenotransplantation than students in art courses. Educational background was also important: Students with a classical or scientific high-school degree showed a higher than average approval of xenotransplantation. Religion and regional background

Rome, or to the Hospitals of Siena and Pozzilli (32); and (5) patients transplanted/candidate for transplantation admitted to the Hospitals of Pozzilli and Siena (29) (Frati et al. 2001: 1884).

[13] *…significant difference at $p<0.05$; **…no significant difference.

[14] 88% in 2004, 85% in 2006.

(urban versus rural) had no significant influence on the assessment of xenotransplantation.

- The first-year survey showed significant gender inequalities: men viewed xenotransplantation more positively than women, and were more aware, though less concerned, about the treatment of the animals involved. However, these disparities did not show up in the survey taken three years later.

Overall, the authors conclude that their research results support the outcomes of existing international studies, e.g. that young people are open towards new technologies like xenotransplantation (see De Bona et al 2004; 2006).

As mentioned earlier, these studies are limited in their representations of the acceptance of xenotransplantation. The study by Frati et al is problematic, because of the small survey sample and the lack of statistical indicators. The studies by De Bona et al (2004) and Canova et al (2006) only polled Italian university students, so have a very narrow range of scope.

The 1996 Eurobarometer survey asked citizens of 15 EU member states about their opinion on the usefulness, riskiness, and moral acceptability of various biotechnologies, e.g. genetically modified food or xenotransplantation, and whether or not research in these areas should be promoted.

- In response to the question of whether xenotransplantation research should be encouraged, Italian respondents were more negative[15] (49%) than positive[16] (41%).[17]

- The majority of respondents (52%) considered xenotransplantation useful.[18]

- However, a minority of 35% thought xenotransplantation was morally acceptable.[19]

Compared to the rest of the EU, Italian respondents considered the usefulness and moral acceptability of xenotransplantation slightly lower than average[20], whereas risk was assessed as higher[21]. Italians evaluated only the usefulness of biotechnology in food production as lower than that of xenotransplantation; all other new biotechnological

[15] This includes the categories “tend to disagree” and “definitely disagree”.
[16] This includes the categories “definitely agree”, “tend to agree”.
[17] 10% of the respondents stated that they had no opinion on this question.
[18] 40% were negative about this question and 8% that they did not know.
[19] 58% were negative about this question and 8% did not know.
[20] Measured on a scale from -2 (low acceptability) to +2 (high acceptability); moral acceptability: mean= -0,37, Italy = -0,40; usefulness: mean= 0,12, Italy= 0,13
[21] On a scale from -2 (low risk) to +2 (high risk); mean= 0,49; Italy= 0,68.

possibilities were rated higher. Xenotransplantation also scored the lowest rate of moral acceptability, and is associated with the highest risk when compared to other technologies like genetic testing or genetically modified food. (Durant et al 1998: 247-260)

The Eurobarometer Survey 2010 showed that xenotransplantation had an overall approval rate of 57,88% in the EU-27 countries[22]. In Italy, 58.3% of respondents had a positive attitude[23] towards xenotransplantation, 35.1% were negative[24] and 6.6% had no opinion (European Commission 2010: 144).

Compared to other biotechnologies – human enhancement, gene therapy, embryonic and non-embryonic stem cell research – xenotransplantation was received least well by respondents.

Table 2 Attitudes of the Italian public towards research areas

	positive[25]	negative[26]	don't know
Gene therapy	69,9	24,9	5,2
Non-embryonic stem cell research	68,6	25,6	5,8
Embryonic stem cell research.	64,5	28,7	6,8
Human enhancement	59,3	33,7	6,9
Xenotransplantation	58,3	35,1	6,6

(European Commission 2010)

2.5 Public Debate and Involvement

Both the CNB and the CNBB recommended public involvement and debate in xenotransplantation; e.g. the CNB emphasized "the need to take every opportunity to hold a public debate to disseminate knowledge of these issues and promote an ethical awareness

[22] Item: "Scientists can put human genes into animals that will produce organs and tissues for transplant into humans, such as pigs for transplants or to replace pancreatic cells to cure diabetes. Would you say that…?" (European Commission 2010: 144)

[23] „Fully approve and do not think that special laws are necessary." or "Approve as long as this is regulated by strict laws."

[24] „Do not approve except under very special circumstances." or "Do not approve under any circumstances."

[25] Respondents that "fully approve and do not think that special laws are necessary" AND those that "approve as long as this is regulated by strict laws".

[26] Respondents that "do not approve except under very special circumstances" AND those that "do not approve under any circumstances".

on the part of everyone concerned, in order to be able to appraise the true level of social consensus on the issue" (CNB 1999). However, according to a European Commission survey sent out to Member States' authorities in 2001, "no public debate" has taken place in Italy on xenotransplantation (European Commission 2001: 15). The governmental official who filled in the questionnaire, responded that "the public has been informed only by the media. Nevertheless xenotransplantation has been discussed in many conferences, and also in some meetings with students" (ibid.).

Interviewees agreed in their assessment that in general there was little public debate on xenotransplantation in Italy (5: 121-122, 9: 288, 6: 340-344). The discussion remained confined to the scientific and health care community, and did not develop into a broad public debate (11: 105-105), despite the aforementioned calls for public involvement and a campaign against xenotransplantation, which showed artist and Nobel laureate Dario Fo with pig's claws on a postcard picture.

Respondents provided several explanations for this absence of public debate.

- Xenotransplantation did not enter clinical research (6: 357-359, 11: 272-276).
- Other topics drew more public attention, such as "genetically modified organism for food or animals, agriculture" (11: 268-270, 5: 66-74) and reproductive medicine.
- The discussion was not controversial and the main protagonists more or less shared opinions (6: 424-432).

Interviewees supporting xenotransplantation, as well as those who were more critical, expressed their dissatisfaction with the public debate that occurred in Italy. Both sides criticized the discussion for lacking nuance. A pro-xenotransplantation researcher referred to the campaign of Dario Fo's mentioned above. The scientist claimed critically that only gut arguments were brought forward, and stated: "we can be in favor, pros or cons xenotransplantation, but what we need is really people to be informed, not having (...) just (...) show up in the journals, in the newspapers or in TV" (8: 347-348). Another researcher more critical about xenotransplantation also complained about this lack of differentiation. Public debate would focus on "images and impressions and gut arguments" (5: 320), instead of dealing with important details, such as what sort of information should be required in order to how to obtain informed consent based on what kind of information.

However, generally speaking, as the main reason why public involvement in discussion about science and technology was difficult and therefore technocratic approach to policy-making was taken, interviewees mentioned a basic lack of infrastructure, support of, and attitude towards public involvement. Institutions that could organize public involvement were missing (7: 567). Moreover, as a respondent put it, "there was no concept of what a public

consultation was" in the 1990s in Italy (5: 178). The situation was different from Northern European countries where traditions of public involvement existed. In Italy public involvement would have been restricted to advertisements and the movement against GMOs, "but there were no institutional forums" to allow for "some kind of democratization of the debate" (5: 180-182). Public involvement, apart from referenda, would still be lacking (5: 183-184). As another interviewee explained, scientists in the late 1990s were not used to communicate with the public, therefore the public was scarcely informed and responded with emotional reactions (7: 41-45). However, this situation would have improved in recent years, and several newspapers started with serious science journalism (7: 54-60). In addition, there would be a certain technocratic tendency in the scientific advisory system (see 4.2.10), which hampered the involvement of a lay public. An interviewee pointed at a number of factors which, in combination, could be responsible for the fact that there was only a small number of personnel which were regarded as elective in Committees such as the CNB. Firstly, the Italian research scene on xenotransplantation, although it existed, was rather small (1: 210-219), thus limiting the number of elective candidates. Secondly, experts, who favor science, would dominate these committees. In the case of xenotransplantation this meant that "on the scientific side very few people were opposing xenotransplantation" (1: 195). These factors, combined with the aforementioned conflict between secularism and Catholicism, lead to a kind of encapsulation of scientific advice and technocracy. As an interviewee put it: "in Italy, this is taken to extremes because the scientific community is quite small and (...) if you combine all these factors, (…) of politics, of a small scientific community, of no culture of public discussion, they are all merged together" (1: 231-233).

