ETICA Project
(GA number 230318)

Deliverable D.3.2.2
Annex I

Reconstructing European Ethics

How does a Technology become an Ethical Issue at the Level of the EU?

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1 Introduction[1]

As part of Task 3.2 of work package 3 (WP3), we will address the question of what kind of information and communication technologies (ICTs) are likely to raise concerns according to the standards documented in ethical reviews, opinions, and advisory reports at the European level.

The evaluation and ranking of the ICTs will concentrate on two questions:

How likely is it that a new or emerging ICT will be discussed as an ethical issue on the EU level?

And if so, how high is the level of controversy in comparison to the other ICTs discussed?

Taking the *Charter of the Fundamental Rights of the European Union*, the documented ethical standards of 7th Framework Programme (FP7) and the Opinions of the European Ethics Group (EGE) as a starting point, we will map out the core values and principles of an „Ethics of European Institutions", on which we will base our evaluation and ranking.

Since the normative-issues matrix in WP2 is built on the academic research, this approach might also be beneficial in bringing forward the areas of agreement and disagreement between Ethics as an academic discipline and the way ethics is framed on the EU level. This does not imply that there is no connection between these two levels, as we demonstrate later on (Chapt. 3).

Therefore, we will examine how ethical issues of Information and Communication Technologies (ICTs) emerge on the political agenda. It seems legitimate to take into account the whole policy field of ethics and ICT in the EU, including the academic community, economic pressure groups and advocacy groups (e. g., the hacker community), in short, everybody, who is voicing an opinion in some organised form. We will also provide a model of how to bring together these different levels of "ethics" and take these thoughts into account in the final ranking.

Finally, a list of issues, questions, and examples of value conflicts is presented which has been used during the evaluation process.

2 Ethics and ICT at the European level

2.1 The Charter of Fundamental Rights of the European Union

Since the European Community moved from a mere economic community to a political Union, it is often referred to as „a community of values"[2]. In our endeavor to

[1] Please note that the first version of this report has been written in March and April 2010. Since this time some of the key concepts of the ETICA project have been renamed. For example, "(meta-) vignettes" are now called "descriptions of technologies" (October 2010). We have re-edited this document for publication, but we do not want to rule out that some of the old terminology may still be found in the text. Also, some ideas sketched out in this annex may not been fully realised in Task 3.2 due to budget constraints.

find a scale that can measure the likelihood of new ICTs becoming an ethical issue in the political realm of the European Union, we need to have an idea of these common values that guide European Union policies, especially in the science sphere. Since the *5th Framework Programme* (1998-2002), e.g., the European Union incorporated as a precondition in its funding process the adherence to and observation of „fundamental ethical principles“.[3]

The „fundamental ethical principles of the European Union“ – as the name already suggests – are valid in the whole of the European Union. As we will demonstrate, the *Charter of the Fundamental Rights of the European Union* has become the key document in this regards. Especially with the *Charter* becoming effective in December 2009, they are now even judicially binding.[4] It seems to be very unlikely that there will be major changes being made in the *EU Charter on the Fundamental Rights* within the next 10-15 years, the time span that the ETICA project is dealing with. Therefore, the formal acknowledgement of the *Charta* is helpful for our task to predict future ethical assessment.

The *EU Charter* assembles for the first time the basic rights of the citizens of the European Union's member states. In the first few paragraphs, the *EU-Charter* sets out what can be viewed as the core values of the EU: **Human dignity**, **freedom**, **democracy**, **equality**, **the rule of law** and the **respect for human rights.**

In addition, there is one aspect of the Charter that is especially relevant in our context. And already the *General Report 1998-2000* of the European Group on Ethics in Science and New Technologies (EGE) stated that the *EU-Charter* „...is (...) unique, since it is the first international instrument of a general nature dealing with Human Rights which makes specific reference to bioethics and infoethics.“[5]

This is apparent in Article 3 (2) and Article 8 of the *Charter*:

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[2] Cf. Preamble of the Charter of Fundamental Rights of the European Union (2000/C 364/01): „The peoples of Europe, in creating an ever closer union among them, are resolved to share a peaceful future based on common values. … the Union is founded on the indivisible, universal values of human dignity, freedom, equality and solidarity; … .“ – The General Report 2005-2010 of the EGE also states: „In his first speech after his nomination on 19 November 2009, Council President Van Rompuy advocated that 'Europe is a community of values'; and Commission President Barroso indicated to the European Parliament: ‚My political guidelines for the Commission's next mandate stress the idea that Europe's actions must be based on its values' (President Barroso, European values in the new global governance, 14 October 2009).“ (EGE 2010, p. 19)

[3] Decision No 182/1999/EC of the European Parliament and of the Council of 22 December 1998 concerning the fifth framework programme of the European Community for research, technological development and demonstration activities (1998 to 2002), Article 7: „All research activities conducted pursuant to the fifth framework programme shall be carried out in compliance with fundamental ethical principles, including animal welfare requirements, in conformity with Community law.“

[4] The EU-Charter of Fundamental Rights became effective together with the Treaty of Lisbon, but, contrary to the envisioned but failed EU-Constitution, where fundamental rights were a part of the Treaty, the new EU-Charter of Fundamental Rights and the Lisbon Treaty are only connected by Title VII of the Charter and Article 6 of the Lisbon Treaty. Furthermore, in an attached Protocol to the Lisbon Treaty, Poland, Great Britain and the Czech Republic have opt-outs from the Charter.

[5] EGE (2000b), p. iii. (Introduction by Noelle Lenoir, President of the EGE)

Article 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.

2. In the fields of medicine and biology, the following must be respected in particular:

- the free and informed consent of the person concerned, according to the procedures laid down by law,
- the prohibition of eugenic practices, in particular those aiming at the selection of persons,
- the prohibition on making the human body and its parts as such a source of financial gain,
- the prohibition of the reproductive cloning of human beings.

Article 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.

2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.

3. Compliance with these rules shall be subject to control by an independent authority.

Furthermore, in Article 51 of the *Charter* its scope is clearly defined as follows:

> The provisions of this Charter are addressed to the institutions and bodies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers.

While we will show in the following that the *EU Charter of Fundamental Rights* is to be regarded as the key document for understanding the „fundamental ethical principles of the European Union", it is also important to point out that its scope is limited by Article 51. Therefore, the „fundamental ethical principles of the European Union" are to be regarded as the foundation of an "Ethics of the European Institutions" and may not be confused with a "European Ethics", in the sense of common moral principles and/or values shared by all citizens of the European Member States. We assume that this is in general terms congruent with the values shared by the people of the European Union.[6] Since the final ranking of the technologies will include the insights from the perspectives of New Member States (Task 3.3) and Gender (Task 3.4), the focus of the "Ethics of the European Institutions" will be balanced by more people-oriented approaches in the final discussion of the ranking. Furthermore, it has to be pointed out that the "Ethics of the

[6] Spring Standard Eurobarometer 693 explored if there is a base of common values shared across the EU and if so, tried to identify such values. The public perception survey was then published in July 2008. For Europeans, human rights, peace and democracy are the main values in Europe. This standard Eurobarometer was carried out between 25 March and 4 May 2008 in 31 countries or territories: the 27 Member States of the European Union, the three candidate countries (Croatia, the Former Yugoslav Republic of Macedonia and Turkey) and the Turkish Cypriot Community. According to data from the above Eurobarometer, 54 % of respondents think that, in terms of shared values, the EU Member States are close to each other. Cf. http://ec.europa.eu/public_opinion/index_en.htm, last access: April 30, 2010.

European Institutions" are also shaped by different actors within society (including NGOs etc.). This will become obvious in the following (cf. Chapt 3).

2.2 Ethics in the 7th Framework Programme

Concentrating more on the ethics of the European Institutions regarding science, we will start by taking a closer look at the 7th Framework Programme (FP7).

