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Editorial
Decision Making in Modern Societies

Driven by the emergence of new technologies, modern societies are confronted with the necessity of making decisions which often turn out to be extremely difficult. Although modern technology is created in order to make life easier – and often does so – decisions at the individual, the organisational or the institutional/societal level are morally more complicated than before. Given this complexity, traditional decision-making patterns are no longer appropriate and new procedures and institutional settings are required.

Certain factors, which have driven this development, can be identified: First, the internationalisation and globalisation of technology, which requires efficient and legitimate global standards of interaction and communication (see the contribution of *Raymund* Werle and *Eric J.* Iversen). Second, the emergence of new forms of cross-border coordination, e.g. in international networks, which go beyond traditional governmental practices and sometimes counteract national policies (see *Petra Ahrweiler, Nigel Gilbert* and *Andreas Pyka*). Third, the compelling force of new technological opportunities and practices such as prenatal diagnostics which invalidates common patterns of decision making in the boundary area of life and death (see *Bernhard Wieser*). Last but not least the increasing autonomy of smart technology which gives rise to technological systems that replace human decision making by automated procedures of tiny, invisible, sensor-equipped computers (or networks of computers, see *Kerstin von Locquenghien*).

In all these cases, human decision making is assisted or even replaced by new technological devices and procedures or by new socio-technical settings in the first place. But rather than eliminating the need for decisions these developments increase the complexity of decision making. As a consequence, the implications concerning opportunities and risks are not adequately considered or remain unknown.

Modern societies need time to cope with the opportunities and the risks of new technology. Social practices and societal institutions change more slowly than technology. And often, the social adoption of new technologies results in unanticipated socio-technical settings. This issue of *STI-Studies* contributes to the reflection about socio-technical transformations which currently take place in different sectors of society.

Ingo Schulz-Schaeffer

Raymund Werle

Johannes Weyer

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Institutions Matter but … Organisational Alignment in Knowledge-Based Industries[1]

Petra Ahrweiler[2] (University of Hamburg)
Nigel Gilbert (University of Surrey)
Andreas Pyka (University of Augsburg)

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Abstract

A comparison of the current structures and dynamics of UK and German biotechnology-based industries reveals a striking convergence of industrial organisations and innovation directions in both countries. This counteracts propositions from theoretical frameworks such as the varieties-of-capitalism hypothesis and the national innovation systems approach which suggest substantial differences between the industrial structures of the countries due to differing institutional frameworks. In this paper, we question these approaches and show that the observed structural alignment can be explained by the network organisation of research and production in knowledge-based industries.

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[2] Corresponding author: ahrweiler@sozialwiss.uni-hamburg.de

1 Introduction

In knowledge-based economies the mechanisms of knowledge creation and utilisation are changing. Industrial economics and new innovation theory consider the increasing complexity of knowledge, the accelerating pace of the creation of knowledge, and the shortening of industry life cycles to be responsible for the rising importance of innovation networks. Knowledge-intensive industries such as IT and biotechnology have already undergone structural changes towards these collective modes of knowledge production and application. Such networks seem to be an important component of the emerging knowledge-based economies in which knowledge is crucial for economic growth and competitiveness.

For some authors, the omni-present networks even "constitute the new social morphology of our societies" (Castells 2000: 500) which are accordingly labelled as *network societies*. However, this suggests that network formation follows some global and universal trend affecting, unifying, and arranging all parts of society in "variable geometries" (Castells 2000) where heterogeneity and diversity is sacrificed for a single over-powering pattern of development. As we have mentioned elsewhere (Pyka/Ahrweiler 2004), this view does not take into account the complex reality of economic phenomena deeply intertwined with cognitive, institutional, organisational and political aspects, i.e. a world of institutional variety, historicity and path-dependence.

In this article, we argue that the relation between knowledge, networks and heterogeneous institutional frameworks is much more complicated than acknowledged by the protagonists of "globalisation" or the so-called network society. Network formation is, on the one hand, closely linked to the knowledge-intensity of a few industries and, on the other, not substituting but complementing the influence of institutional frameworks in order to co-ordinate economic action. The next paragraphs will work out these propositions in more detail.

2 Institutions matter

"At the start of the twenty-first century the role of institutions and the conditions for institutional change are at the core of the economic debate in Europe" (Amable 2003: 1). Neo-institutional approaches (e.g. North 1981; Olson 1984) claim that institutions shape the structure and dynamics of societies: they emphasise that each national society has developed a context and path dependent institutional infrastructure (politics, law, economy, culture). Economic actions are strongly influenced by these specific infrastructures, which accordingly lead to different national industrial structures and performances.