2.6 Summary

Apart from the opinions by CNB and CNBB, as well as an authorization by the CSS, for a single clinical trial there was no regulation of xenotransplantation in Italy until 2011. Applications for clinical trials are currently decided by the Ministry of Health on a case-by-case basis. Mazzoni and Tallacchini criticized the “inadequacy of existing provisions” for several reasons. Firstly, the Italian regulations were governmental acts and did not pass parliament. Secondly, they would “impinge on fundamental constitutional rights that may be not too easily limited without a legislative act” (2008: 61). Some provisions might “go against the Italian Constitution (Art. 32, Right to health)” (ibid.). Thirdly, the documents produced by different institutions are contradictory and their conclusions differ: “the CNB judges clinical experimentation still premature and excessively risky, while the Consiglio Superiore della Sanità, although establishing cautionary measures aimed at preventing the spread of infections, expresses a substantial acceptance of xenotransplantation” (ibid. 61 ff.).

The drive to address xenotransplantation did not come from politicians. The CNB took up the issue based on a Recommendation of the Council of Europe for a moratorium on clinical trials; the CNBB put xenotransplantation on its agenda on its own initiative and the CSS responded to an application for a single clinical trial.

Xenotransplantation was mainly portrayed as a risky proposition. Newspapers reported about xenotransplantation as a cutting edge science carried out abroad, which was currently facing risk and rejection. The CNB framed xenotransplantation according to risk, individual benefit and the protection of collective health. It adopted a precautionary approach and embraced the Council of Europe's recommendation for a moratorium. At the same time it called for intensifying basic research to overcome the problems of risk and infection. The CNBB framed xenotransplantation through playing the benefit for individual patients off against the potential risks for the entire population, and provided detailed strategies to tackle them. Both advisory bodies called for public debate and involvement. However, these calls remained unanswered and there was little public discussion on this issue in Italy.

The TA process was split between two organizations. The CNB dealt with ethical issues, whereas the CNBB addressed technical ones. The aim of the TA was to inform and advise policy makers. The processes were completely expert led, and involved a small number of experts from the natural sciences and ethics.

There was no PTA in Italy to discuss the issue of xenotransplantation.

Questions of gender differences were not addressed in the process.

Routine practices of policy-making involved activities of the CSS to authorize a clinical trial, as well as routines of advisory bodies to prepare their advice. The CNB rather quickly produced a short opinion based on the discussion it was involved in at the Council of Europe, whereas the CNBB set up a working group, which composed an extensive document on how to deal with xenotransplantation.

The Parliament was never involved in the issue of xenotransplantation (5: 99-102, 108-109). All institutions actually dealing with xenotransplantation are attached to the executive branch. However, none of the documents, apart from the CSS authorization, had an actual impact on policy making, due to several reasons: firstly, interest in xenotransplantation research faded through lack of results; secondly, the advisory bodies, apart from CSS, do not possess any regulative power; thirdly, politics in Italy is hesitant to deal with issues of ethics on principle. Documents providing information about policy-making in the area of xenotransplantation, apart from the final documents, were not accessible for research.

There was little public debate about xenotransplantation, and the little discussion that did occur - as several interviewees pointed out - was mainly emotive, insufficiently nuanced and dominated by gut arguments. Despite calls for public debate and a postcard campaign by a popular actor and writer, no noteworthy debate developed. Likewise, citizens were not involved in policy-making and were predominantly included as survey public, either in EU Barometer surveys or academic research, which gave rather limited information about public

attitudes towards xenotransplantation (see 4.1.). Interviewees mainly referred to the public as uninformed.

Several documents called for public discussion, though without providing any detailed plans on how this should be accomplished.

3 The Holy See

3.1 Introduction

The Vatican as a state cannot be compared with most other countries or international organizations. It is not a democratic state *per se*, but an absolute elective monarchy (Marxer/Pállinger 2009: 947) and theocracy (ibid. 951). The Catholic Church is organized in strict hierarchy, with almost no right of participation for common believers and lower members of that hierarchy. Decision-making mostly happens in secret, concealed from the public (ibid. 951). There are no democratic elections and no formal parties in this system. There is also a tendency to suppress pluralism and the formation of different factions within the Church to emphasise its unity. Power is concentrated within the office of the Pope (ibid. 951), which unifies the offices of legislature, executive and jurisdiction (ibid. 947). The Secretariat of State can be considered the government of the Vatican and is appointed by the Pope. Administration is carried out by the Curia, which is divided into various departments (Dicastries), such as Pontifical Councils, Commissions and Academies.

On 26 September 2001 the Pontifical Academia for Life (*Pontificia Academia pro Vita*, PAV) published the document "Prospects for xenotransplantation. Scientific Aspects and Ethical Considerations". The following section describes the PAV and the content of the document; it analyzes the working process leading to the paper as well as its status within the Church and its impact on xenotransplantation research.

3.2 Pontifical Academy for Life

Interviewees characterized the PAV as an "organism in the Catholic Church" (9: 223-224). This description gives rise to the following questions: What is the objective of the PAV and what is its relation to other departments within the Curia, the administrative apparatus of the Holy See, and the Church more generally?

Pope John Paul II established the PAV, which is a section of the Pontifical Academy of Science, on 11 February 1994 by the Motio Proprio[27] "Vitae Misterium" (1994). The goal of the PAV is to

- "study questions and issues connected with the promotion and defence of human life from an interdisciplinary perspective;

- foster a culture of life – in relation to those aspects that belong to its specific range of competence – through suitable initiatives, and always in full respect of the Magisterium of the Church;

[27] A Motio Proprio is an apostolic letter of the Pope which has been decided by him personally.

- inform the authorities of the Church, the various institutions of the biomedical sciences, social-health care organisations, the mass media, and the civil community in general about the most relevant results of its study and research activities in a clear and prompt manner" (PAV 2012b: § 2).

One objective of the PAV is to support other departments within the Curia by "studying (...) ethics, but primarily scientific" aspects of new biomedicine (10: 302-306). The PAV can be considered a think tank, or as an interviewee defined it, a "center of research, debate and proposal concerning the new challenges coming from biology, medicine and the development of medical technologies concerning the impact for human life, the dignity of the person and in which way to manage the ethical problems present in this (…) new situation" (11: 4-7). The role of the PAV, however, is not restricted to advice to the Curia. It should also provide dialogue with the "scientific community, the public and (...) inside the Church". (11: 8-10). The PAV is perceived by interviewees as a service for the Church, the scientific community and civil society "to see (…) ethical problems and to offer some principle criteria to manage all these aspects" (11: 10-12).

The PAV fulfills its goals by bringing together scientists and asking their opinions (10: 311-323). The PAV convenes annually at general assemblies which deal with different topics. The resulting proceedings are published in English and Italian (PAV 2012b: Art. 7). The PAV also establishes study groups to deal with particular topics of interest (ibid. Art. 8).