The FP7 was announced in 2006 by the *Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)*. There it is stated that „Research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union. The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account."[7] In Article 6 of the *Decision*, this ethical imperative is further specified towards the research process: „All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles."[8]

In an additional *Regulation*[9] laying down the rules for the participation, Article 15 specifies that „a proposal which contravenes fundamental ethical principles (…) shall not be selected. Such a proposal may be excluded from the evaluation, selection and award procedures at any time."

The applicants must describe in their proposals „the ethical, safety and socio-economic issues by the research proposed" (Pauwels 2007, p. 16). They are guided in this by a list of ethical questions. This „ethics check list" asks for reflecting on the main ethical dilemmas that arise in research, among them questions dealing with **informed consent**, **privacy** and **dual use**.[10]

Projects that touch on especially sensitive ethical issues[11] are reviewed by „Ethics Review Panels", composed of experts from different disciplines (e.g., law, sociology, philosophy, medicine, information technology) and different member countries (looking at the numbers for FP6, with a striking majority coming from Germany, France and the UK). (Pauwels 2007, p. 14)

In addition to the above mentioned checklist, there is specific information provided on „Ethics related to undertaking ICT research in FP7"[12], including a list of the main legislation and regulation in the European Union concerned with Ethics in ICT-

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[7] Decision No 1982/2006/EC, L-412/4

[8] Ibid.

[9] Regulation (EC) No 1906/2006 of the European Parliament and of the Council of 18 December 2006.

[10] cf. check list in Annex 2. The Commission also published a handbook (Pauwels 2007).

[11] Listed are research interventions on human beings, the use of embryonic stem cells, and the use of non-human primates. (cf. Pauwels 2007, p. 16) In FP6, 8% of all project proposals who were subject to an ethical review by an external panel were ICT projects. The total number of projects that underwent an ethical review was 885 (11% of all FP6 projects). (EGE 2007b, p. 17)

[12] Online: http://cordis.europa.eu/fp7/ethics-ict_en.html, last access: April 30, 2010.

Research (EU-Charter, Directive 95/96/EC on data protection, European Convention on Human Rights, Directive 90/385/EEC and the relevant Articles in Decision 1982/2006/EC) and links to other documents and institutions worldwide dealing with Ethics and ICT. The idea is to provide researchers with sources and experts, to identify ethical issues that might emerge with their technology and/or during their research. In this list, the EGE is named first place for ICT ethics resources, and especially Opinions No. 10, 13, 20 and 21 are highlighted.[13]

Provided also is a „Guide for Applicants - Information and Communication Technologies ICT" in which Annex 5 exemplifies in what ways the questions of the above mentioned check-list can be translated into ICT research. The Annex highlights especially implications for **privacy** and **autonomy** of ICT research and advocates the „(...) identification of precautionary actions proportional to the potential risk/harm," as „new dangers associated with the process of ICT research can exist".[14]The use of animals in ICT research is also addressed and specific guidance in some current sensitive areas such as **ICT implants** and **eHealth (especially with regards to genetics)** are presented.

Hence, within the documents on the FP7 programme **autonomy** (e.g., informed consent), **privacy**, and **dual use** are presented as the major ethical issues of new ICTs. Also, ICT implants and genetic information are highlighted in these documents.

We can conclude that ethics plays a significant role in the FP7, as violations of the above mentioned principles and rules could lead to the denial of grants. Janez Potočnik, European Commissioner for Science and Research, even states: „Ethics must be given the highest priority in EU funded research. It is an integral part of research, from conception to publication. Ethics permeates every area of research and it is only by getting the ethics right that research excellence can be achieved." (Pauwels 2007, p. 5)

Yet, it has to be noted that Ethics in FP7 concentrates on the research process. Control mechanisms are not in force when it comes to the products of research or possible ethical implications of their use, misuse or unintended consequences of mass use. (Stahl et al 2009, p. 7)[15] But there are several research programmes *within* the FP7 programme (and already in the previous Framework Programms), dealing primarily with ethical questions of ICT. ETICA is just one example.[16]

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[13] Our analysis will be focusing on the Opinions 13, 20 and 21. Opinion No. 10 does address general issues in the 5th Framework Programme and does include some references to topics relevant for ICTs. However, the parts relevant for our subject are rather short. E.g., at 2.9 the "principle of individual autonomy (entailing … respect for privacy and particularly the confidentiality of personal data)" is mentioned as one of the "fundamental ethical principle". But since the other three opinions are much more detailed with regards to the ethical evaluation of ICTs, it is reasonable to focus on the later opinions.

[14] Annex 5: Ethical Guidelines for undertaking ICT research in FP7, in: Guide for Applicants - Information and Communication Technologies ICT, p.1. – Cf. http://cordis.europa.eu/fp7/ict/participating/home_en.html, last access: April 30, 2010.

[15] Cf. the recommendation given EGE Opinion No. 10 concerning the 5th framework Programme concerning the ethical assessment of research projects on three levels. (EGE 1997, p.:5) This statement was not changed by EGE Opinion No.22.

[16] For a list of projects cf. Annex 3.

Therefore, if ethical research has been carried out on a specific ICT within the FP7 program (including ethical subproject within more technological oriented research projects), it can be taken as an indicator for an increased likelihood for emerging ethical issues in connection with the ICT in question.

But there is another institution in the European Union, which takes a closer look at ethical issues in Science and new Technologies beyond the research process and outside of the Framework Programme with the programmatic title „European Group on Ethics in Science and New Technologies" (EGE). As noted earlier, it is linked to the FP7 in the "Rules for submission of proposals, and the related evaluation, selection and award procedures" (Version 3, 21 August 2008; COM(2008)4617)[17] in a way that the "opinions of the European Group on Ethics in Science and New technologies are and will be taken into account" within the "Ethical Review Procedures" (Annex A, p. 26).

Unlike other forms of ethical evaluation of new technologies (e.g., research carried out within the framework programme) therefore it has to be taken into account that the EGE Opinions are part of the FP regulatory framework.

Therefore, if a technology has already been subject of an EGE Opinion, further research on this technology (or similar technologies) has to be seen as a strong indicator for an increased likelihood of emerging ethical issues.

As ICT is heavily funded within FP7 over the next couple of years[18], and, regarding the mandate and the past work of the EGE, it seems reasonable to forecast that ethical issues of ICT will be further dealt with by EGE either by proposal of the EC or on its own initiative.

Since we focus on the question of how emerging ICTs may become an "ethical issue" at the European level, there is no need to claim that the EGE is the only body that is able to deal with these issues in an appropriate way. In analyzing how a new technology might become the subject of an EGE opinion we even do not have to assume that the EGE will not be replaced by another body. But we do have to recognize that in the current setting, delegating major ethical issues to the EGE is the standard procedure for issues identified as "major ethical challenges" in the sciences and humanities at the European level. Hence, our analysis of the EGE is not so much about the Group itself, but about the kind of issues that are delegated to the Group.

2.3 The European Ethics Group (EGE)

Before we take a closer look at the EGE Opinions so far dealing with ICT, we will give a short introduction into the organisation of the EGE, name the core documents the EGE itself is referring to, and outline their general understanding of the core values of the European institutions. This will give us important insights into their way of argumentation and taken that

[17] Cf. ftp://ftp.cordis.europa.eu/pub/fp7/docs/fp7-evrules_en.pdf, last access: April 30, 2010.

[18] „ICT research: EU invests €500 million in Future and Emerging Technologies (FET) to improve people's lives", MEMO 10/140, 4/20/2010. – Online: http://cordis.europa.eu/fp7/ict/programme/fet_en.html, last access: April 30, 2010.

a) this is one of the prominent bodies, where ethical issues of ICT in the EU will be dealt with, and

b) it is valid to extrapolate from past developments to future developments,

it will help us to rank the likelihood of ethical discussion of the discussed ICT.

2.3.1 The EGE 1991-2010

The EGE is a group of fifteen experts, appointed by the European Commission, to deliver opinions on new developments in Science and Technology. The Group is an independent body, and it can deliver opinions either on request by the European Commission, or by its own initiative. According to its current mandate[19], the group should organize Round Tables and expert talks and strengthen the ties with National Ethics Committees. Their opinions and statements should inform the formulation of the EGE's Opinions.