2.1 Varieties of Capitalism

Although, as the sociological "varieties of capitalism" (VoC) thesis states, national industries do look different, each formation can offer a particular comparative institutional advantage enabling economic success within the different national frameworks (Hall/Soskice 2001). VoC studies (e.g. Petit/Amable 2001; Amable 2003) maintain that UK and Germany have completely different institutional infrastructures: while the UK is labelled as a "liberal market economy", Germany is deemed to be a "co-ordinated market economy". The differences are traced back to national regulations of labour and corporate law, to institutional differences in competence development and technology transfer, and to differences in financial systems. Considering these wide-ranging differences in the institutional frameworks in UK and Germany, summarised in Table 1, it seems reasonable to expect substantial differences in the organisation of their national industries. Generally, Ger-

Table 1- National institutional frameworks in Germany and the UK

	Germany	UK
Labour Law	regulative (coordinated system of wage bargaining; constraints on employee dismissals)	liberal (decentralised wage bargaining; fewer barriers to employee turnover)
Company law	stakeholder system (two tier board system plus codetermination rights for employees)	shareholder system (minimal legal constraints on company organisation)
Skill formation and technology transfer	organised apprenticeship system with substantial involvement from industry. Close links between industry and technical universities in designing curriculum and research	no formal apprenticeship system for vocational skills. Links between universities and firms almost exclusively limited to R&D activities and R&D personnel
Financial system	primarily bank-based with close links to stakeholder system of corporate governance; no hostile market for corporate control	primarily capital market system, closely linked to market for corporate control and financial ownership and control of firms
		Source: Casper/Kettler 2001: 14

many is considered to be burdened with an "old" institutional infrastructure compared to the UK. German industrial society contains nationally unified institutions such as large industrial corporations, bureaucratic organisations, professional management, dual professional education systems, social security systems, labour unions and formal regulation, hierarchical co-ordination and a taylorised structure of work. As Heidenreich states: "There are no signs that Germany and other Continental European economies will follow the British lead and will get rid of their institutional structures developed over decades. These particular institutional settings cannot be dismissed as the *old garbage of industrial society*" (Heidenreich/Toepsch 1998: 14; own translation).

Compared to the UK, some requirements of modern knowledge societies (see e.g. OECD 1996) are less likely to be fulfilled by the institutional infrastructure in Germany. Focussing on knowledge creation, knowledge transfer and the commercialisation of knowledge, knowledge-based economies require permanent access across borders between nations and firms as a pre-condition for economic action. This is needed to achieve, for example, quick commercialisation of scientific results from basic research, easy access to finance for risk-intensive projects, the motivation of scientific entrepreneurs, and the availability of participative management skills. To satisfy project requirements, highly-qualified and flexible staff have to be able to migrate without the hindrances resulting from firm and education barriers (for German difficulties in this area see Soskice 1997, EPOHITE 2000). Table 1 summarises the issues.

The VoC literature would seem to predict that innovative industries, characterised by a high research intensity, extensive capital needs, and high risk and uncertainty, would face difficult development conditions in Germany and would be far less developed than the UK's – and that this will stay as it is because institutions change slowly, if at all. Compared to the UK, the comparative advantage of Germany would be best maintained by concentrating its strength in the conventional industrial sectors.

2.2 National Innovation Systems

The notion of "national innovation systems" (NIS) was introduced to innovation research in the 1980s to emphasise the important role played by the specific national institutional settings and non-economic actors for the innovative performance of an economic system. According to Beije (1998), an innovation system "can be defined as a group of private firms, public research institutes, and several of the facilitators of innovation, who in interaction promote the creation of one or a number of technological innovations [within a framework of] institutions which promote or facilitate the diffusion or application of these technological innovations" (Beije 1998: 256).

The NIS approach (Lundvall 1992; Nelson 1993) focuses on actors and their interactions embedded in a national institutional infrastructure. Innovation and innovation-based economic performance is organised differently across national borders. Like the VoC literature, the NIS approach concentrates on "the systemic aspects of innovation [and of] diffusion and the relationship to social, institutional and political factors" (Fagerberg 2003: 141). Lundvall, additionally, contributes an emphasis on competence building and the learning capabilities of individuals, organisations, regions and nations (Lundvall/Tomlinson 2002: 218, see the Aalborg-Freeman approach of NIS (Lundvall 1992)). Differentiating, elaborating and complementing the NIS concept, recent research targets sectoral systems of innovation (Malerba 2002), technological systems, regional innovation systems and local technology clusters (Feldman et al. 2005).

The NIS approach suggests a diagnosis similar to that of the VoC studies[3]. Balzat summarises the results of the 2003 innovation report of the German Ministry of Economics: "On the negative side, Germany has problems to catch up with the USA and with the Nordic European countries in the development and dissemination of technologies such as ICT and biotechnology. A rapid reversal of the German "backwardness" in this high technology field seems rather unlikely for three main reasons. First, Germany has lost ground in the level of ICT expenditure within the last decade. Second, the German labor market falls short of highly qualified workers and technical engineers. Third, the industry in the Eastern part of Germany is still far behind the West German in productivity levels and in the innovativeness of business firms" (Balzat 2004: 115). In order to compare different national institutional frameworks of innovation, Balzat constructed a NIS model containing 54 indicators that operationalise 19 sub-blocks of six main NIS components (knowledge base, financing conditions, internationalisation, innovation and learning incentives, innovative efforts, framework conditions)[4]. Figure 1 shows a simplified version of his NIS performance model.