The PAV consists of a maximum of 70 members, so called Academicians. They are appointed by the Pope "after hearing the opinions of the Governing Council" of the PAV (PAV 2012b: Art. 5 § 1). Academicians are selected "on the basis of their academic qualifications, proven professional integrity and expertise, and faithful service to the defence and promotion of the right to life of every human person" (PAV 2012b: Art. 5 § 1). As an interviewee pointed out, Academicians should have basic scientific education and excel in their research area. This is measured, e.g., by looking at the number and quality of their publications. But there are also Academicians without this scientific background whose appointments were based on other criteria, i.e. their strength of faith (10: 331-368). Members do not have to be of Roman-Catholic faith, but "are required to sign a 'Statement of the Servants of Life': a testimony to the permanent decision of each one of them to promote and defend the principles related to the value of life and the dignity of the person, in conformity with the Magisterium of the Church" (ibid. Art. 6). According to interviews, the PAV currently strives to increase the emphasis on scientific qualification as a criterion to recruit members (10: 720-726). Members can be proposed by various sources: existing members, local bishops or a nuncio. Long lasting acquaintances and working relationships in Catholic institutions, as well as past activities in the PAV, also play a role in recruitment policies.

Academicians remain ordinary members until the age of eighty and become Emeritus Members thereafter (PAV 2012b: Art. 6). In addition to the ordinary Members, there are also

so called Corresponding Members, who are appointed for a five year period, with an option for renewal. According to an interviewee there is a rather stable core of long-term members, consisting of jurists, philosophers, theologians and clericals, and another, less stable group comprising natural scientists, whose appointment is guided by current thematic priorities (2: 67-72).

The governing body of the PAV, the so-called Presidency, consists of a President, a Chancellor, a Governing Council and an Ecclesiastical Adviser (PAV 2012b: Art. 3).

3.3 Putting Xenotransplantation on the Agenda

According to its statute, the President of the PAV is authorized to assemble a study group to investigate a topic. He can either do that on his own initiative or "in response to a request from any Dicasteries of the Roman Curia" (PAV 2012b: Art. 8 § 1). In the case of xenotransplantation, the topic was put on the Academy's agenda on request of departments within the Curia.[28] They asked the PAV to study xenotransplantation from a scientific and ethical perspective (6: 19-22), because the Academy would be the competent body within the Church for these questions (6: 65). The request arose from many questions directed at the Holy See from all over the world about whether it would be licit to use animal parts in transplantation (6: 10-15). Such requests came from theologians, researchers, and also bishops in dioceses with Catholic universities where xenotransplantation research was carried out (6: 349). A more general reason why the PAV started studying this topic was that "the Church", as an interviewee put it, "is very careful not to repeat past errors" and tries "to prepare (herself) well in order to know the details" (10: 157) of a scientific topic. Should Ixenotransplantation become a reality, the Church wanted to be prepared "because", as an interviewee mentioned, "we realized if an ethical question comes forward (...) it is necessary to be well informed (…), not to say things that are untrue" (10: 180-185). As several respondents pointed out, there was also a certain sense of urgency to deal with xenotransplantation, because it seemed likely that clinical application would be imminent (6: 196-201, 10 549-559, 11: 202-209).[29]

3.4 Composition of the Study Group

The working group consisted of 22 experts of various areas and was chaired by Bishop Elia Sgreccia, then the Vice President of the PAV. The study group had a scientific, as well as an ethical-anthropological section.

The group responsible for the scientific section comprised nine researchers and/or physicians. Six of them came from the field of xenotransplantation and had additional

[28] According to interviews this request came either from the Secretary of State or the Congregation of the Doctrine of Faith.

[29] For the significance of this assumption in regulating xenotransplantation see Beynon-Jones/Brown 2011.

expertise in immunogenetics, veterinary, preclinical and clinical experimentation, biotechnologies, molecular biology and genetics, as well as virology-microbiology. Other experts in this group came from the field of transplantation and human genetics. The group involved: Prof. Fritz Bach (Harvard Medical School), Prof. Fulvio Calise (Cardarelli Hospital, Naples), Prof. Felix Cantorovich (Coordinator of the national Commission on xenotransplantation, Buenos Aires), Prof. Emanuele Cozzi (University of Cambridge), Prof. Marialuisa Lavitrano (University “La Sapienza”, Rome), Prof. Ignazio Marino (Mediterranean Institute for Transplants and Highly Specialized Therapies City Hospital, Palermo), Prof. Eraldo Seren (State University Bologna), Prof. Angelo Serra (Sacred Heart Catholic University Rome), Prof. Jonathan P. Stoye (National Institute for Medical Research, London).

The group of experts responsible for the ethical-anthropological section had ten members; the majority of them were experts in moral theology, either solely in this area or in combination with bioethics. Two members were experts in bioethics only. Another two members were experts in law and one in philosophical anthropology. This group included: Rev. Maurizio Calipari (Pontifical Academy for Life), Msgr. Prof. Ignacio Carasco De Paula (Sacred Heart Catholic University, Rome), Prof. Maurizio P. Faggioni, o.f.m (Alphonsian Academy, Rome), Msgr. Prof. Nunzio Galantino (Southern Italy Faculty of Theology, Naples), Prof. Bonifacio Honings, o.c.d., Msgr. Osvaldo Neves de Almeida (Secretariat of State, Sect. for Relations with States), Prof. Renzo Pegoraro (General Secretariat of Lanza Foundation, Padova), Msgr. Prof. Angel Rodriguez Luno (Holy Cross Pontifical University, Rome), Prof. Antonio G. Spagnolo (Sacred Heart Catholic University, Rome), Justice C. G. Weeramantry (Former Vice-President, International Court of Justice, Sri Lanka).

The study group also included representatives of the Holy See. These were: Msgr. Tullio Poli (Secretariat of State, Sect. for Relations with States), Dr. Maria Isabel Telleria Tapia (Secretariat of State, Sect. for Relations with States). According to interviews, they kept the records (10: 205-210) and did not participate actively in the discussions (9: 327-330).

In summary:

- According to its objective and self-perception as scientific society, the study group included only experts from science and ethics. No representatives of NGOs were involved;

- the working group equal numbers of scientific experts and experts in ethics;

- the majority of scientific experts were researchers active in xenotransplantation,

- the majority of ethical experts were also clerics;

- there was a strong bias towards organizations located in Italy and the Vatican. Eleven members came from organizations located in Italy, five from the Vatican State. Two members were from the UK and one each from Argentina, the U.S. and Sri Lanka. One person was not affiliated to a country;

- with only two women, the working group was strongly gender imbalanced;

According to the statute it is within the responsibility of the President to select and appoint members of study groups from within and outside the Academy (PAV 2012b: Art. 8 § 2). In the case of xenotransplantation, membership of the study group was self-selected, as appointment was based on recommendations and existing acquaintances. However, this process is not uncommon for recruiting scientific committees (Griessler 2012). Proposals for members of the scientific section were based on recommendations by an Italian scientist who was active both in xenotransplantation and in regulating this research on Italian and international level (12: 11-40, 48-52, 66-67).

Interviewees considered the composition of the study group balanced, as regards the positions on xenotransplantation (6: 314-316), political affiliation and confession. One interviewee was conscious that some experts were also "involved in industry" (9: 75), but thought that this was not an economic interest in the strict sense. Another interviewee particularly pointed out the "democratic" (8: 585) attitude of the Vatican manifested in the involvement of experts with opposing political backgrounds: "people from the (…) **very** left party, people from (…) Catholic, [.], really all together around the table discussing (...) I was really very impressed for the open mind (...) of the Vatican" (8: 596-599, emphasis in the original).

3.5 Content of the Document “Prospects for Xenotransplantation”

The document of 23 total pages is divided into a scientific and an ethical section. The five pages dealing with scientific aspects provide a historical background of xenotransplantation, and recount experiments from the 1970s until the 1990s. Moreover they explain why for ethical and practical reasons pigs and not non-human primates are the favorite source animals for xenotransplantation (Pontifical Academy for Life: 4). The document continues with a description of the by then current state of the art of research, explaining different phases of organ rejection, experimental methods (small and large animal models), xenozoonoses and developments in biotechnology and molecular genetics related to xenotransplantation.