In 1991, a mandate of the European Commission established the Group under the name of „Group of advisers to the European Commission on the ethical implications of biotechnology (GAEIB)". During its mandate, it already grew in size from initially six to later nine members.

In the second mandate 1998 to 2000, the GAEIB was given its new name „European Group on Ethics in Science and New Technologies (EGE)". This was in light of the fast developments in Information and Communication Technology and the felt need that there as well, ethical issues need to be considered and discussed. The number of experts of the Group rose from 9 to then 12 members. The right to request an Opinion by the EGE was expanded to the European Parliament and the Council of Ministers.[20]

The third mandate 2000-2005 broadened in its duration of the term, which is now four instead of three years. And finally 2005-2010, again the number of experts rose from 12 to now 15 members in the Group.

During the mandate of the GAEIB the experts appointed to the Group were drawn from bioethics, genetics, moral philosophy and law. With the change of focus to include Information Technology since 1998, the Group includes now as well experts on Information Technology and Data Protection.

The constant enlargement of the Group seems to be for two reasons: first, the enlargement of the EU made it appropriate to enlarge EU-institutions accordingly. Second, the broadening of the topics to be considered made it reasonable to include more experts from different fields. Although it seems that there still is a heavy majority of bioethics and genetics experts, also visible in the thematic spectrum of the Opinions (cf. chapter 2.3.4 in this paper).

2.3.2 Facts and Figures

Between 1991 and 2010, 25 Opinions have been issued, approx. two per year. 17 were requested by the European Commission, 8 Opinions were issued on the initiative of

[19] EGE Mandate 2005-2009, Commission Decision 2005/383/EC of 11 May 2005.

[20] In practice, except of one request by Parliament which in the end did not turn out into an Opinion, this right was not executed so far.

EGE itself. The length of the published Opinions increased over the years, especially since Opinion 15 (Nov 2000), when summaries of the Roundtables and expert studies were added to the published Opinions. The Roundtables held by the EGE in preparation of an Opinion cover a wide range of expert opinions on a topic, to which the Opinions reference. Furthermore the Group has the right to commission an expert study on a specific topic, which is also part of the publication.

Three Opinions so far dealt especially with ethical issues concerning ICT:

- Opinion 13: Ethical issues of healthcare in the information society (July 1999)
- Opinion 20: Ethical aspects of ICT implants in the human body (March 2005), and
- Opinion 21: Opinion on the ethical aspects of nanomedicine (Jan 2007)

The focus of the thematic discussion will lie on these Opinions especially.[21]

Apart from the Opinions themselves, the EGE published three General Reports at the end of every mandate, to summarize the activities of the Group during the mandate.

The EGE also provides information on its web site,[22] where all publications are available as free downloadable content. This includes the newsletter "Ethically speaking", which – like the Opinions and the General Reports – is also available in print (free of charge). The newsletter includes reports by National Ethics Committees (NECs) and similar bodies and has to be taken into account as one of the links of the EGE to these bodies.

„Having regard to"-Documents

Every Opinion (except the first three) starts with a list of reference documents. The documents can be divided into three groups: EU-documents, documents by other International (Governmental) Organizations,[23] and expert studies. The number of references made grew massively over the years. From under ten mentioned documents until Opinion 9, the numbers rose to over 50 documents in the last three Opinions, mostly due to an increase in numbers of mentioned EU-documents.

EU documents comprise the EU-Treaties[24], EU-Directives, Parliament Resolutions, Council Decisions, Communications and Green Papers. Documents by other International Organizations are most frequently documents by the European Council, most notably the Convention on Human Rights and Biomedicine of the Council of Europe (1997), but also the UNESCO's Universal Declaration on the Human Genome and Human Rights (1997) or UN Documents.

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[21] As stated above, we do not include Opinion No. 10, which does have some relevance with regards to ICT. See: Footnote 13 of this document.

[22] http://ec.europa.eu/european_group_ethics/index_en.htm, last access: April 30, 2010.

[23] Since the legal perspective is discussed by other experts of the WP 3, we only look at some general numbers and observations, without going into details of the references' content.

[24] Depending on the year of the Opinion the Treaty of the European Union (Nov 1993), the Treaty of Amsterdam (May 1999), the Treaty of Nice (Feb 2003), and the Treaty of Lisbon together with the Charter of Fundamental Rights of the European Union (Dec 2009) are referred to.

Looking especially at the „ICT Opinions“ (Opinions 13, 20, 21), they all refer to the EU-Charter, emphasizing Articles 3 and 8 (except Opinion 13, published before the Charter was established) and a range of other EU documents, the European Councils‘ Convention on Human Rights and Biomedicine (1997) and the Universal Declaration on the Human Genome and Human Rights by the UNESCO (1997).

More specifically, Opinion 13 further takes into account:

- Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases;
- Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector;
- Council of Europe Convention 108 for the protection of individuals with regard to automatic processing of personal data of 28 January 1981;
- OECD Recommendation of the Council concerning guidelines governing the protection of privacy and transborder flows of personal data, adopted by the Council on 23 September 1980;
- United Nations Guidelines concerning computerised personal data files, adopted by the General Assembly on 14 December 1990;
- WHO Regional Office for Europe Declaration on the promotion of patients' rights in Europe of 1994.

Opinion 20 takes further into account:

- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector;
- Directive 95/46/EC of the European Parliament and of the Council of the European Union of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of the Council of Europe of 1 January 1981;
- Declaration of Principles of the World Summit on the Information Society of 12 December 2003, in particular Article 58 on the use of ICTs and Article 59 on the abusive uses of ICTs.

And Opinion 21 further takes into account:

- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector;
- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;

- the Declaration on Human Genetic Data adopted by UNESCO on 16 October 2003 and the Universal Declaration on Bioethics and Human Rights adopted by Unesco on 19 October 2005;
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data adopted by the Council of Europe on 1 January 1981;
- the United Nations Declaration on Human Cloning adopted by the UN General Assembly on 8 March 2005.

In conclusion, it seems the EU is the main source of reference, but other international instruments are, if necessary and complementary, taken into account. Here, of course, the Directives on privacy and data protection are central.

Especially for ethical issues of ICT, UNESCO documents, Conventions of the European Council and also the WSIS-Declaration are also taken into account.

2.3.3 Thematic Overview

Out of the 25 Opinions issued by the EGE so far, 19 are dealing with ethical issues of biotechnology. Out of these, three are especially concerned with the patenting of biotechnological inventions / elements of human origin, and eight Opinions are discussing ethical questions of genetics.

Looking at the Opinions given and the ethical principles and values stated, there is a core of norms that is to be found in each of the Opinions.

For a first principle, each **new invention should be undertaken for the better welfare of human life**.[25] Sometimes the economic success and competitiveness of the European Union are also acknowledged as valid driving forces of new research and inventions. But this goal does not justify all means, the inventions and practices for the bettering of the human life have then to be waged with certain „costs“ or principles of how to obtain them. In most Opinions, mentioned first is the **dignity of the human beings**. Also at the core of each Opinion is the principle of **safety**, e.g. food safety or health safety of the consumer. **Animal protection** and **protection of biodiversity** are also widely mentioned in the Opinions, as is the **obligation or need to inform** the consumers or citizens in general to ensure an objective forming of opinion and an informed decision making.

These main ethical principles deployed in the Opinions, shifting in emphasis and depth of discussion, depending on the issue at hand, are also summarized in the EGE's General Reports 1998-2000 and 2000-2005.[26] They are mirroring, in most part, the ethical review principles we already met in the FP7.

New innovations in biotechnology and in ICT are often closely linked. Nevertheless, regarding the content of the Opinions, only three so far have dealt with questions of ICT. They generally follow the above mentioned emphasises. To give some more in-depth insight into how the above mentioned values and principles are envisioned in

[25] In the following section the highlighted terms will be used to build a list of "ethical key issues". Cf. section 2.3.5 of this document.

[26] Cf. EGE 2000b, pp.10-11, and 2005b, pp. 1-6.

practice by the EGE, we will have a closer look at the argumentation in these three Opinions.

