Policy impacts of ethical advisory bodies on the societal regulation of biotechnology

Franc Mali, Toni Pustovrh, Blanka Groboljsek

University of Ljubljana, Faculty of Social Sciences, Kardeljeva pl. 5, 1000 Ljubljana, Slovenia

Introduction

The main aim of our contribution is to provide a preliminary overview of institutional expert advice on ethics in a selected group of European countries. Given the complexity of the topic, the emphasis will be on to the ethical issues of biotechnology. Presently, we can observe a lack of more empirically oriented analyses concerning the role of expert advice in the governance of ethically contentious issues in new and emerging sciences and technologies such as biotechnology, nanotechnology, etc. In policy theories and practices, there have been a lot of discussions on how to organize and use expert knowledge in policymaking processes. The classic technocratic ideal of good political decision-making was the government of experts.[1] The opposite of the classic model is decisionism. In this model, decision-making is assumed to be the true responsibility of the political system, which itself creates the normativity involved (Grunwald 2004; Lagerspetz 2008; Weingart 1999). In modern political democracies, experts or politicians cannot represent the ultimate decision-making authority. The positivistic separation between experts and laymen (facts and values) or the voluntaristic separation between citizens and politicians have both been shown to be outdated.[2] In order to keep political sensitivities at bay, a narrow technocratic or decisionist approach, where decisions are made without the participation of citizens, is not enough. This is especially true in cases of contentious ethical issues in the new and emerging technologies. Thus, the need to develop "hybrid forums" (Callon et al. 2009, 34) where experts, politicians and ordinary citizens come together and create new forms for the social regulation of science and technology, has emerged in the new type of democracies. This is the great challenge for all European democracies that was recently raised in regard to the participation of the civil society and other stakeholders in science and technology policymaking.

The starting assumption of our contribution will be that rapid progress in the new and emerging technologies creates genuinely new demands on the current use of expertise in science and technology policy decision-making, as modern societies are being confronted with an increasing number of ethically contentious issues that arise from scientific and technological development. A representative case of this can be observed in converging technologies (CT).[3] On the one hand, CT and their applications carry great potentials for innovation and manipulation of the natural world, while on the other, they carry great risks that might extend from threats to health, safety and societal stability, all the way to global

catastrophic risks. The potentials of CT to inflict serious damage to human well-being on a global scale due to unintended consequences and dual use as weapons are realistic.

The emphasis of our contribution will be on providing the results of a first preliminary overview of ethics advisory bodies (EABs) that offer policy recommendations to political actors. The main research question will examine whether the national ethics committees (NECs) that were established in most European countries during the last two decades have dealt with any of the themes arising from the tremendous progress of CT and human enhancement technologies (HET)[4] and whether these committees have performed any type of public participation events. The results of our analysis presented in this contribution are part of the research performed in the context of the 7th FP project entitled Ethics in public POlicy-making: the Case of Human enhancement (EPOCH). The overarching aim of EPOCH is to provide better insight into the role of ethics, and ethical expertise in particular, in the formation of EU policies on science and technology. It will also provide guidance regarding the development of European public policies on the topic of 'human enhancement' and, more broadly, on the governance of contentious normative issues in S&T.

The institutional proliferation of expert advice on ethics in the selected group of European countries

In the first stage of our analysis, we examined the institutional proliferation of expert advice on ethics in 32 European countries, more specifically in all 27 EU Member States and in 5 non-EU Member countries (Croatia, Iceland, Norway, Serbia, Switzerland). Based on an extensive review of websites and other relevant sources, we identified the official NECs in most of the selected countries, and in countries where no such institutions could be identified, we selected other national EABs that are most similar to NECs in structure and function. Additionally, we have included the European Group on Ethics in Science and New Technologies (EGE) in our preliminary review. The EGE is a trans-European ethics committee that was established in 1998 as an independent, pluralistic and interdisciplinary transnational body, which advises the European Commission on various ethical implications of scientific and technological progress.

Of the 32 selected countries, 16 countries have been included in our analysis and categorization. The list of included and excluded countries is given in Table 1, which also lists reasons why the other half of the selected countries was excluded: no website, no available documents, no thematically relevant documents, etc. Most of the excluded countries belong to the group of East European post-communist countries, and it seems that more developed ethics advisory mechanisms tend to be linked with West-European countries that have a longer tradition of democratic political order. In the old communist regimes, the

politics were to larger extent based on utopian communist ideology rather than on expert knowledge. There predominated an absence of political concepts, defined by Karl R. Popper as "piecemeal social engineering" (Popper 1997, 16).