The eight pages of part two include “anthropological and ethical aspects” (ibid. 9), and address so called preliminary and bioethical issues. The first category raises the question of whether xenotransplantation would be a justified medical treatment from a theological viewpoint. The arguments considered:

1. “the acceptability of man’s intervening in the order of the creation;

2. the ethical feasibility of using animals to improve the chances for the survival and wellbeing of human beings;

3. the possible objective and subjective impact that an organ or tissue of animal origin can have on the identity of the human recipient” (ibid. 9).

The section on “bioethical issues” (ibid. 12) deals with the problems of “health risk” (ibid.), “’transgenesis’” (ibid. 14), “informed consent” (ibid.), “allocation of health care resources” (ibid. 15), and the “patentability and xenotransplantation” (ibid.). The final section of the document consists of two pages on “practical guidelines” (ibid. 17).

The first fundamental question, i.e. whether “human intervention in the created order is justified” (ibid. 9), is clearly answered in the affirmative. Drawing on the bible, the encyclical “Laborem Exercens”, the Second Vatican Council, as well as on statements of Saint Irenaeus of Lyons, the documents reaffirm “the right and duty of man, according to the mandate from his Creator and never against the natural order established by him, to act within the created order and on the created order, making use as well of other creatures in order to achieve the final goal of all creation: the glory of God and the full and definitive bringing about of His Kingdom, through the promotion of man” (ibid. 10).

The second question posed in the preliminary section is also answered positively. Recognizing that “animals have their own specific value which man must recognize and respect” (ibid. 10), the document occupies the middle ground between “species-ism”, and a position where “man can use animals arbitrarily without being limited by ethical considerations” (ibid.) by reaffirming “that humans have a unique and higher dignity” than animals. Humans, however, “must also answer to the Creator for the manner in which they treat animals” (ibid.). If it is for the “benefit of man”, the “sacrifice of animals can be justified (…) even when it involves experiments on animals and/or genetically modifying them” (ibid.). However, the document adds, “unnecessary animal suffering must be prevented; criteria of real necessity and reasonableness must be respected; genetic modifications that could significantly alter the biodiversity and the balance of the species in the animal world must be avoided” (ibid.). This general approval also applies to non-human primates, though there would be the “question of differing levels of sensibilities between animals of different species” (ibid.). Since there are no principle objections in Catholicism to using parts of certain animals, “the question of acceptability (…) becomes cultural and psychological”, necessitating in certain cases the provision of support to patients (ibid.).

The third question of the preliminary part addressed the question of whether xenotransplantation changes personal identity. The document states that “the implantation of a foreign organ into a human body finds an ethical limit in the degree of change that it may

entail in the identity of the person who receives it" (ibid. 12). The PAV distinguishes subsequently between organs "which are seen as being purely *functional* and those with greater *personalized significance*" (ibid. emphasis in the original). It concludes, referring to Pius XII and John Paul II, that xenotransplantation would be legitimate as long as "the transplanted organ does not affect the psychological and genetic identity of the person who receives" the transplant, and that the transplantation has "proven biological possibility" of success without "exposing the recipient to excessive risk" (ibid.).

The document continues with bioethical issues. It deals with the problem of "risk", discussing the concept of risk itself as well as "probability", "extent of damage", "probable event", "hypothetical event" and "acceptability" (ibid. 13). Given the uncertainties and the lack of knowledge concerning xenozoonoses the PAV concludes that it "is an ethical requirement to proceed with the greatest caution" in xenotransplantation. Patients should be carefully selected based on certain criteria, and monitored "very closely and constantly" (ibid.). Quarantine, monitoring of close contacts, restrictions on procreation and obligation to sexual abstinence might be necessary (ibid.). However, whether these dramatic restrictions on human rights are acceptable is not discussed any further.

As regards the genetic modification of animals ('transgensis'), which is a prerequisite for xenotransplantation, the document remains positive, if "some fundamental ethical conditions" are met, including: (1) "concerns for the well-being of genetically modified animals should be guaranteed" (…) "limiting the levels of stress and pain, suffering and anxiety experienced by the animal"; (2) "effects on the offspring and possible repercussions for the environment should be considered; (3) animals should be tightly controlled and kept in captivity; (4) the number of animals should be kept to a minimum; (5) removal of organs should be done in one single surgical operation; (6) ethics committees must constantly be involved" (ibid.).

Informed consent should be obtained from patients after providing them with information about pathology, prognosis, xenotransplantation operation and therapy, probability of success, rejection risk, the "real and hypothetical risks of zoonoses" (ibid. 15), necessary precautions in the case of infection (need for quarantine, avoidance of physical contact), "the need to remain under medical supervision for the rest of his/her life" as well as alternatives. Relatives should be informed, but consent in the strict sense would only be necessary from the patient, because "it is the patient who is ultimately responsible for the choices concerning his own health" (ibid.).

As concerns the debate about the proper allocation of health care resources, the PAV concludes that xenotransplantation "is justified by the urgent need to try to save the lives of so many patients who would otherwise have no chance of survival" (ibid.).

The paper closes with practical guidelines, stating that pre-clinical trials should continue until researchers consider that clinical trials on humans are sufficiently promising. Clinical trials

should “initially involve only a restricted group of patients (…) who cannot be chosen for allotransplantation” (ibid.). Patients should be monitored carefully. However, research in alternatives to xenotransplantation should be continued, including “the therapeutic use of adult stem cells” (ibid. 17).

3.6 Working Procedure

The document was written in less than a year and the working group met several times in the Vatican (Pontifical Academy for Life: 2001: 1, 9: 316). Although the scientific and the theologian-anthropological section of the paper were written by different groups of authors, the study group held its meetings as one body and discussed the document as a group. The study group followed, as an interviewee explained, Elio Sgreccia’s handbook for bioethics, according to which the scientific aspects of a problem have to be studied first. Thereafter anthropological aspects were considered. Again this was followed by ethical conclusions (9: 100-111). In general the interviewees expressed their satisfaction with the mutual cooperation of the different groups of researchers (6: 448-449, 11:222-238, 12: 56-66), though interdisciplinary work of ethicists and scientists was also considered difficult at times (10: 706-719).[30]

3.7 Status of the Document

Interviewees from the PAV emphasized that the document would be scientific and ethical, but not political. The aim of the group was "to study (the matter) from a scientific and ethical point of view" (9: 381-382). The document was not supposed “to have a public **impact**, or a political impact”, but it was intended “to discuss without (…) pressure from the biotechnology industry or from different groups (…) in a scientific way, in an anthropological, in a bioethics way” (9: 170-174, emphasis in the original). In this sense the document was not considered a political document. It should “not (…) interfere in legislative political matters” (Pontifical Academy for Life 2001: 17). This, as an interviewee put it, contrasts with the approach taken by the Catholic Church in other issues such as abortion, where it clearly has “the intention of entering into legislative and political matters” (9: 682-699).

The PAV also had no intention of involving the public in the development of the document. The public could discuss the topic later on, after experts had produced their paper.[31]

[30] An interviewee not involved in this, but in other PAV study groups, emphasized the scientific quality of PAV meetings (2: 97-98). He recognized that the resources available to members and the quality of organization would exceed other comparable national and international bioethics committees (2: 143-149).

[31] The text states: “There is thus an ethical need to acquire correct information on the topics of greatest public interest with regard to the potential benefits and risks. This information should be communicated to as large a segment of the public as possible. Moreover, by means of debates and public discussions in small and large groups, society itself, through its representatives, should help to identify the conditions under which they would find it acceptable to invest resources and hope in this new therapeutic approach, in light of the scientific uncertainties which are still present and the urgent need to increase the availability of organs which can be transplanted” (Pontifical Academy for Life 2001: 17).