Human dignity, understood as a value not only to be respected, but protected (EGE 2005a, p. 16), prohibits the transformation of the body into a mere source of information, or into an object that can be manipulated and controlled remotely (EGE 2005a, pp. 20,33). Human dignity is at the same time the basis for a list of other values mentioned. The limitation of the **freedom** or **autonomy** of a person by the possibility of individual and/or group surveillance by ICT must be „evaluated carefully" (EGE 2005a, p. 30) and ICT implants should not „result in any discrimination or abuse contrary to human rights" (EGE 2005 a, p. 30). „Surveillance applications of ICT implants may only be permitted if the legislator considers that there is an urgent and justified necessity in a democratic society... and there are no less intrusive methods. ...The same general principles should apply to the use of ICT implants for military purposes." (EGE 2005a, p. 34) A „data subject" should always have the right to „object to an implant and have it removed, if this is technically possible" (EGE 2005a, p. 20).

Referring to a person already as a „data subject" is in line with the general emphasis given in the three Opinions to **privacy and data protection**. As all three Opinions deal with ICT in the health sector, it is personal health data that is looked at, and which is understood as „part of the personality of everyone" (EGE 1999, p. 9). The confidentiality of health data has to be „guaranteed at all times" (EGE 1999, p. 9), and the „collection of and access to this data is limited to practitioners and third parties with legitimate use (non-medical practitioners, healthcare and social security personnel, administrators, ...)" (EGE 1999, p. 10), again securing confidentiality from all mentioned parties (EGE 1999, p. 10). Confidentiality in this case includes data concerning ordering drugs or getting information via the Internet and continues after the death of a person (EGE 1999, p. 10). Especially if health data, be it derived from a personal health record on a chip or from an implant in the body, is embedded in a network, it has to be scrutinized and asked who will have access to this network (EGE 2005a, p. 16). On the other hand, no one wearing an ICT implant should be forced to declare the implant and it should be possible to wear them unrecognized. „The right to privacy includes the right to have an ICT implant" (EGE 2005a, p. 32).

Safety, meaning that a new technology causes no harm, is in principle stressed by all three Opinions, with a special emphasis in Opinion 21 on Nanotechnology. As the risks of nanomedicine for patients and the risks of free-floating nano-particles for the society and environment in general is yet unknown (EGE 2007a, p. 37), the EGE stresses risk assessment as the most important task to implement the safety principle. „The Group proposes that relevant authorities should carry out a proper assessment of the risks and safety of nanomedicine. Such risk assessment should cover the whole life cycle of the products, from production to handling of waste. The same level of safety currently applied to medicine and medical devices should then apply to nanomedical products." (EGE 2007a, p. 54) Risk assessment should also cover how to adress accidents and the social effects in Europe as well as in developing countries (trade implications and the danger of a „nano-divide"). (EGE 2007a, p. 56)

The latter point is closely linked to the principle of **solidarity**, again referred to in all three Opinions. Questions of equal access to health care are the most obvious ones. But underlying are issues of discrimination, e.g. because of disease dispositions or a refusal to use ICT implants (this discussion can already be seen with the cochlear

implant, putting the deaf communicating with sign language in the position of having to defend themselves for not taking the treatment to become „normal“).(EGE 2005a, p. 24) Thus, in Opinion 21, the EGE demands „a considerable amount – up to 3% – of the budget invested in research in nanotechnology should be set aside for ELSI (Ethical, Legal and Social Implications) research... to promote more research on philosophical, ethical and anthropological questions raised by recent developments in nanomedicine, looking into the broader questions of nanomedicine, among other things individual responsibility, including the shifts in the concept of the self, personal identity, societal goals and global health care. For this purpose, a dedicated European Network on Nanotechnology Ethics should be established and financed by the Commission under FP7“. (EGE 2007a, pp. 60f.) Furthermore, „ICT implants are not used to create a two class society or to increase the gap between the industrialized countries and the rest of the world. According to the Opinion (EGE 2005a:33f.) the following possibilities should be banned:

- ICT implants used as a basis for cyber-racism.
- ICT implants used for changing the identity, memory, self perception and perception of others.
- ICT implants used to enhance capabilities in order to dominate others.
- ICT implants used for coercion towards others who do not use such devices.

Coming to the **funding of research in ICT**, „patenting and private gain derived from research funded by public money raises the issue of the fair sharing of burdens and benefits between taxpayers and companies, and should therefore be further explored.“ (EGE 2007a, p. 59) Indeed, funding of ICT research raises another concern, besides the question of solidary use of taxpayers' money: „(...) it is important to ensure that **patents** in these new areas do not alter the current balance. There are risks of overly broad patents being granted that may hinder their therapeutic availability.“ (EGE 2007a, p. 58)

All three opinions deal with ICTs in the health sector, but the line between medical and non-medical applications is seen as a thin line, e.g. implants or nanotechnology used to cure diseases or enhance the possibilities of humans above the currently „normal“. All Opinions try to define this thin line. „Implanting ICT for purposes that are, broadly speaking, profit-related ... should not be permitted.“ (EGE 2005a, p. 16) Invoking the **proportionality principle**, the EGE states that „the proportionality principle rules out the lawfulness of implants such as those that are used, for instance, exclusively to facilitate entrance to public premises“ (EGE 2005a, p. 20), and even goes further in making the general point that „non-medical applications of ICT implants are a potential threat to human dignity and democratic society. Therefore, such applications should respect in all circumstances the principles of informed consent and proportionality“. (EGE 2005a, p. 32)

Also in the realm of proportionality, the **data minimisation principle** „rules out the lawfulness of ICT implants that are only aimed at identifying patients, if they can be replaced by less invasive and equally secure tools“ (EGE 2005a, p. 20). Implantation of ICT devices for health purposes should be governed by the principles that:

a) the objective is important, like saving lives, restoring health or improving the quality of life;

b) the implant is necessary to achieve this objective; and,

c) there is no other less invasive and more cost-effective method of achieving the objective. (EGE 2005a, p. 30)

„Ultimately, all these principles supplement one another. After identifying a legitimate purpose for using an ICT implant, one should establish whether this is actually necessary as well as whether the tools (to be) used are relevant and proportionate." (EGE 2005a, p. 19)

The **informed consent**, already highlighted as a general principle of all EGE Opinions, is understood as a principle to assure the **self-determination, participation** of the individuals, as well as **transparency** of research and use of ICT. Concerning health data, the individual should have the right to know and determine which data is collected and who uses them for what purposes and should have the right to restrict access and correct data (EGE 1999, p. 10f.) To ensure the security of data, encryption technology should be used where appropriate or closed networks for transfer or personal health data. (EGE 1999, p. 11) Taking into account the novelty of the technologies, „the lack of knowledge and the uncertainties that exist create problems for the attempts to provide adequate and understandable information and obtain consent that cannot exclusively be met by informed consent forms signed by patients. The Group encourages further efforts at national and European level to develop improved methods of providing information and obtaining consent e.g. through research projects under the ELSI (Ethical, Legal and Social Implications) programme ... initiatives should be taken at national and European level to prepare surveys of public perception of the benefits and risks of the applications of nanotechnologies, with special reference to medical sectors." (EGE 2007a, p. 59)

Furthermore, the following recommendations are given:

- There should be an EU website on ethics and nanomedicine which is updated regularly, and where citizens can find information and raise questions;
- There should be academic and public debates on problems and possibilities of present and near-future nanomedicine;
- attention should be drawn to the question of labeling of nanomedical products and a thorough analysis of this issue by the Commission is recommended. (EGE 2007a, pp. 59f.)