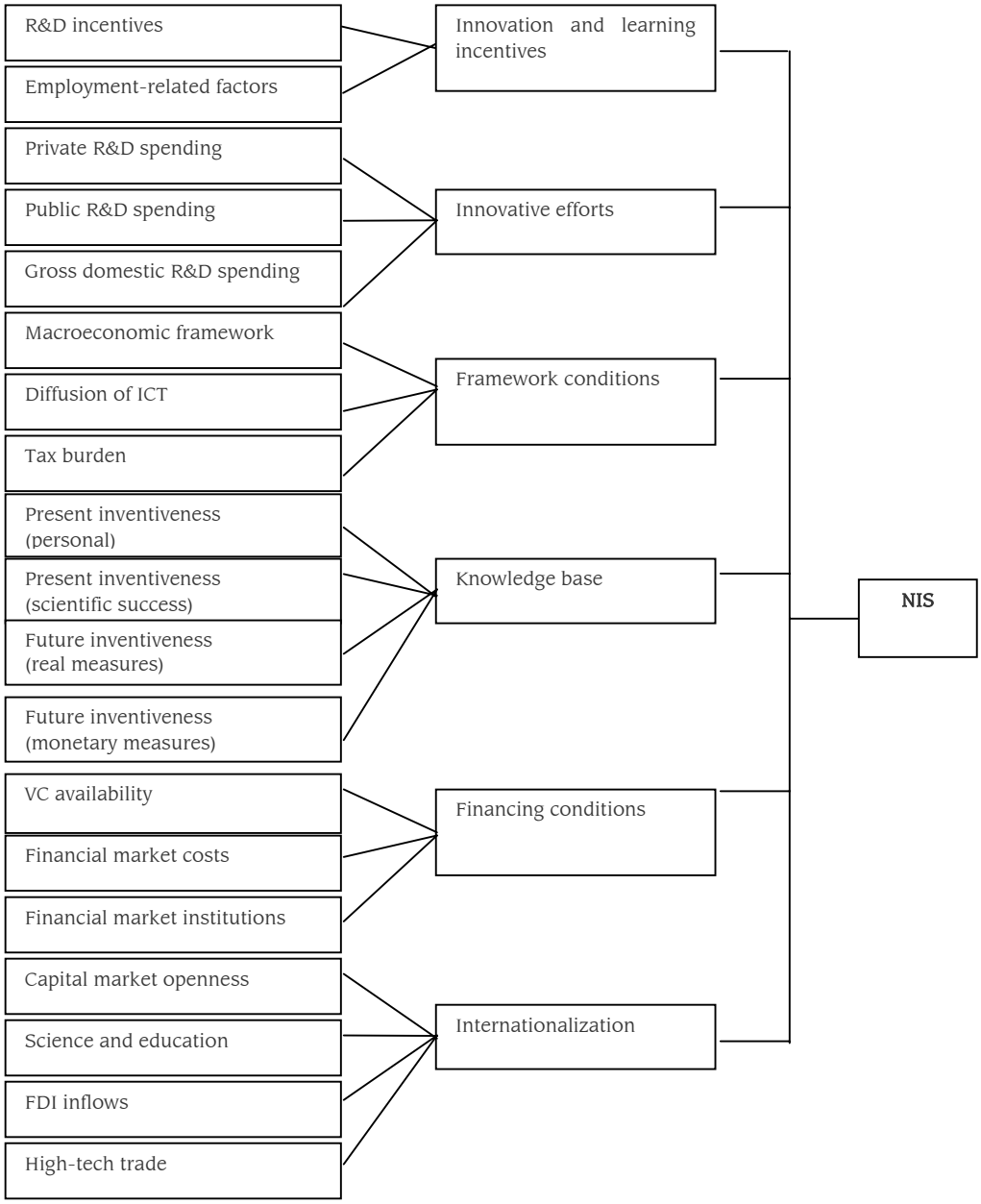
Using this set of indicators with the operationalisation mentioned in Balzat (2004), the differences between the national innovation systems of UK and Germany can be visualised as in Figure 2. The different designs of the national innovation systems in UK and Germany can easily be seen. Whereas the German system performs better in the dimensions of innovative efforts, knowledge base and internationalisation, the UK system shows advantages with respect to financing conditions,.

[3] For a detailed comparison of recent NIS and VoC approaches see Werle 2005.

[4] For a discussion of parameter construction, indicator building and interpretation of results, see Balzat 2004: 156-218.

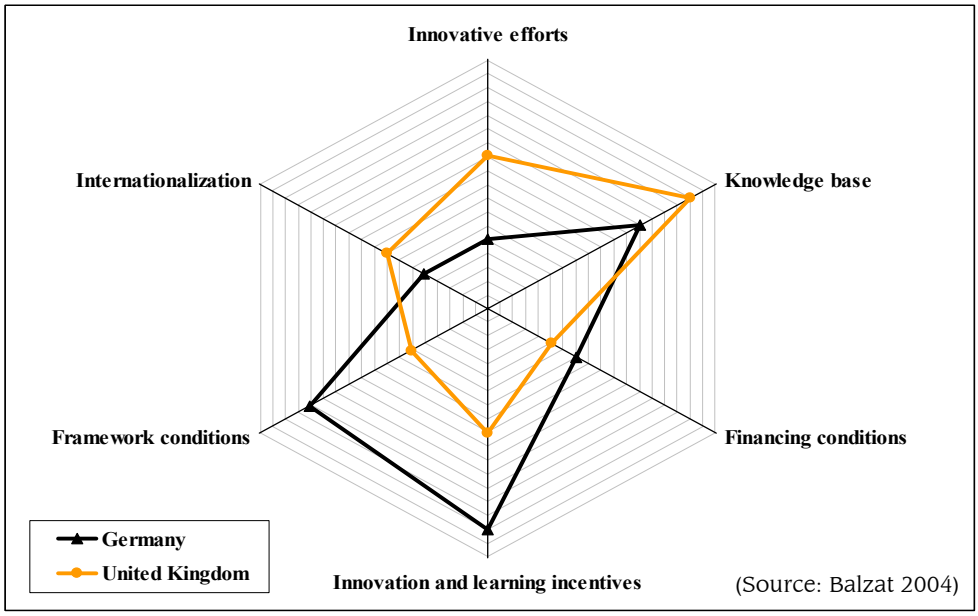
Figure 1: Indicators for comparing different institutional frameworks