Thereafter, “maybe the association[s] or the public could use this document for their consideration. It was not the aim of the group to involve the different parties because (…), there [was] not the aim to produce a document, a public or political document, but scientific document" (9: 175-178).

Interviewees from the PAV turned out to be rather ambiguous when asked about the official status of the document. On the one hand they qualified the paper’s authoritative significance. The text would not be definitive; it was not a Papal document with the same authority as an encyclical (9: 339) such as Evangelium Vitae, which condemns abortion and euthanasia. An interviewee rated the authoritative status of the document in the hierarchy of Church documents as "almost zero" (10: 226). No member of the Church would have a moral obligation or duty to follow the document (10: 545-546). Nevertheless it would be a "legitimate document", which would allow believers the freedom either to approve of xenotransplantation or oppose it (10: 618-621).

And in fact the document was not unchallenged within the Catholic Church. The organization “Catholic Concern for Animals”, a UK based Catholic group which aims to “influence the Christian Church and, ultimately the wider society, into adopting a more just, understanding and compassionate attitude towards the animal creation” (Catholic Concerns for Animals 2012) criticizes the document “for not including due consideration for the God-given rights of animals not to be used as 'spare parts' for people” (Catholic Concern for Animals w. d.). However, this critique seemed not to resonate much with interviewees, who were unaware of the organization and its position.

On the other hand, the interviewees inside the Church saw the document as an "important text" (10: 236-237), the authority of which would rest on its reason and the stringency of its argumentation as well as the credibility of the members of the study group. It would be an official document of the PAV, which, in accordance with its statute (PAV 2012 b: Art. 8 § 4) underwent approval by the PAV’s Presidency before publication. The text was published after a press conference[32] as a supplement to *L’Osservatore Romano* on 26 September 2001 and on the Internet. Moreover, members of the study group reported on the document in the Journal *Nature*, and informed researchers about the PAV’s positive stance towards xenotransplantation, stating that “in xenotransplantation the service of animals to man represents a totally new application that is not in conflict with the order of creation” (Sgreccia et al 2001).

Moreover the document should also be used for guidance, either for those “who - at an international, national, regional and local level - are responsible for leading society” (Pontifical Academy for Life 2001: 17) or as future guidance for the Church. If clinical trials

[32] http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_conf-stampa-xenotrapianti_it.html, accessed: 13/2/2012.

were to become imminent and questions about the position of the Church were to arrive at the Holy See, the Pope might refer to the document as guidance. Thus the document would provide directions because "often the Church does not say you have to do this (...) they give you a direction and say, (...) if you go this far over here, you are being unreasonable, if you go this far over here, you are being unreasonable, but you are going that direction, and so this allows us a reasonable direction" (10: 257-259).

This official status is also underlined by the fact that Pope John Paul II thanked the working group for the document in a meeting on 1 July 2001. He acclaimed their work as being “in the interest of man because it accrues from the necessity to solve the problem of the immense lack of human organs suitable for transplantation” (2001: 1, translation EG). He stated that the “caution and clear conditions for the realization of xenotransplantation, which have been emphasized (by the study group; comment EG), are fruits of this dialogue and convergence” of science and ethics (ibid.).

3.8 Impact

The ambiguity way in which insiders of the Catholic Church evaluated the text is in stark contrast to the unambiguous assessment by an interviewed xenotransplantation researcher, who considered the text to be of the highest authority, even close to a dogma.[33] The expert explained: "People were very much interested in knowing (…) the official opinion of the Church. (…) The document released by the Pontificia Accademia per la Vita is actually a document released by the Pope (…). And this means, that this kind of, you know, dogmas”. The researcher also considered the document’s impact on xenotransplantation research as being rather high: “since (…) the Catholic community is very much sensible of what the Vatican say[s], (…) the document was of high impact. And the fact that the Vatican (…) [was] open to accept the hypothesis of xenotransplantation, of course **if** and **when** (…) the condition could be accepted, was very important" (12: 133-139, emphasis in the original). An article in the Journal *Xenotransplantation* referred to the text, reporting an “open and favorable position” by the PAV on xenotransplantation “as long as xenotransplantation does not threaten the dignity and identity of human beings” (Tallacchini 2002: 372). This positive assessment by the PAV was also an important resource for xenotransplantation researchers to legitimise future funding from the perspective of ethics (12: 139-140). Thus, although members of the PAV qualified the importance of the document, it nevertheless had significant impact on the discussion about the ethics of xenotransplantation.

[33] This might also be due to fact that the Church seems to be less monolithic than perceived from the outside. An interviewee described the Church as diverse, heterogeneous and in flux. He pointed at diversity by emphasizing: "the information (...) on the position of the Church is not always correct information. Even within the Church there are some ideas of what (…) the position of the Church is which are not correct, not complete. Even many bishops (...) are not well-informed for example" in the area of bioethics (10: 84-97). He also highlighted the complexity and plurality within Church, by pointing out there would be Internet "blogs” of Catholic groups “everywhere, going in every direction" (10: 606-609).

3.9 Summary

Though the opinion of the PAV is an official text and is meant to provide guidance, it is not a definitive document with highest Papal authority. In principle the PAV was positive and supportive of xenotransplantation, so long as certain conditions were met. Xenotransplantation was framed as a scientific, fundamental theological and bioethical problem, and no fundamental objections were raised.

The Curia dealt with the problem of xenotransplantation by delegating it to its PAV, which was created just a few years previously to concern itself particularly with questions of biomedicine from scientific and ethical perspectives. The development of the document was not accompanied by any documents which were accessible to research and the public. The only documents available are the text itself, a press release from the press conference, and an article in the journal *Nature*.

The PAV considers itself a scientific expert organization. Therefore, only experts in science and ethics, and all but two of them male, participated in the process. Appointment was based on a self-selecting process. The document was developed in an interdisciplinary seminar which considered aspects of science, theology, bioethics and anthropology. Thus, in contrast to many other comparable international exercises, the study group not only mentioned ethical aspects, but actually dealt with them in detail. The aim of this document was to discuss these questions in a scholarly manner and to advise the Curia, scientists and the public. Several interviewees pointed out that the aim of the work was not to produce a political document.

The participation of the public is not part of the PAV's self-perception; there was no public involvement in policy-making. Potentially antagonistic NGOs, such as patients' organizations and animal welfare activists, were considered by an interviewee as difficult to include because they would not be ready for dialogue. Instead, another interview partner assumed that knowledgeable experts would take into account what they thought would be the concerns of the public (6: 329-335). The public was informed about the document only later on in press releases, publications and online. Policy makers were encouraged in the document to stimulate public discussion. The public was defined in the document as lay citizens, individual patients and relatives.

Members of the study group were altogether satisfied with this expert oriented process. Insiders and outsiders of the Church were divided in their assessments of the status of the document. Whereas the former qualified the document as not definitive and as guidance only, the latter considered the status of the text to be much more definitive.

4 Annexes

4.1 Political System Italy

After the Second World War and more than two decades of fascist power, Italy was re-established as a democratic Republic and the period of the "First Republic" began. Italy entered decades of modernization and economic growth, soon featuring among the globe's most important economic powers. The first decades of this "First Republic" were very much shaped by two parties and the conflict between these two: The Christian Democracy (*Democrazia Cristiana*, DC) and the Italian Communist Party (*Partito Comunista Italiano*, PCI). Indeed, these parties, as well as a list of smaller ones, shaped not only the formal process of political decision-making but also Italian society.

In the early 1990s, however, the "First Republic", which political scientists referred to as the "Republic of Parties", collapsed. This was due both to international processes such as the end of the Cold War, which brought the Communist Party into identity crisis, and processes within Italy, such as the major "Tangentopoli" scandal. Parties such as the Democrazia Cristiana, which had shaped Italy for decades, disappeared, and the Italian political system entered a period of transition, which was soon referred to as the "Second Republic." Attempted constitutional reforms were a recurring theme in these years of transition, but most of them failed.