In the discussion of safety and of informed consent it already became obvious that the EGE views new ICT as a highly innovative field, in which the possibilities and outcomes of research are not yet very well known. To underline for example the uncertainty imbalance of ICT implants, Opinion 20 lists a three page collection of „knowledge gaps" concerning ICT implants (EGE 2005a, pp. 24ff.) Therefore it is stated in Opinion 20: „The existence of a recognised serious but uncertain risk, currently applying to the simplest types of ICT implant in the human body, requires application of the **precautionary principle"**. (EGE 2005a, p. 20)

The Commission's *Communication on the precautionary principle* (2000) defines the practical scope of the principle for situations "specifically where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the

Community" (Commission of the European Communities 2000, p. 2). The EGE further explains: "The basic constituents and the prerequisites for the application of the precautionary principle are existence of a risk, possibility of harm, and scientific uncertainty concerning the realisation of this harm." (EGE 2005a, pp. 17f.)

In analysing the risks of new ICT, the precautionary principle should be especially evoked in the „management of risk" (Commission of the European Communities 2000, p. 2), following Hans Jonas' famous phrasing: „Act so that the effects of your action are compatible with the permanence of genuine human life." (Jonas 1984, p. 11) Therefore „the precautionary principle is of a ‚procedural' rather than ‚substantive' nature, which means that it is not applied to gauge an innovation as such but rather its effects. If the negative effects are found to be absent, or if the application mechanisms are modified, then a given scientific or technological innovation may be regarded as acceptable. Therefore, the precautionary principle is a dynamic tool that can follow the evolution of a sector and continuously verify that the acceptability conditions of a given innovation are fulfilled – thereby enhancing governance in what has been called the ‚risk society'." (EGE 2005a, p. 18) By saying this, „the EGE has recommended caution as a general ethical principle with regard to information and communication technologies. This principle entails the moral duty of continuous risk assessment with regard to the not fully foreseeable impact of new technologies as in the case of ICT implants in the human body". (EGE 2005a, p. 23)

2.3.4 List of ethical key issue

From the thematic overview given in the previous section, the following list of key issues can be derived which has been amended by ethical issues and recommendations presented by the EGE (2010) in its "General Report 2005-2010".[27] Using the core values stated in the preamble of the European Charter of Fundamental Rights as categories, we will furthermore list the values and principles along these lines. These lists will be used as a basic scheme to identify ethical issues in the evaluation process:

A technology might raise the following "ethical issues":[28]

- safety
- protection of environment and biodiversity
- animal welfare
- consumer rights (EGE GR)
- biomedical research and health care (EGE GR)
- biosecurity, prevention of bioterrorism, dual use (EGE GR)

[27] It has to be noted that the General Report has been released in late 2010, while the first version of this document has been finished by the end of April 2010. However, since the list in the General Report has been used in the evaluation carried out we choose to include some of the issues from this list later on. It also has to be mentioned that the outcome of our original analysis was very close to the list presented by the EGE in the report, which is based on Opinions 21 to 25.

[28] This list is based on our own analysis of the Opinions of the EGE and supplemented by an overview presented by the EGE in its General Report 2005-2009 (cf. EGE 2010, pp. 33-35). All issues marked "(EGE GR)" are mentioned in this list.

- governance (EGE GR)
- data security (EGE GR)
- intellectual property (EGE GR)
- trade / global justice
- need for science and society dialogue
- research support (including priority setting and funding) (EGE GR)

These and other issues might be connected with the following values which might be violated and principles that might be invoked:

Human dignity

- right of the integrity of the person
- welfare of human life
- autonomy (self-determination, informed consent)

Freedom

- privacy and data protection
- freedom of the arts and sciences/ freedom of research (Funding of research in ICT by EU)
- obligation or need to inform

Justice (equality and solidarity)

- non-discrimination
- cultural, religious and linguistic diversity/pluralism
- improvement and protection of health and safety
- democracy/participation
- equal access to health care and education
- environmental protection/animal welfare
- consumer protection
- respect for human rights
- patents (ownership)

Principles

- principle of transparency
- principle of proportionality (including: data minimisation principle)
- precautionary principle

3 How ethical issues (of ICTs) emerge on the political agenda; some theoretical insights

We traced the „fundamental ethical principles of the European Union" back to the *Charter of the Fundamental Rights of the European Union* and several other documents, and to the EGE Opinions, and pointed out that these principles can be found in the ethical review process of FP7. It seems fair to say that every stakeholder acting on a European level (e.g. applying for scientific funding) has to take these ethical principles into account.[29]

But, in order to help the attempt of ranking, which is the aim here, we need to look over the rim of what we focused on until now and explore the political framework in which the Commission, the EGE, and also the FP7 operate. We will do this along two dimensions:

(1) We will start our brief journey with the structure of this peculiar political framework, localizing where ethics in the European Union takes place, how it is organised, and determining the actors' respective tasks and aims.[30]

(2) Secondly, we will look at the processes of policy-making, especially pointing out channels of communication and power relations between the actors.

In doing this, we will have covered the classic triangle of policy analysis: structure (polity), content (policy) and process (politics). (Patzelt 2003, p. 29)

This descriptive part will be followed by some ideas about how it could be *explained*, that a new ICT raises ethical interests in this framework. There are different theories of explanations and we will give hints on what hypotheses could be tested by a thorough political analysis. We will conclude by favorising the utilitarian liberalism as the theory with the anticipated biggest explanatory strength on how ethical issues of ICT become an issue at the European level.

[29] Which brings with it the problem of „language politics". We have to be aware of the different languages being used by the academia towards their own discourses and towards the funding economy. The language of proposals is oriented in great parts towards the funding guidelines and prerequisites. The formulation of the ethical dimension of an academic research, if an ethical review is demanded, is no exception. By assessing new technologies, we always have to ask how the material we get from the developers is shaped by the funding guidelines.

[30] Not going into detail though for the academic and hacker community, as this is done elsewhere in the project (WP2).

3.1 Policy analysis: polity - the structure of the ethical framework

The „fundamental ethical principles of the European Union“ – as the name already suggests – are valid in the whole of the European Union. Nonetheless, there are certain bodies within the European Union that are especially concerned with these fundamental principles and their relation to future technologies in one way or the other:

EGE

- composed of: scientists and academics
- task: advising the European Commission on ethical issues on new technologies
- aim: evaluating ethical risks and chances of new technologies

Inter Service Group on Ethics and EU Policies

- composed of: the EGE (Secretariat) and Commission Services in the fields of ethics and EU Policies
- task: to coordinate and organise meetings between EGE and different other Commission Services in the fields of ethics and EU policies.
- aim: enhance information exchange between the Commission services in the fields of ethics and EU policies.

National Ethics Council (NEC) Forum

- composed of: chairpersons and secretaries of national ethics councils; President of the EGE is invited to the meetings
- task: an idependent informal platform (expenditures reimbursed by EC), Role described as complementary to the EGE; no advisory function to any EU body
- aim: exchange information, experiences and best practices.[31]

Unit L3 - Governance and Ethics

- part of the EC-framework
- main tasks: Implementing the ethical review and ethics audits of funded research projects under FP7; Enhancing the understanding of ethical issues in research and fostering transnational debates.[32]

The European Parliament and the Council of Ministers are connected to this policy field by passing the Decision for the 7th Framework Programme[33] and their right to request an EGE Opinion.

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[31] Cf. http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1305, last access: October 20, 2010.

[32] Cf. http://ec.europa.eu/research/conferences/2009/rtd-2009/documentation/science_economy_and_society/governance_and_ethics.pdf >, last access: October 20, 2010.