Table 1: Country sample after survey: included and excluded countries

INCLUDED COUNTRIES	
Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom	
EXCLUDED COUNTRIES	
Reason for exclusion	**Country**
Closed	Ireland
No website	Bulgaria, Latvia, Malta, Romania, Serbia, Slovakia
No documents	Czech Republic, Croatia, Estonia
No documents in German or English	Hungary, Luxembourg, Poland
No thematically relevant documents	Iceland, Lithuania, Slovenia

NEC opinion documents on the ethical, legal and societal implications (ELSI) of the new and emerging technologies

In the second stage of our analysis, we conducted a survey of all available NECs and EABs websites, and of all the documents in English and German that are accessible on these websites. We then constructed a thematic classification of all opinion documents and public participatory events that address various ELSI issues of CT and HET. Clustering the overlapping themes from the opinion documents and participatory events, we established a classification scheme with 30 categories of technological applications, to which we assigned individual countries and the EGE, depending on whether or not they had produced documents or organized events dealing with the technological application category in question. The basic results of this classification show that the common feature of almost all the categories constructed from the topic analysis of the NECs' documents is that they include a biotechnological component, which means that they either incorporate insights or components from biological systems, or are directly applied to plants, animals or humans. Practically all technology categories can also be seen as drawing their enabling knowledge and components from the domain of the NBIC CT (for example, biomedicine, cybernetic implants, genetic testing and modifications, nanotechnology and nanomedicine). The concept of CT is not explicitly mentioned, though six countries have produced documents on human enhancement, showing that it is becoming a topic of growing salience. The categories for which the largest number of countries have produced opinions are Human biomaterial banking and use (11), Personal genetic testing (12), Prenatal and preimplantation diagnosis

(13), both combined Stem cells categories (7+9), Reproductive technologies (10) and also Human cloning (9).

We also investigated if the EGE acts as an agenda-setting leader for other NEC and EAB, by examining whether it published opinion documents on selected themes first or whether one of the other EAB published them first, since the EGE should in some way assist in building a more open and effective discussions about contentious ethical issues in the new and emerging technologies. In the period from 2000 to 2010, the EGE produced opinions on 15 of the 30 categories of technological applications. We focused our attention on 4 biotechnological categories that represent applications which have stirred up considerable debate because of their potential ELSI ramifications. Two of them, Genetic testing for insurance and employment and Prenatal and pre-implantation diagnosis, already have applications in commercial use, while the other two, Human cloning and Human genetic modifications, are still in the experimental stages. As is evident from Table 2, the EGE was the first to produce opinion documents in three of the four categories, and was second to the UK NEC in the category on Genetic testing for insurance and employment. The EGE can thus be seen as anticipating the technological developments that bring major innovation potentials and ELSI ramifications ahead of national ethics bodies.

Table 2: Temporal succession of opinions by EGE and NEC in selected categories

Genetic testing for insurance and employment					
UK	EGE	Swe	Cypr	Gre	Ita
1993	2003	2003	2008	2008	2008

Prenatal and preimplantation diagnosis												
EGE	Neth	Fra	Den	Aus	Swe	Switz	Cypr	Gre	Por	Bel	Ger	Nor
1996	2001	2002	2003	2004	2004	2005	2006	2007	2007	2009	2010	2010

Human cloning								
EGE	Bel	Den	Aus	Fra	Gre	Switz	Fin	Por
1997	1999	2001	2003	2003	2003	2003	2005	2006

Human genetic modification				
EGE	Neth	Swe	UK	Fra
1994	2001	2002	2002	2003

The prescriptive and descriptive type of NEC policy recommendation

In the third stage of our analysis, we performed a content analysis of opinions produced by NEC, focusing on whether these documents contain any recommendations or prescriptions

regarding individual or institutional actions on policy (prescriptive documents) or whether they only describe the current state of affairs without giving any advice on policy (descriptive documents). In cases of prescriptive documents, we further distinguished between self-regulation advice for individuals or institutions (self-regulation), and calls for governmental regulatory measures (regulatory measures). For the content analysis, we selected the category of Personal genetic testing, as a field of new and emerging applications that are already both in institutional medical and for-profit commercial use (for example, the privately owned company 23andMe offers testing of genetic risk for 170 diseases and conditions), and as a category that has also opened up numerous ethical dilemmas, ranging from predictive reliability to psychological effects on users upon receiving unfavorable results.

The results of our content analysis show NEC in 12 countries (Austria, Belgium, Cyprus, Denmark, Finland, France, Greece, Italy, Netherlands, Portugal, Sweden, UK) have produced opinion documents on Personal genetic testing, but two of them (Denmark and Netherlands) provide only summaries that do not give indications as to their specific recommendations. Of the ten remaining documents, all were of a prescriptive nature, offering NEC advice on measures that should be undertaken in regard to personal genetic testing. Four NEC (Austria, Greece, Italy, UK) give prescriptive recommendations for self-regulation, one (Cyprus) gives prescriptive recommendations for self-regulation and regulatory measures, four (Finland, France, Portugal and Sweden) give prescriptive recommendations for regulatory measures, and one (Belgium) documents a split between its members, with one group recommending self-regulation and one recommending regulatory measures.