4.1.1 Cabinets

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

In the last two decades, all governments were formed by coalitions. With the exception of the 13th legislature (May 1996 - June 2001) and the brief 15th legislature (May 2006 - May 2008), which were characterized by centre-left coalitions, all governments were formed by parties of the centre-right, among which the dominant party was "Forza Italia" (Go ahead Italy), which was re-established as "Popolo della Libertà" (People of Freedom) in 2009.

Between 1946 and 2008 there were 62 cabinets, which were mostly very short-lived. Therefore, Italy has a tradition of governmental instability. This instability derives from the relatively fragmented and polarised landscape of the political parties. From the establishment of the Republic in 1946 till the early 1980s, the DC was the dominating party, even though sporadically there had been internal power struggles. Not only the DC, but also the left wing parties such as PCI had to deal with faction crises. Furthermore, the DC often had to form

minority governments, or coalitions with up to four partners (with the PSI[34], PSDI[35], PRI[36] and/or PLI[37]).

Despite the frequent changes of cabinets there had been a personal continuity, to some extent. On behalf of legislation, the permanent governmental crises were circumvented through special decrees (decreti legge), which have force of law and can be enforced without the approval of parliament.

Since the 1980s the power of the DC and most of the other existing parties declined. In 1992/93, fuelled and accompanied by political corruption and bribery scandals, the First Republic ended and the Second started with the inauguration of a new electoral law. During this process there had been a transition of power: The old parties lost strength, changed or dissolved (see Party system).

During the last two decades only coalitions of different leftist electoral alliances (e.g. the Left Democrats - DS[38]) and Forza Italia resp. Popolo della Libertà under Silvio Berlusconi, as well as the Lega Nord (Umberto Bossi) were in control or played an important role (Ullrich 2009: 651-656).

In November 2011, after the retirement of Silvio Berlusconi as prime minister, a technocratic cabinet has been put in place with Mario Monti as new prime minister, and party-independent ministers.[39]

4.1.2 Legislature

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

The Italian Parliament consists of the Chamber of Deputies and the Senate of the Republic. The Chamber of Deputies has 630, the Senate 315 Members, who are elected for a period of 5 years. Former state presidents and five persons of honour also have seats in the Senate. Both houses are rank equally (bicameralism perfetto), which makes the Italian legislative system unique. Because of this, draft laws have to be confirmed by both houses, which can lead to a long and complicated process of consent finding, the so-called navetta.

---

[34] Italian Socialist Party - Partito Socialista Italiano.
[35] Italian Social Democratic Party - Partito Socialista Democratico Italiano.
[36] Italian Republican Party - Partito Repubblicano Italiano.
[37] Italian Liberal Party - Partito Liberale Italiano.
[38] Democratici di Sinistra
[39] http://www.independent.co.uk/news/world/europe/mario-monti-announces-new-cabinet-6262968.html; accessed 9.2.2012.

Different political groups use this ponderous system for their own ends through procrastination of decisions. (Ullrich 2009: 648-651, Cotta and Verzichelli 2007: 142).

Members of parliament have to be associated with a fraction, whereas a fraction does not necessarily represent a political party alone. In the last two decades fractions gained importance because of the decreasing influence of traditional parties. Delegates and senators are covered by political immunity, although this was limited after the revelation of systemic corruption in the political field in the early 1990ies. (Ullrich 2009: 650-651)

A legislative process can be initiated by the government, members of parliament, fractions, regional and communal politics. Civil society can start an initiative by collecting 50.000 signatures of supporters.

Committees, which have to represent the fractional situation in the two houses in their composition, review draft laws and make modifications, but can under special circumstances even accept a law (sede deliberante). As such they play an important role in the legislative process. This system often leads to legislation that is driven by particular interests (Ullrich 2009: 657-658).

A characteristic of Italian law-making is the use of regulations that have power of law, the so-called decreti legge. Initially, they were meant as an emergency instrument, but have become a normal means of political acting. A decreto legge has to be approved by parliament within 60 days or else become obsolete (ex tunc). Overall, in the Italian legislative branch a high number of laws and law initiatives are accepted (Ullrich 2009: 656).

Scientific advisory is not institutionalized in Italy, but there is a strong tradition of calling experts into the law making process in the houses of parliament, commissions and government (Allansdottir 2011: 25).

4.1.3 Executive-legislative relationship

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

The Italian political system qualifies as a “parliamentary democracy”. This implies that the voters elect members of Parliament. The head of the government is not elected directly. Instead, the President of the Republic entrusts the candidate that heads the winning party or coalition with the task of forming a government. The government has to win a vote of confidence in both houses. Given that the government mirrors those parties that constitute the majority in Parliament, in theory the executive-legislative relationship is fairly consensual. In practice, however, the Italian party system has proven to be quite volatile, and – as a

consequence – the relationship between the executive and the legislative power in Italy has sometimes become more antagonistic in kind. In the last two decades, this has been the case in particular during the 15th legislature, when Prime Minister Romano Prodi was the head of a government that assembled many parties, as well as during the recent legislature, when some members of the "People of Freedom" (*Popolo della Libertà*) split from this party, and formed a new one.

The constitution offers the parliament several possibilities of controlling the government: Parliament can hold a vote of (no) confidence, put a parliamentary request or start an inquiry. However, the instrument of decreti legge is frequently used and makes it hard for the parliament to exert its control function. For a long time, this was even more difficult because of the dominance of the political parties. Even nowadays, control of government is carried out especially in fiscal policy. In contrast, the parliament is influence on European topics is rising.

4.1.4 Bureaucracy

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

Italian bureaucracy has been the object of several attempts to reform since the 1990s (Bull and Newell 2006). It is a fairly huge but nevertheless not very coherent body which is often judged as inefficient.

4.1.5 Judicial review

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

Judicial review is not as important in Italy as in the United States, yet it does have a role which has also become more salient over the last two decades. Indeed, various laws that had been passed by the Italian Parliament were judged (in part) as unconstitutional by the "Constitutional Court" (*Corte Costituzionale*).

Jurisdiction is constitutionally divided from the legislative and executive branches of government. Courts played an important role in the early 1990s change of the political system: Milanese judges started the investigations concerning political corruption on many levels (mani pulite) and thereby were prototypes for other courts and also for wider social and political movements.

Judges and attorneys are organised in the Consiglio Superiore della Magistratura (CSM), which appoints or promotes them. It consists of judges (2/3) and members of parliament

(1/3). In their duty, judges and attorneys are independent from the CSM, which is under political influence.

The Italian constitutional court is at foremost political importance in the review of referendums, but its duty is also to evaluate if regional and nationwide laws are constitutional (Ullrich 2009: 693-695).

4.1.6 Party system

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

Currently, there are representatives from eleven parties in the Chamber of Deputies and in the Senate. If compared to the previous legislations, this is a fairly modest number. The dominant party of the centre-right coalition is "Popolo della Libertà" (People of Freedom), which has been founded in 2009 through a unification of "Forza Italia" and "Alleanza Nazionale" (National Alliance) and several other small parties. The dominant party of the centre-left is the "Partito Democratico" (Democratic Party) which was also formed before the last elections through a unification of various parties.

In the early 1990s the attempt was started to overthrow the so-called "partitocrazia", the strong influence of the political parties on every aspect of society which went hand in hand with corruption and partisanship. This put most parties under political and financial pressure. During the political crisis of 1992/93 many established parties disappeared (DC, PSI) and new ones emerged. Since then, Italy has seen the formation and dissipation of various coalitions, the longest -lasting under premier minister Silvio Berlusconi. Stable conditions have not yet been reached, and some characteristics of partitocrazia still exist.