As for non-state actors in this framework, we can distinguish three main groups, two of which are dealt with in more detail in other parts of the project: the scientific and academic community (1) and the hacker community (more general: grass roots advocacy groups) (2). As a third non-state group on the European level, we have to consider economic pressure groups (3), lobbying in most cases for open and unrestricted markets. We will be not able to address the influence of economic pressure groups in this report. However, the impact of such activities is not to be underestimated. For example, Colin J. Bennett and Charles Raab (2006) have pointed out to millions of dollars spent by the European Direct Marketing Association and other groups to shape the *Directive on the Protection of Personal Data* (1995). Although it clearly was not in the indent of these groups to influence the European *research* policy, it effectively did so.[34]

3.1.1 Policy Analysis: politics - communication and power relation in the framework

The European Commission, the Council of Ministers, and to a lesser degree the European Parliament are the only bodies within this framework who are able to take legally binding decisions. The closest influence to this decision making lies with the EGE, although its Opinions towards the Commission have the status of non-binding advices. They can gain power and influence, when they are incorporated as reference documents in Council Decisions, as happened e.g. in the Decision No 1982/2006/EC on the FP7.[35]The EGE itself holds its ties with other bodies within the EU dealing with ethical issues in their respective fields (agriculture, security etc.) through the Inter Service Group on Ethics and EU Policies. Through the participation of the EGEs head at the summits of the NEC Forum, these two bodies are linked as well. Another link between the EGE and National Ethics Committees is the EGE newsletter "Ethically Speaking" in which opinions and decisions of National Ethics Committees are published on a regular basis.[36]

Through its "Report on the Charter on Fundamental Rights" (EGE 2000b) and its Opinions on FP5 (Opinion No. 10) and FP7 (Opinion No. 22), the EGE had indirect influence through its advisory role on the European Commission. How much the Opinions influenced and reshaped the EU-Charter and the ethical review process of

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[33] European Parliament and Council Decision 1982/2006/EC of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013). Article 6: "All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles".

[34] Another example is the influence of economic pressure groups on the EU's security research program (Hayles 2006).

[35] Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013): „The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account". Also mentioned in the "Rules for submission of proposals, and the related evaluation, selection and award procedures" (Version 3, 21 August 2008; COM(2008)4617), Annex A, p. 26.

[36] Cf. http://ec.europa.eu/european_group_ethics/publications/index_en.htm, last access: April 30, 2010.

FP5/FP7 is hard to determine in detail, but it seems safe to say that there was some influence especially on the formulation of Article 3 and 8 of the Charter and also on the FP7 (through the more general Opinion No. 10), as the EGE is prominently mentioned on the FP7 homepage and several of its Opinions are linked for further consideration (Opinions 10, 13, 20, and 21). In the "General Report 1998-2000" the role of the GAEIB in bringing the acknowledgement of „fundamental ethical principles" into research funding of the EU through a note sent to the Commission is furthermore prominently highlighted. (EGE 2000b, p. 10) But in the end, the EGE is highly dependent on the good-will of the Commission and, to much lesser degree, the European Parliament. First, the EGE acts under the mandate of the European Commission, which has to renew it every four years. Second, the European Commission can commission Opinions and a majority of the Opinions published since the EGE came into existence were requested by the Commission. And thirdly, the Opinions have the status of a non-binding expertise.[37] In order to exercise an influence on the decision-making process, an atmosphere of mutual trust and at least a basic consensus on general political lines about how to „translate" the fundamental ethical principles into the realm of funding, legalising, patenting or restricting new technologies seems to be needed. Therefore, it is safe to say that the Commission is the strongest actor in the field.

Considering the communication channels of the listed non-state actors, there are three main channels, through which these groups can access the political field: through participation, through lobbying[38] and through activating the mass media.

As we can see above, the scientific and academic community is participating not only through the EGE (Experts appointed to the EGE, Roundtable, Expert Studies), but also through the NEC Forum. To a certain degree, also NGOs, or other societal groups (religions, e.g.) also have access through participation, e.g. the Roundtables held by the EGE in preparation of an Opinion.[39]Also, in the newsletter published by the EGE there is constant reporting from National and International Ethic Committees.

But this access is not institutionalized and rests on an ad-hoc invitation to the Round-tables. For NGOs, making their opinions heard therefore primarily rests on lobbying and using the mass media. That mass media can become an influential factor can be

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[37] While Decision No 1982/2006/EC requests that EGE opinions should be taken into account in evaluating a proposal submitted to the FP7 programme, the opinions themselves are no legally binding documents. Of course, "taking into account" also does give room for diverse readings of the texts. Cf. footnote 35 of this document.

[38] For more insight in the peculiarities of lobbying in the EU, cf. Schendelen (2005).

[39] The publishing of the Roundtable meetings are infrequent. Four documents have been published: "The Ethical Aspects of Nanomedicine: Proceedings of the Roundtable Debate" (2006), "The ethical aspects of animal cloning for food supply: Proceedings of the Roundtable Debate" (2007), "Ethics of modern developments in agriculture technologies: Proceedings of the roundtable debate" (2008), and "Ethical aspects of synthetic Biology: Proceedings of the round-table debate" (2009). Looking at the list of participants, we can distinguish different groups of participants: members of NGOs, Agencies and Associations; Representatives of Industries; Academics; Representatives of Religion; Media; and members of other EU Commission Institutions. The speakers at the Roundtables come from all over the different groups, according to topic and expertise. All documents are available through the EGE's web site.

seen for example in the section on "Public involvement and science-society Dialogue" in EGE Opinion No. 25 (EGE 2009, pp. 37-38), where the results of a study on press coverage are being used to point out the specific European view on „Synthetic Biology".

Ordering the different stakeholders along the different steps of a decision-making process, we could conclude that the EGE, NEC Forum, the scientific and academic community, the economic pressure groups and the grass root advocacy groups are part of the decision-making process. The European Commission, the European Parliament and the Council of Ministers (and through this, the national governments) together are responsible and able to make legal binding decisions. The Governance and Ethics Unit is primarily concerned with the implementation process of the fundamental principles of the European Union concerning new technologies.[40]

3.1.2 Explanation Models

As we noted earlier, it is useful to have a look at the political framework in which the EGE operates. We learned about other actors in this ethical framework and how they are connected with each other. But why might this be important? Why is it not enough to look at the fundamental ethical principles and decide by this whether a technology might become an ethical issue on the political agenda of the EU?

Simply put, because politics is not only about content, but also about structure and process. Structure and process have explanatory power as well.

Any explanation is the attempt to take a look in the black box where the different „ethics" of academia, advocacy groups and politics are going in on one side and „fundamental ethical principles of the European Union" coming out on the other.

What we just did in the above chapter was to very briefly *describe* how it looks inside this box, of which actors the network is composed. In a second step, we want to explore some ways of *explaining* what is happening in there.

There are different theories emphasizing either the role of actors in shaping structures, or structures shaping the behavior of actors. The main problem with putting structures as the explanatory variable is, that it becomes nearly impossible to explain (or forecast, for our purposes) transition and change. (Thiery 2003, p. 227)

Therefore we will concentrate on an actor-centered approach. One of these approaches is Utilitarian Liberalism, a theory of International Relations (e.g. Frank & Rittberger 2001). Utilitarian Liberalism holds some assumptions that match our political framework. What makes Utilitarian Liberalism interesting in our case is that it looks into the political framework especially for two things: interests and powers. And it seems helpful to look at interests and power regarding ethics in the European Union to rank the likelihood of an ICT becoming an ethical issue.

Without giving a full political analysis, some intuitive assumptions concerning the interests of the different groups can nevertheless be generated with the help of the description above:

[40] Of course, the judicial institutions are also concerned with the implementation insofar new technologies are conflicting with existing legislation.

- The European Commission (like any political-administrative stakeholder) has an interest in getting reelected, or, more appropriate for the EC, re-appointed. It is in their interest then to follow the interest of their constituencies or their national governments who appoint the Commissioners.[41] As we can understand existing legislation as the already adapted interests of the constituents, following its own Decisions and Regulations is part of the ECs interest.
- The interest of the economic pressure groups is the economic well-being of their clients and companies. They will become especially active in two cases: when new regulations restrict their business, or if a new technology looks especially profitable.
- The interest of the grass root advocacy groups lies in their respective organisational aims. This could be data protection/security, rights of the disabled, or others. They all become especially active in two cases: if new regulations or research funds facilitate research or business that contradicts with their organisational aim, or if a new technology would help their organisational aim. We can intuitively assume that especially issues of data protection and issues of implantation and enhancement of the human body will raise concerns within this group in the near future.
- The scientific and academic community seems to be split in half, one part researching into new Technologies and therefore stressing the positive impact and competing for funding, and another half, who is concerned with the ethical and societal impact of new technologies and rather looking at existing documents and treaties to protect human inventory spirit from losing sight of human rights and the well-being of society as a whole.