(Source: Balzat 2004: 158)



learning incentives and framework conditions, all features important for the evolution of entrepreneurial industries. Summarising, both the VOC and the NIS approaches leave us with the same set of research hypotheses about Germany's and the UK's knowledge-based innovation. For the UK, as the example *par excellence* of a *liberal market economy* (Amable 2003), we expect entrepreneurial knowledge-intensive industries supported by progressive venture capital focussing on blockbusters following radical product innovation strategies. For Germany, as the example *par excellence* for a *co-ordinated market economy* (Amable 2003), we expect, *mutatis mutandis*, industries with a small rate of entry, conservative venture capital if any, and focussing on incremental innovation, i.e. process innovation.

Figure 2 - Comparing NIS components of UK and Germany



3 Institutions matter but…

There seems to be general agreement about the varying institutional frameworks of UK and Germany. For the manufacturing industries, in the last twenty years this has lead to divergent developments in Germany and Britain (e.g. machine tools and car manufacturing, for an overview comparing industrial structures in both countries cf. Matraves 1997). As the varieties of capitalism hypothesis states, this is also – and even especially – expected for the knowledge-intensive industries.

In the following sections we shall consider the so-called "red" biotechnology sector, which covers pharmaceutical applications of molecular biology, also often referred to as "biopharmaceuticals". Contrary to the expectations we derived from the VoC and NIS approaches, we shall observe striking structural and procedural similarities. The biopharmaceutical industries of the two countries have become more and more similar both in their focus on product *and* process technologies, and in the make-up of their industrial organisations (clusters, start-ups, spin-offs etc.).

3.1 Empirical evidence: the biopharmaceutical sector

In this section we will present some statistics describing the biopharmaceutical industries in the United Kingdom (UK) and in Germany (D).[5]

Figure 3 demonstrates market sizes and their growth, measured by the percentage of GDP of pharmaceutical sales. The markets are of similar size in both economies and the trends show the same direction.

Figure 4 compares the markets for pharmaceuticals in UK and D by depicting the market shares of novelties introduced by national companies within the last 5 years. Again the development and the overall sizes are rather similar for Germany and the United Kingdom. However, the German figure is slightly above the British figure over the whole time period.

[5] Except that, in some cases, the data we would like to have presented is not available and so we have used data about the pharmaceutical sector as a whole. A considerable part of the new technologies in the pharmaceutical sector are based on methods from biotechnology.