In the late 1980s the Northern League (Lega Nord) under Umberto Bossi came into existence and gained first political ground through criticism of the partitocrazia and the promotion of federalism, up to separatism and xenophobic nationalism. Through their populist politics they influenced the reinforcement of regional divisions (see Constitutional division of territorial power).

In 1994 the businessman and majority shareholder of a large media group, Silvio Berlusconi, founded Forza Italia (FI), which succeeded in its first election of 1994 and also won in 2001 and 2005. The highly concentrated media structure in Italy, state-driven RAI and the Berlusconi controlled FININVEST group, shared 90% of television viewers, supporting Berlusconi's political success. Forza Italia and the later formed Popolo della Libertà (PdL), a coalition including FI, AN and other smaller parties, are to be considered centre-right, catholic-conservative in values, and liberal in economics.

Some of the old parties transformed, for example the neo-fascist party Movimento Sociale Italiano (MSI), who got rid of some of its most extreme wings, and renounced anti-semitism and fascism in an attempt to be integrated into the mainstream party system as Alleanza Nazionale (AN).

On the left side of the political spectrum there have been several groups in the last twenty years, often having to cope with fragmentation. In 2007 the coalition Partito Democratico (PD) was founded through the merging of the Democratici di Sinistra (DS) and Democrazia è Libertà – La Margherita (DL). The PD internally divided, especially on the topic of Catholicism vs. Secularism.

4.1.7 Interest group system

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

Italy belongs to the group of countries with a corporatist tradition. Over the past decades, however, corporatism has been expanded.

Like the party political system, the different interest groups and trade unions have been fragmented and polarised, partly because they are oriented towards different parties. For some years, trade unions have also had to cope with the aging of their membership. Furthermore, the influence of smaller trade unions and specific workers' associations is rising.

The three main trade unions – the so-called Triconfederale – are the Confederazione Generale del Lavoro (CGIL), the Confederazione Italiana dei Sindacati dei Lavoratori (CISL – a Catholic trade union) and the Unione Italiana dei Lavoratori (UIL – the trade union of social democrats and republicans). The most important employer's association is the Confindustria. They are all in a close relationship to a political party.

The Catholic Church as an interest group takes a special position by law: It has more privileges than other religious groups and is referred to on ethical questions. Therefore it plays a role in politics, e.g. it took a firm stance in the referendum on stem cell research in 2005 (Ullrich 2009: 683-688).

4.1.8 Direct democracy

What instruments of direct democracy are provided for by the constitution (e.g. plebiscite, popular initiative by a certain number of signatures, mandatory referendum in the case of

constitutional changes, petitions signed by a certain number of MPs/voters to be processed by Parliament) and have they been important until now?

The Italian Constitution provides the following instruments of direct democracy:

- referenda;
- petitions;
- people's legislative initiatives;

Of these three instruments, referenda are the most important ones. Within this category, there are "confirming referenda" – such as those on constitutional laws that have been passed by Parliament – and "abrogative referenda". The latter allow the Italian electorate to repeal a law in part or entirely, after the law's enactment. At least 100,000 signatures have to be collected to call for an abrogative referendum. Subsequently, the Constitutional Court decides if the petitions are admissible (a number of matters, such as the budget law, cannot be made the subject of an abrogative referendum). This instrument has been used extensively over the past three decades; in most cases, these referenda have failed due to a low turnout (indeed, a minimum of 50% of the Italian electorate have to cast their votes for such a referendum to be valid).

4.1.9 Political culture

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

Entire books – many of which are now deemed "classics" of political science – have been written on Italian political culture or the lack thereof. Among this list feature such classics as Gabriel Almond and Sidney Verba's (Almond and Verba 1963) studies on "political culture", as well as the more recent study by Putnam and colleagues on "civic tradition" (Putnam, Leonardi, and Nanetti 1994). While Almond and Verba have painted a fairly negative picture of Italian political culture in general, depicting it as being characterized by "parochialism", Putnam differentiated between an Italian North with a strong "civic tradition", and a South that he judges to lack such a tradition.

Identification of the people with the state is traditionally weak in Italy during the post-war period; parties (Communist and Christian Democrats) and the Catholic Church have been much more secure anchors for society. Voter participation was high, also because of the sharp polarisation between Catholics and Communists, but has been declining for years (Ullrich 2009: 688-690).

4.1.10 Science-society relations

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

According to Allansdottir "Italy has traditionally been characterized by a primarily technocratic approach to policy-making on science and technology, where decisions would be taken by civil servants in collaboration with scientific experts in the relevant field, and discussed in parliamentary committees before being put before Parliament and Senate. There is no strong tradition of technology assessment and the Italian Parliamentary Technology Assessment body has little room for public dialogue in their deliberations"[40] (Allansdottir 2010: 77). This view is also supported by an interviewee who considers the CNBB to be closest to a technology assessment organization in the Italian context (5: 269).

Glynn et al also paint a sobering picture of the effects of scientific advice on Italian policy making. They list a number of facts and observations which are liable to decrease the significance of scientific advice for policy making, such as the rather low percentage of Gross Domestic Product (GDP) spent on scientific research in comparison[41] with the rest of Europe, the lack of a specific Ministry of Science and Technology, the fact that science "does not have a relevant role in the politician's mind", and the low public interest in matters of scientific research. As a consequence the number of bodies of scientific advice is rather small, given the size of the country, devolved and "doesn't show a high degree of formalization" (Glynn et al 2003: 265). Important ministries have their own permanent committees, composed of experts directly appointed by the Minister. However, there is also a well-established tradition of calling experts into groups and committees within the cabinet, the Senate and the Chamber of Delegates (Glynn et al 2004: 265, Allansdottir et al 2011: 25).

Italian policy making in general is described in the literature as a "highly technocratic institutionalised approach" (Allansdottir/Veltri 2011: 25), although there is not one main TA institute like in other European countries. Instead, the policy process is often fragmented and supported by various expert bodies, which are appointed by diverse political bodies.

There is not a single centralized advisory body on science and technology in Italy, "procedures, mechanisms and structures depend and differ according to sector" (Allansdottir/Veltri 2011: 25). There is also "no real tradition of institutionalized Technology Assessment bodies as such in Italy" compared to other European countries (Allansdottir/Vitri 2011: 28).

[40] http://www.eptanetwork.org /EPTA/members.php?country=Italy, http://vast16.camera.it/

[41] In 2000 the Gross domestic expenditure on Research and Development (GERD) in % of the GDP in Italy was 1,05; in 2008 it was 1,18 in comparison to the EU average of 2008 of 1,89 (Allansdottir/Veltri 2011: 4).

Until recently, citizen participation does not appear to have been systematically promoted by the political system, although there are examples of uninvited and top-down public involvement in the political decision-making process, such as in areas of high speed trains, alternative energy and waste disposal (Allansdottir/Veltri 2011: 13 ff). Furthermore, the public interest in participation seems to be rising sharply according to a 2005 Eurobarometer survey (ibid. 13). The existing examples of public engagement – e.g. an abrogative national referendum on a law restrictive IVF law in 2005, which failed – are not close to being a normal part of the legislative process yet. Instead initiatives for public participation are promoted by civil organisations or NGOs (ibid. 21 ff.)