As the supplement „utilitarian“ in "Utilitarian Liberalism" already suggests, actors are understood as rational. The actors act rationally when they are pursuing their interests.[42]

Taking this together, a first set of assumptions can be made:

If it is in the interest of national governments or the constituents to fasten or loosen legislation concerning ethical standards and new technologies, the EC will act accordingly through its means (Decision, Communcation, Regulation, or requesting an Opinion by the EGE).

If new legislation curtails business or if new especially lucrative ICT is developed, economic pressure groups will lobby against this legislation and in favour of funding and allowing research in this field.

If new technologies especially concern issues of data protection and the intrusion into the human body (implants, enhancement), or if any other topic is touched that is covered by a grass root advocacy group active on the European level, these advocacy

[41] The Treaty of Lisbon introduces a direct link between the election of the Commission President and the results of the European elections.

[42] Following the concept of rationality in the understanding of Max Webers „zweckrationalem Handeln“ (rational means to rational ends), cf. Weber (1922), p. 17.

groups will rally support through lobbying or mass media attention to fight for their interests.

If a new technology or the prospect of technological development raises concerns of collision with established legislation or documents, institutions concerned with the adherence to „fundamental ethical principles“ (e.g. the EGE), will publish statements, to start and/or influence a decision-making process.

The main assumption of utilitarian liberalism is that the decision-making is determined by the interests of the *most powerful actor* in the network. In our model, power can be determined either by closeness to decision-making or the ability to rally mass (media) support.[43] In the description above, we determined the EC as the most powerful actor, and the EGE as the closest actor of the ethical framework to the EC. The most powerful actor to render mass (media) support is given to advocacy groups, as it is their main mean in the framework to make their voice heard.

Assuming this, the following hypotheses can be drawn from the above description:

- **If the hacker community voices ethical concerns about a new ICT and is able to enlist mass media support, then the likelihood of it becoming an ethical issue in the whole framework increases.**
- **If the academic community voices ethical concerns about a new ICT and is able to have this concern discussed in national ethics committees, the NEC Forum, or other international bodies, then the likelihood of it becoming an ethical issue for the EGE, and therefore gets in the recognition of the EC, increases.**
- **If value hierarchies conflict between different groups or contradict existing Decisions and Declaration of the EC, the likelihood of this becoming an ethical issue for the EC increases.**

The example of ICT implants might illustrate the model provided. As stated above the European Commission is to be regarded the as the most powerful actor, yet it is bound by the European Charter of Fundamental Rights and other documents. Since “ICT implants” are likely to cause infractions to the rights stated in Article 3 on the “Right to the integrity of the person”, and Article 8 on “Protection of personal data” it is in the self-interest of the EC to limit the funding of scientific research of this kind of ICTs. However, there is also a need to recognize the interests of members of the scientific community who reject this strict view. Especially actors like Kevin Warwick, who is a highly visible actor in the mass media (Interviews were published by CNN, BBC, Wired Magazine, etc.),[44]seem to have been able to question the strict interpretation of the Charter, that would have been in the self-interest of the EC. Also, the EC could not ignore, that the general development in the field of medical devices

[43] Media not only comes into the picture as being used by different groups for their interests. Media can have an influence by its own via the process of „framing“. Framing, according to Goffman and Bateson is the process by which the media organizes and makes sense of the news. Craig (2000) argued that especially with complex technologies (he is referring to medical topics like stem cell research or cloning, but it seems valid to assign it also to new ICT), the inclusion of the ethical dimension gives readers „handles“ for understanding science.

[44] The list of media appearances is based on the information provided by Kevin Warwick on his web site, cf. http://www.kevinwarwick.com/interviews.htm, last access: October 20, 2010.

already pointed to “ICT Implants” as the next step. There might also have been substantial lobbying activity by companies (like Applied Digital Solutions), but also by NGOs (like CASPIAN, founded in 2002, or the transhumanist movement). This is reflected by the considerable number of publications on the topic in the media. With regards to the media in general the popularity of the topic in fiction (“Cyborgs”) has also to be recognized. Hence, EC was forced into considering “ICT implants” as an ethical issue, and reacted by requesting an EGE opinion on the subject. Later on, there was also specific research carried out within the FP6 project “ETHICBOTS.”

There, we conclude that a look at the ethical political framework on the EU level can not only help to determine the likelihood of a new ICT becoming an ethical issue on the agenda. It also becomes clear looking at the provided model, that the expected degree of controversy on the technology or application can be anticipated by the widely differing values, interests and attitudes on issues between the different groups concerned with the technology.

4 Ranking guideline: A Questionnaire

We now have an idea of the ethical principles that guide ethical thinking on a European level, or more precisely ethical judgement within institutions of the European Union.

If a technology is against a certain law, it is a matter for the courts to show the boundaries of the eligible. But especially with new and emerging technologies, there is either a lack of legislation for a new field, or developments might just rise concerns, without yet tackling the law, or we are talking about prospective developments in the future, where law is not yet applicable. It is in these rather "soft spots", where the "fundamental ethical principles" can give us interesting insights into the discussions that might arise.

We have then two indicators for the probability of a new ICT becoming an ethical issue: (1) the ICT is in rather harsh contrast to one or more of the fundamental ethical principles (2) the ICT brings with it value conflicts. The bigger these conflicts, the more likely it will become an issue.

Now how do we measure "value conflict"?

Value conflict here can be understood in two ways:

First, different values can conflict with each other. Deriving from the EGE Opinions we will give some examples of conflicting values. If an ICT matches with one of these sets, or similar value conflicts are plausible, it is likely to become an issue.

Second, the values (or the hierarchy of values) of different groups in the political framework on the same issue can conflict. If this is foreseeable for a certain ICT, it should be described accordingly.

Taking all this together, answering the following questions will help us to assess the likelihood and level of controversy of various ICTs:

Issues: (measuring the likelihood based on the assumption that, if something has already been dealt with on the European level, it is more likely to happen again)

Was the technology or a similar technology already mentioned in an EGE Opinion/NEC or part of an FP (sub)project?[45]

A technology might raise the following "ethical issues":[46]

- safety
- protection of environment and biodiversity
- animal welfare
- consumer rights
- biomedical research and health care
- biosecurity, prevention of bioterrorism, dual use
- governance
- data security
- intellectual property/patents
- trade / global justice
- need for science and society dialogue
- research support (including priority setting and funding)

Values

Does the technology foster or threaten any of the following values?

Human dignity

- right of the integrity of the person
- welfare of human life
- autonomy (self-determination, informed consent)

Freedom

- privacy and data protection
- freedom of the arts and sciences/ freedom of research (Funding of research in ICT by EU)
- obligation or need to inform

[45] A list of ICT technologies mentioned by the EGE can be found in Annex 1.

[46] The following list has already been presented in Chap. 2.3.4. However, we decided to repeat the list in order to provide a better overview in connection with the other information needed for the evaluation process.

Justice (equality and solidarity)

- non-discrimination
- cultural, religious and linguistic diversity/pluralism
- improvement and protection of health and safety
- democracy/participation
- equal access to health care and education
- environmental protection/animal welfare
- consumer protection
- respect for human rights
- patents (ownership)

Principles:

Are these principles for good ethical practice met? Would it be necessary to invoke them (politically)?