Figure 3 - Market Size in UK and D

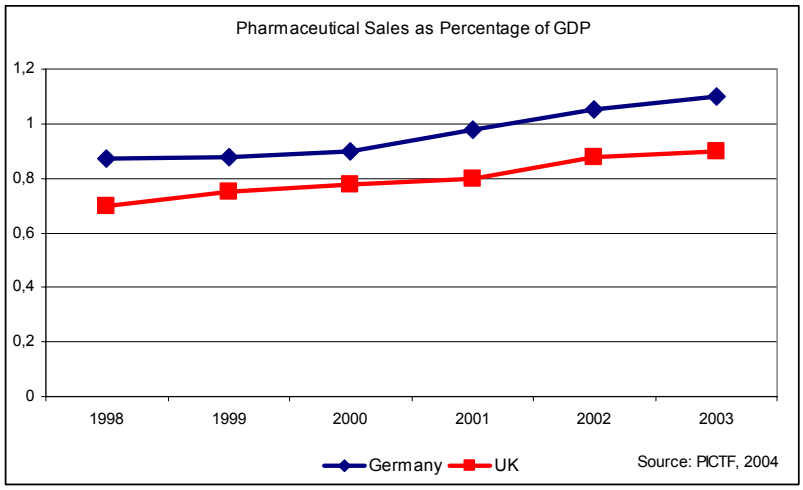


Figure 4 - Share of innovations in the pharmaceutical market in UK and D

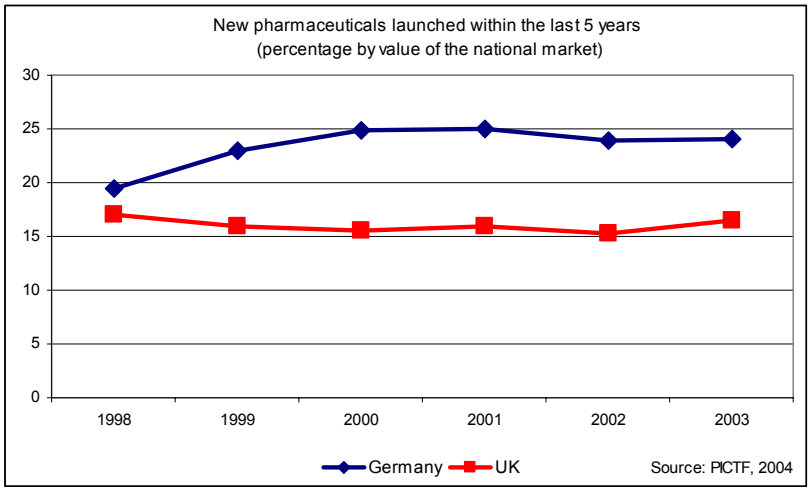


Figure 5 - International comparison of the number of core biotech firms

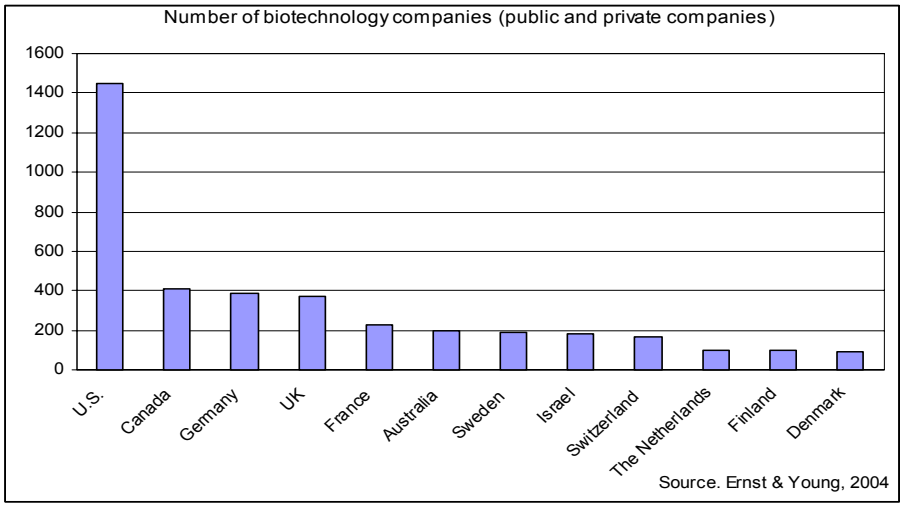


Figure 6 - Development of private biotech firms in UK and D

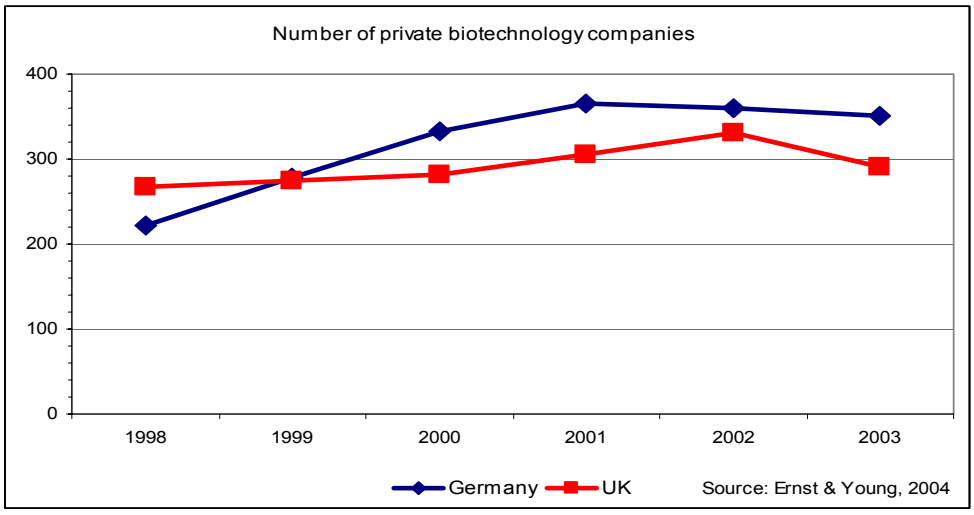
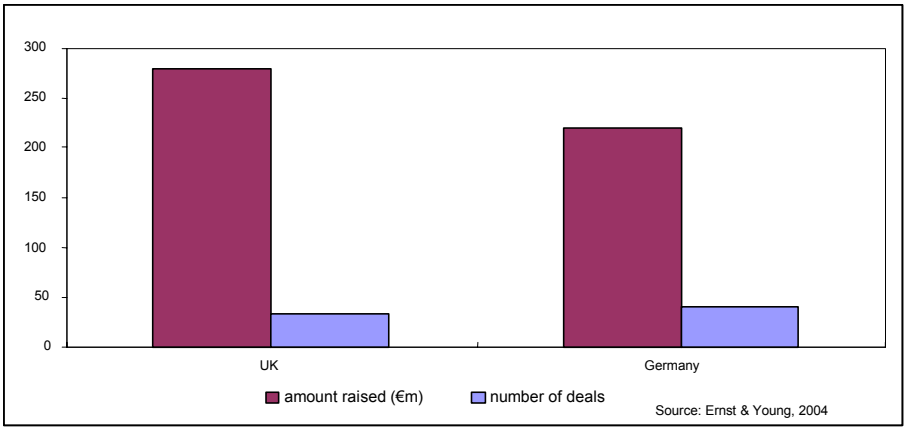


Figure 5 describes the size of the biotech firm population. For 2003, Ernst & Young (2004) records a rather similar number of firms in the two nations. If we look at the development of the firm population over time (Figure 6) we see that the number of German biotech firms has increased continuously and since 1999 is even slightly greater than the number in the UK in the same years.