The inclusion of the lay public into the expert advisory processes

In the fourth and final stage of our analysis, we examined the mechanisms of NEC for including the public in expert advisory work and policy decision-making by surveying and identifying the key documents produced in the period between 2000 and 2010. We determined the activities and mechanisms intended to reach out to the broad public (publications, discussions and meetings open to the public, organization of events) in order to explore whether they suggest any specific public participatory method and to identify whether the individual NEC practice more active or passive public involvement. The results show that NECs use different practices and forms of public involvement, although involvement in the phase of forming the opinions and recommendations were uncommon. The use of consultation papers in the process of opinion forming in UK Nuffield Council on Bioethics is a rare exception. In the Netherlands, the committee recommends that decision-making on certain issues (for example nanotechnology) requires a diverse committee specifically appointed for that purpose and composed of independent scientific experts as

well as stakeholders and representatives of the general public. Another rare example is the German ethical council and its “open to the public” meetings, meaning that interested persons can attend and gain an insight into the Council’s approach to topics and discussion process. The public meetings provide insight into the work of the Council and increase transparency. Another specific feature of the German NEC is that according to the founding act, the council shall hold at least one public event per year. Activities that attract publicity and media attention are otherwise common amongst EU NEC, taking the form of annual seminars, conferences, press releases and educational events.

Our conclusion is that NECs obviously recognize the importance of public involvement in contentious science and technology issues, however it remains unclear how to realize this in practice. Based on the gathered data on the participatory functioning of NECs in the selected group of European countries, we observe no radical shift towards a more democratic involvement of citizens in European expert advisory structures. They are still organized as pure expert bodies without any kind of public involvement and transparency concerning their proceedings.

Notes

1. An expert is someone who masters skills with recognized (indeed, certified) competence, and which he calls upon (either on his own initiative or in response to a request addressed to him) in a decision-making process (Callon et al. 2009, 228).
2. Both practices suffer from deficiencies and dilemmas of legitimization. As the German sociologist of science Peter Weingart observes: »Beide Modelle zusammengenommen stellen die beiden Seiten des Legitimationsdilemmas dar, in dem sich Politiker und ihre Experten in den modernen massendemokratien befinden: Dezisionistische Entscheidungen leiden tendenziell unter einem Legitimationsdefizit aufgrund der ihnen inhaerenten Rationalitaetsluecke. Technokratische Entscheidungen leiden tendenziell unter einem Legitimationsdefizit aufgrund des Mangles oeffentlicher Zustimmung.« (Weingart 2001, 137).
3. At the beginning of the 21st century, converging technologies have been defined by US experts as innovative technologies that are emerging from the synergistic combinations among the four major “NBIC” (nano-bio-info-cogno) domains: (a) nanoscience and nanotechnology; (b) biotechnology and biomedicine, including genetic engineering; (c) information technology, including advanced computing and communications; and (d) cognitive science, including cognitive neuroscience (Roco and Bainbridge 2003, ix).

4. During the last decade, the concept of human enhancement, i.e. the idea that human capabilities can be extended beyond the existing reference values through direct technological interventions into the human body and brain, has increasingly become a topic of intense debate and controversy in some scientific and academic circles and specific issues are now entering public debate (Savulescu et al. 2011).

Bibliography

Callon, Michel, Pierre Lascoumes and Yannick Barthe (2009), *Acting in an Uncertain World*, Cambridge and London: The MIT Press.

Grunwald, Armin (2004), "The normative basis of (health) technology assessment and the role of ethical expertise", *Poiesis and Praxis* 2: 175–193.

Lagerspetz, Eerik (2008), "Ethical Expertise in Democratic Societies", in Lanus, Veikko and Juha Raeikka (Eds.), *Genetic Democracy: Philosophical Perspectives*, Springer Science + Business Media, 21–29.

Popper, Karl R. (1997), *The Poverty of Historicism*, London and New York: Routledge & Kegan Paul.

Roco, Mihail C. and William Sims Bainbridge (Eds.) (2003), *Converging Technologies for Improving Human Performance: Nanotechnology, Biotechnology, Information Technology and Cognitive Science*, Dordrecht: Springer.

Savulescu, Julian, Ruud ter Meulen and Guy Kahane (Eds.) (2011), *Enhancing Human Capacities*, Wiley-Blackwell.

Weingart, Peter (1999) "Scientific expertise and political accountability: paradoxes of science and politics", *Science and Public Policy* (26) 3: 151–161.

Weingart, Peter (2001), *Die Stunde der Wahrheit? Zum Verhaeltnis der Wissenschaft zu Politik, Wirtschaft und Medien in der Wissensgesellschaft*, Velbrueck Wissenschaft, Weilerwist.