4.1.11 Constitutional division of territorial power

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

Italy's First Republic was characterized by a central state that was much more important than the regions. Over the past two decades, however, regions have become increasingly important. Indeed, "federalist reforms" were an important feature of the past two decades, and such reforms were not only discussed but also partly implemented. In the beginning, these were advocated in particular by the "Lega Nord" (Northern League), which originally emerged to promote this issue, sometimes not shying away from promoting it in fairly militant ways. Gradually, however, the issue cause of reforming towards a more federal distribution of powers and responsibilities was taken up by other political players and parties, and reforms that re-organized regional governments brought a "devolution" of issues and tasks from the central government to regional governments. These reforms were incremental in shape; however, the reform by the Constitutional Law 3/2011 – which is often referred to as "Titolo V" (Fifth Title) – was the most important step in this reform process. Cotta and Verzichelli (2007: 190-191) note that this law "redefined the distribution of powers between central state and local governments", in particular by strengthening the "political role of the regions". The matters that are now either entrusted exclusively to the regions, or where the state and the region share powers and responsibilities (with the stage enacting "leggi quadro" that define the fundamental principles implemented by the regions with ordinary laws) have grown and include matters such as energy and health.

4.1.12 Electoral system

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

In the last 20 years two major changes took place on behalf of the Italian electoral system: In 1993, during the transition to the Second Republic, a new electoral law was passed which inaugurated a mix of a majority voting system (for 75% of the seats in parliament) and a

proportional representation (24% of seats). Until then, there had been a pure proportional representation system in place which, because of the fragmented and polarised party system, led to unstable political conditions.

In 2005, the second Berlusconi cabinet introduced a proportional representation system with a majority bonus. It is based on a block voting system where only parties or lists with more than 4% of the votes enter parliament. However, it is possible to avoid this threshold by forming a coalition with other parties/lists. Therefore even very small groups are courted by the major parties. A coalition has to have at least 10% of votes and at least one list with more than 2%. Coalitions have to be announced in advance and seats are divided as follows: The party or coalition with relative majority receives at least 55% of seats, while the remaining 45% of seats are distributed proportionally among the other parties or coalitions.

Because of the dissimilar system of allocating the majority bonus in the two houses – in the Chamber the nationwide votes are counted, in the Senate the votes on regional level – different majorities in the Senate and Chamber of Deputies are possible.

Thus even candidates of very small parties and lists have a chance to become a member of parliament or even the governmental cabinet. They only need 2% of votes if they form a coalition with (bigger) parties (Ullrich 2009: 660-669).

4.2 Policy Field Italy

The way that matters involving science, politics, and the life sciences have been dealt with in Italy was and still is highly issue-specific. Some matters, such as GMOs, IVF technologies and stem cell research have attracted a lot of attention and were presented as moral issues. Other matters that have caused controversy in other European countries, however, neither emerged as controversial issues nor as moral ones. This implies that it is not possible to describe general patterns in a policy-field of bio-medicine or red biotechnology. This does not seem to exist in Italy *per se*. Rather, the institutions that shape policy-making, as well as those deemed responsible for making decisions, differ from issue to issue.

In this context, silence on one particular issue seems important. Indeed, whereas in countries such as the United Kingdom, as well as on the scale of the European Union, a narrative has emerged over the past decade that deems investments in the life sciences an important strategy for the generation of wealth and health, such a “bio-economic” narrative has not emerged on a national scale in Italy. This does not imply that no research takes place in Italy, or that no bio-medical innovations circulate; yet, these are not ordered in a centrally-oriented or coherent way, but in a fragmented way where responsibilities are shared by a multiplicity of actors, and which is characterized not only by decision-making but also by non-decision-making.

4.2.1 Cabinets, Legislature, and their relationship, buraucracy.

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

Please see below, 4.3.3

4.2.2 Legislature

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

Please see below, 4.3.3

4.2.3 Executive-legislative relationship

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

With the exception of GMOs, where individual ministers had a prominent role, cabinets are not very important in the handling of matters at the intersection of the life-sciences and politics. Italian Parliament had a prominent role in the regulating of all those matters that were highly moralized – such as IVF. However, decisions are not taken along party lines. Parliament had no role in those matters that were framed as more scientific or technical in kind (such as xenotransplantation). There is no history of adversarial relations between the executive and the legislative in the ordering of the life-sciences.

4.2.4 Bureaucracy

Are there specific units which have dealt with the policy problem at hand? Is there any cooperation with other political actors?

Italy has an extensive list of historically-grown bodies that oversee and produce information on research- and health-related issues. This implies that the production of knowledge and the regulation of such issues are often fairly fragmented.

4.2.5 Judicial review

What is the tradition of law (Common/Roman), and are the courts important for the policy field?

Courts did have a role in highly moralized issues. For instance, in the case of IVF technologies carriers, of genetic conditions that had become a blind spot when Parliament enacted the law that governed IVF and embryo research in 2004, used courts and the institution of constitutional review to make themselves heard. However, they had no role in matters that were deemed to be more technical (such as xenotransplantation).

4.2.6 Party system

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

In general, parties are not very powerful players in these policy fields. For instance, most parties have been reluctant to take a stance on controversial bio-medical issues; and debates and voting patterns on bio-medical issues have not followed party lines.

4.2.7 Interest group system

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

With the exception of the Catholic Church, particular interest groups did not hold a prominent place in these debates. Most often, they did not speak with a coherent voice.

4.2.8 Political culture

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

In Italy, "participation" in politics and processes of decision-making is highly issue-dependent. However, if we restrict the scope of the answer to the issue at hand and similar ones (and hence to issues at the intersection of society, politics, and bio-medicine), a pattern seems to emerge. Indeed, in contrast to, for instance, the United Kingdom, Italian policy makers do not generally seek to give citizens or "publics" a say. Instead, they tend to rely on expert knowledge. As a consequence, participation is not the result of "top-down" processes, but of "bottom-up" processes, in which enraged citizens and uninvited "publics" try to have their say in processes from which they tend to be excluded (see also Allansdottir/Veltri 2011). Hence, decision-making processes tend to be fairly closed, and yet contested by citizens who draw upon either institutionalized "entrance points", such as abrogative referenda or constitutional review, to make themselves heard (as, for instance, in the case of IVF technologies and hESC research). The latter instance also shows that the "enraged citizens" tend to number researchers and scientists, who, over the past decade, have also drawn upon less-institutionalized methods of participation and engagement to render their

marginalized research visible, for instance by opening up their laboratories in “nights of science”.

4.2.9 Science-society relations

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

In the area of biotechnology there are a high number of different bodies. Among other committees, there are the CNB, the CNBB and the CSS. As Glynn et al (2003: 268, 273) observe “the coordination between these different bodies is quite low, and there is the suspicion that such a fragmented structure can have significant consequences on the impact of advice issued. Faced with different pieces of advice, in fact, there’s a strong temptation for the decision-maker simply to pick up the one that is more in line with his political preferences”.

4.2.10 Direct democracy

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

Please see above, 4.3.8.

4.2.11 Constitutional division of territorial power

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

In Italy, constitutional reforms that delegated to the respective regions issues previously controlled by the central state, rate among the institutional innovations of the past two decades. Next to the European Union, whose Framework Programmes have become an important source of funding, regions are an important reality for life-scientists in Italy.

4.2.12 Demand for xenotransplantation

Are there interests asking for xenotransplantation (scientists, pharmaceutical industry, patient organizations etc.)?

No.

4.2.13 State-EU policy relationship

How do EU policies enter and affect the political system ("download of policies")? How do national policy initiatives enter and affect the EU ("upload of policies")?

Policies of the European Union are very important in Italy. Indeed, a considerable portion of existing regulations are the result of the implementation of European policies.

Authors: Erich Griessler, Alexander Lang, Ingrid Metzler, Vera Truttmann

Title: Xenotransplantation Policies: Italy and The Holy See

Reihe Soziologie / Sociological Series 103

Editor: Beate Littig
Associate Editor: Andrea Haslinger

ISSN: 1605-8011
© 2012 by the Department of Sociology, Institute for Advanced Studies (IHS),
Stumpergasse 56, A-1060 Vienna • ☎ +43 1 59991-0 • Fax +43 1 59991-555 • http://www.ihs.ac.at

ISSN: 1605-8011