If we examine the number of venture capital (VC) cooperations in both countries shown in figure 7, a corresponding similarity can be observed. The number of deals in Germany is slightly above those in the United Kingdom, whereas the amount of money involved in transactions is higher in the United Kingdom than Germany.

These findings seem contrary to what would be expected from the VoC literature concerning a comparison between the German and the UK biotech industries. A considerable entry of firms was only expected for the UK; for Germany, a similar development was not expected at all. Of course, a major reason for the proliferation of biotech firms in Germany must be the huge efforts to support entrepreneurial behaviour coming from technology policy.

Figure 7- VC cooperations in UK and D



3.2 Empirical evidence: firm strategies

The VoC studies also suggested that German firms would pursue innovation strategies that excluded product innovation, e.g. the development of therapeutics, expecting this country to stick with process innovation. Instead, data from 2004 show that more than half (56%) of the German biotech companies consider the development of therapeutics as their main area of action. A more detailed comparison from 2002 also points in this direction:

Table 2: Products in pipeline in 2002: comparison of Germany and UK

	Germany	UK
Products in pipeline	200	194
* pre-clinical	117	65
* clinical phase I	34	50
* clinical phase II	22	56
* clinical phase III	3	23

Source: Ernst & Young 2004

In 2004, 32 firms in each country were developing therapeutics that had already reached the clinical phase. Managers from UK and Germany reported similar reasons for their strategic decisions (Ernst & Young 2004). Chances, possibilities and risks are estimated in similar ways by managers in the two countries. A comparison of the number of new drugs introduced to the market in both countries (figure 8) shows that also the final outcome in UK and Germany is relatively similar.

Figure 9 shows German and British R&D efforts in an international comparison. The relative position of Germany slightly worsens in the time period shown, but both nations have very similar shares of the global total.

In Figure 10 we see the percentage of all pharmaceutical patents awarded to a country divided by the percentage of R&D efforts of its pharmaceutical industry, a measure of R&D efficiency. The efficiency for UK is higher over the four periods investigated. However, again the trend is in the same direction for both countries.

Figure 11 shows the time elapsing between the first application in any market and the launch in the particular national market in Germany and UK. The three main reasons for delay are company strategy (when to apply, when to launch), the length of the regulatory process, and the length of the pricing and reimbursement process. The time between approval and launch in the national market is somewhat shorter in Germany compared to the United Kingdom. However, in Germany it takes considerably longer if the time span between the first application and the application to the national market is considered. The regulatory conditions in Germany are accordingly less favourable in this single respect.

This section has clearly indicated the overall structural similarity of UK's and Germany's biopharmaceutical industries. The similarity is also visible from other countries: the foreign direct investment (FDI) inflows show that Germany, a 'co-ordinated' market economy according to the VoC thesis, is deemed as attractive as the UK, a 'liberal' market economy. Table 3 signifies the general FDI inflows for certain years without distinguishing sectors (here, Germany even overtakes the UK). While there is no data specifically for the biopharmaceutical sector, FDI Media Information (2005) shows that there were 23 FDI projects in the UK and 18 in Germany for the pharmaceutical sector as a whole.

Table 3: FDI inflows (as a % of GDP)