- principle of transparency
- principle of proportionality (including: data minimisation principle)
- precautionary principle

Value Conflicts: (measuring the likelihood based on the assumption that the higher the probability that this technology will cause one or more value conflicts, the more likely it will become an ethical issue)

Examples of value conflicts dealt with in EGE Opinions:

Effectiveness versus confidentiality:

- The need to know and share patient personal health data in order to provide good quality of care creates a situation of shared secrecy which may compromise confidentiality. (EGE 1999, p. 8)

Privacy versus the collective good:

- Privacy may be traded for certain collective goods (research, administration, planning, prevention...) that benefit the community or population at large. (EGE 1999, p. 8)

Freedom versus the collective good/solidarity:

- The personal freedom to use one's economic resources to get an implant that will enhance one's physical and mental capabilities might contradict what society at large considers desirable or ethically acceptable. (EGE 2005a, p. 23)
- As in other areas, the freedom to use ICT implants in one's own body, i.e. the principle of freedom itself might collide with potential negative social effects. In these cases ethical counselling as well as social and political debate might be necessary. (EGE 2005a, p. 23)

- Potential conflict between limiting the freedom of people dangerous to others by surveillance and promoting the safety of others.(EGE 2005a, p. 23)

Quality assurance versus professional autonomy:

- Some professionals fear that quality assurance standards (protocols, clinical guidelines, clinical pathways, etc.) may restrict or diminish professional autonomy. (EGE 1999, p. 8)

Efficiency versus beneficence:

- While beneficence indicates giving the best possible care for every patient, this may be very expensive and not feasible. In the context of limited resources, to give a patient expensive care could deprive another patient of much needed basic treatment, a second best treatment may be the most appropriate. (EGE 1999, p. 9)

Freedom of research versus safety:

- Freedom of researchers may conflict with the obligation to safeguard the health of research subjects. (EGE 2005a, p. 23)
- Freedom of research against obligation to avoid physical, mental and economic harm as a result of participation in research. (EGE 2005a, p. 31)

Economic growth versus human dignity:

- Concern for economic competitiveness and other economic values (economic growth) may come into conflict with respect for human dignity. (EGE 2005a, p. 23)

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6 Annex No. 1 to 3

ANNEX 1: ICT Technologies mentioned in the EGE opinions 13, 20, and 21

Opinion 13:

- Electronic Health Record
- Network-systems and telemedicine
- Electronic Health Card (chip card, practitioner- or patient held)
- Decision support technologies
- Medical databases
- Internet

Opinion 20:

- Medical devices: biosensors, artificial hippocampus, cortical implant for the blind, occular implant or artificial retina, brain-computer interfaces
- Surveillance or tracking devices: wearable ICT devices for tracking the human body, subdermal GPS personal location devices
- Enhancement or commodity devices: prosthetic cortical implants, artificial vision, audio tooth implant or tooth phone, artificial hippocampus

Opinion 21:

- new diagnostic techniques: in vitro („lab on a chip“ diagnosis of blood, urine, etc.), in vivo (biosensors, implants, surgical tools
- Imaging
- Biomaterials
- Drug development and delivery
- Cosmetic applications

ANNEX 2: Ethical Issues Table

Questions ask in: Guide for Applicants Information and Communication Technologies ICT[47]

Informed Consent

- Does the proposal involve children?
- Does the proposal involve patients or persons not able to give consent?
- Does the proposal involve adult healthy volunteers?
- Does the proposal involve Human Genetic Material?
- Does the proposal involve Human biological samples?
- Does the proposal involve Human data collection?

Research on Human embryo/foetus

- Does the proposal involve Human Embryos?
- Does the proposal involve Human Foetal Tissue / Cells?
- Does the proposal involve Human Embryonic Stem Cells?

Privacy

- Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)
- Does the proposal involve tracking the location or observation of people?

Research on Animals

- Does the proposal involve research on animals?
- Are those animals transgenic small laboratory animals?
- Are those animals transgenic farm animals?
- Are those animals cloned farm animals?
- Are those animals non-human primates?

Research Involving Developing Countries

[47] Annex 5: Ethical Guidelines for undertaking ICT research in FP7, in: *Guide for Applicants - Information and Communication Technologies ICT*, p.1. – Online: http://cordis.europa.eu/fp7/ict/participating/home_en.html, last access: April 30, 2010.

- Use of local resources (genetic, animal, plant etc)?
- Benefit to local community (capacity building i.e. access to healthcare, education etc.)?

Dual Use

- Research having direct military application?
- Research having the potential for terrorist abuse?

ICT Implants

- Does the proposal involve clinical trials of ICT implants?

ANNEX 3:
Research Programmes dealing with ethical questions of ICT under FP7

The following list was derived from CORDIS databank. Since it has been complied at an earlier stage of the project it includes projects on "synthetic biology" and "nanotechnologies". For various reasons is has been decided not to include these technologies as subjects of the ETICA project later on. However, we decided not to make any changes to the list since its documents the original starting point of our evaluation.

Research area SiS-2007-1.1.2.1

Ethical frameworks of new technologies

- STEPE: Sensitive technologies and European public ethics
- EFORTT: Ethical frameworks for telecare technologies for older people at home

Research area SiS-2008-1.1.2.1

Ethics and new and emerging fields of science and technology

- SYBHEL: Synthetic biology for human health: Ethical and legal issues
- HEALTHGOVMATTERS: Health Matters: A social science and ethnographic study of patient and professional involvement in the governance of converging technologies in Medicine
- EGAIS: The Ethical GovernAnce of emergIng technologieS New Governance Perspectives for Integrating Ethics into Technical Development Projects and Applications
- SYNTH-ETHICS: Ethical and regulatory challenges raised by synthetic biology
- PHM-ETHICS: Personalized health monitoring (PHM)- Interdisciplinary research to analyse the relationship between ethics, law and psychosocial as well as medical sciences
- ICTETHICS: ICTethics. An interdisciplinary approach for addressing ethical, social and legal aspects of ICT
- ETHENTECH: Ethics of enhancement technology
- VALUE ISOBARS: The landscape and isobars of european values in relation to science and new technology
- ETICA: Ethical issues of emerging ICT applications
- TECHNOLIFE: a Transdisciplinary approach to the emerging challenges of novel technologies: Lifeworld and imaginaries in foresight and ethics

Research area SiS-2009-1.1.2.1

Privacy and emerging fields of science and technology: ethical, social and legal aspects

- PRACTIS: Privacy - Appraising challenges to technologies and ethics
- PRESCIENT: Privacy and emerging fields of science and technology: Towards a common framework for privacy and ethical assessment

Research area SiS-2007-1.1.2.2

Research underpinning policy related to ethics, precaution and sustainable development

- INNOVA-P2: Pharma-innovation - patent-2

Research area: SiS-2007-1.2.2.1

European ethics and documentation centre

- ETHICSWEB: Inter-connected European information and documentation system for ethics and science: European ethics documentation centre

Research area SiS-2007-1.2.2.3

Ethics and security research

- HIDE: Homeland security, biometric identification and personal detection ethics

Research area SiS-2008-1.2.2.1

Promotion of pan-European and international awareness of the ethical aspects of security technologies

- ETHICAL: Promoting international debate on ethical implications of data collection, use and retention for biometric and medical applications
- RISE: Rising pan-european and international awareness of biometrics and security ethics

Research area SiS-2009-1.3.2.1

Governance and Ethics of the responsible development of Nanosciences and Nanotechnologies

- NANOCODE: A multistakeholder dialogue providing inputs to implement the European Code of Conduct for Nanosciences & Nanotechnologies (N&N) research

Research area NMP-2007-1.2-2

Analysis of the ethical, regulatory, social and economic environment of nanomedicine

- NANOMED ROUND TABLE: Nanomedicine ethical, regulatory, social and economic environment

Research area PEOPLE-2007-2-1.IEF

Marie Curie Action: "Intra-European Fellowships for Career Development"

- INEST: Intuitive ethics and sensitive technologies
- ENHANCEMENT ETHICS: Ethical aspects of human enhancement and the ownership of biological material

Research area SEC-2007-6.5-01

How to take the necessary measures to ensure the security of the citizens while respecting the civic rights and how this is implemented in practice, particularly addressing the issue of privacy and security

- DETECTER: Detection technologies, terrorism, ethics and human rights

Research area SEC-2007-6.5-02

Ethical implications of the continuum of internal and external security

- INEX: Converging and conflicting ethical values in the internal/external security continuum in Europe

Research area: ERC-SG-SH2

ERC Starting Grant - Institutions, values, beliefs and behaviour

- DIGIDEAS: Social and ethical aspects of digital identities. Towards a value sensitive identity management

Research area ICT-2007.5.3

Virtual physiological human

- RADICAL: Road mapping technology for enhancing security to protect medical and genetic data