	1995	1999	2002
UK	1,8%	5,8%	1,6%
D	0,5%	2,6%	1,9%

Source: PICTF 2004

Figure 8 - Number of drugs introduced by UK and German firms

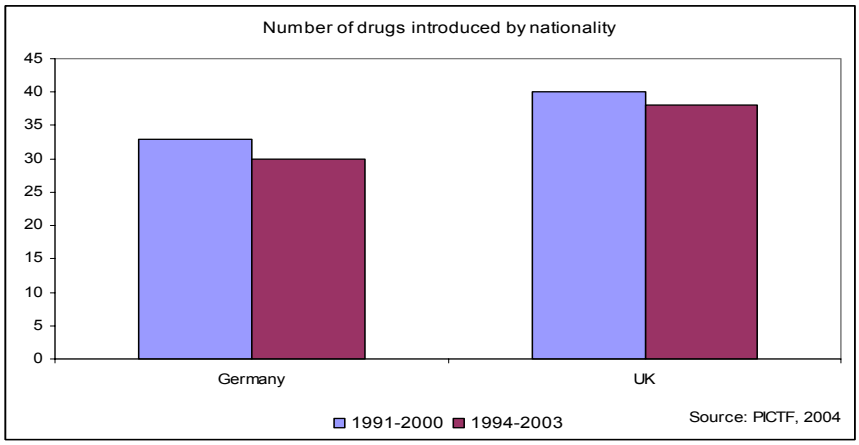


Figure 9 - Relative weight of research in the pharmaceutical industries

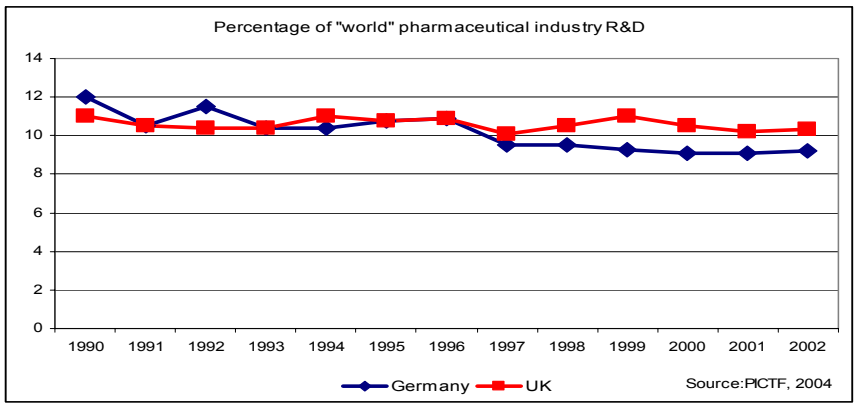


Figure 10 - R&D efficiency

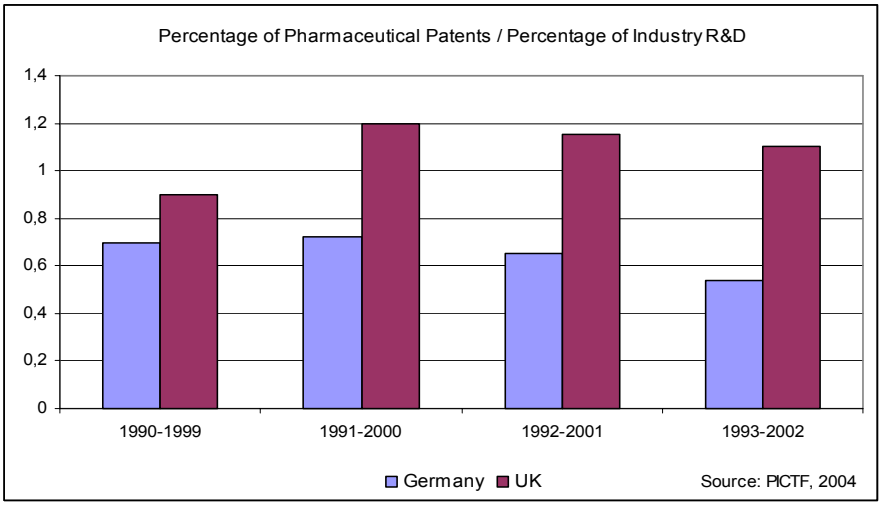
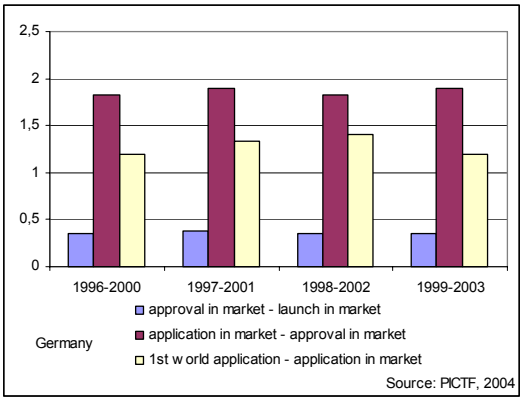
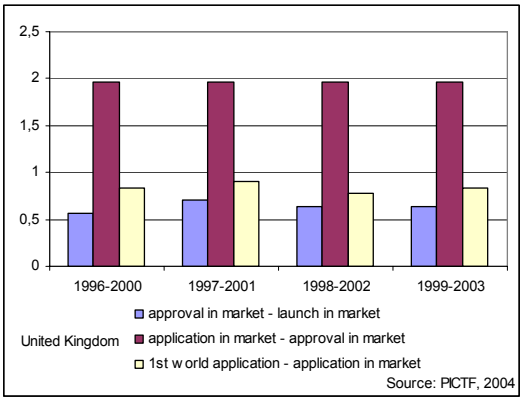


Figure 11: Time spans for market introduction of novelties

Germany



United Kingdom



Having now presented empirical support to show that the postulated differences between the German and British economies fail to be revealed when the recent development of biopharmaceuticals is examined, the observed convergence needs explanation.

3.3 Explaining the data: organisational alignment via innovation networks

Why do we observe these strong similarities in comparing the UK's and Germany's biopharmaceutical industries? The data summarised in the previous sections clearly offer no support for the research hypotheses arising from the VoC and NIS literature that predicted large differences in the two national settings. One possibility is that the national innovation systems, i.e. the institutional frameworks, of both countries, have themselves converged. However, this potential explanation is ruled out by recent studies focussing on their persistent differences (cf. Amable/Barré/Boyer 1997; Balzat 2004). Another potential explanation could be that the biopharmaceutical sector has some special characteristics which might overwhelm the effects of national institutional differences.

Our hypothesis is that *all* knowledge-intensive industries have characteristics which differ greatly from other industrial sectors: these characteristics directly affect innovation performance and provoke network formation and internationalisation. In the long run, the network effects of collaborative innovation mitigate or even overcome the effects of differences in institutional frameworks.

What are the special characteristics of the biopharmaceutical sector that trigger interactional collaborative innovation? Taking drug development as the most prominent feature of radical innovation in the biopharmaceutical industries, the first characteristic is the demand for up-to-date expertise which requires a permanent connection with the frontiers of research. For example, Herrera (2001) states: "research is the engine of Europe's Biotech Industry". Biotech firms are permanently "operating at the cutting edge of a set of technologies" (ibid) closely connected to universities and public research organisations. Furthermore, the development of a single drug needs a combination of different knowledge stocks and specialised expertise in a number of fields; it requires, for example, extensive clinical testing. Small firms such as university spin-offs have to build up a close connection to hospitals and big pharmaceutical firms in order to get access to relevant knowledge in these areas.

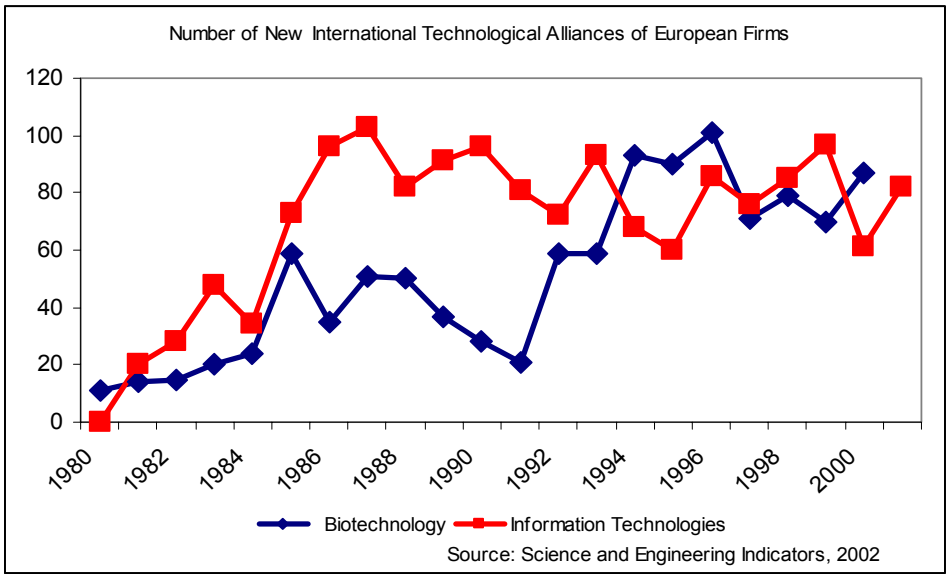
Because biopharmaceutical innovations rely on 'combinatorial technolo-

gies', large firms also have a need for networking: "Vertical integration is no longer the only way for pharmaceutical companies to have access to complementary and specific assets, especially at the first stage of cooperation. They take advantage of the complementary and combinatorial nature of biotechnologies to conceive new organisational forms within a cooperative relationship with both start-ups and public or quasi-public research organisations. Most pharmaceutical companies are engaged in more or less complex operations such as mergers and acquisitions, joint ventures, cross-licensing and, more generally multi-firm alliances. They often involve several bilateral strategic alliances with different actors. In this context, the strategy is to focus on many partnerships with widely diverse competencies and goals. At the industry level, this leads to a very complex mapping of ties between actors" (Staropoli 1998: 13-23).

How can these high demands for expertise, knowledge and R&D in various disciplinary fields be satisfied when they require the collaboration of actors from all over the world located in different types of organisations? By using the national public and private R&D efforts as input indicators and the number of national patents and other similar measures as output indicators, the VoC and NIS literatures conclude that national knowledge bases are restricted. External and in particular foreign knowledge sources are not adequately considered. Facing the global knowledge requirements mentioned above, these restrictions must be overcome on the firm level by actors who combine their competences and expertises – competences that cannot necessarily be found only at the national level. Innovation performance in knowledge-intensive industries, either incremental or radical, can only be achieved via international and inter-organisational partnerships.

Accordingly, we observe high and increasing collaborative activity in knowledge-intensive industries. Illustrating the general trend, figure 12 shows the new international strategic technology alliances for IT and biotechnology. The amount of collaborative activity at least matches and sometimes overtakes the cumulative number of collaborations for all other

Figure 12: Increasing network activity in knowledge-intensive industries



technologies (National Science Board 2002 Fig. 2-36).

In knowledge-intensive industries network formation does not seem to be a passing phenomenon, which disappears with the maturation of the industry. Instead, networks persist as the main structuring principle of the biotech industry despite firms changing their components, attachment strategies and structural properties. For example, in the UK and German biopharmaceutical industries, collaborative activity can be observed as a permanent feature. Collaboration is so important that a number of "matchmaking" firms (e.g. Pharmalicensing Intl. Inc., BioScan) have been established whose role is to inform companies about possible international partners.

For example, 86 percent of German dedicated biotechnology firms have R&D partnerships either with other firms or with research organisations (EBIS 2000). Not surprisingly, for both Germany and the UK, we observe a strong increase of collaborative activity in the early phase of the development of their biotech industries because of missing absorptive capacities and the inflexibility of established big firms (large diversified firms, LDFs), which have to rely on specialised small high tech enterprises (dedicated biotech firms, DBFs) to act as translators in order to bridge knowledge gaps (Pyka/Saviotti 2005). For their part, DBFs need the LDFs as commercialisers of their technological knowledge. As a result, we observe a change of the sectoral knowledge base: LDFs collect competences via fusions and acquisitions; and DBFs and LDFs form networks in order to benefit from one another's competences. The observed early co-operations between LDFs and DBFs are not restricted to a national level, as can be seen in table 4.

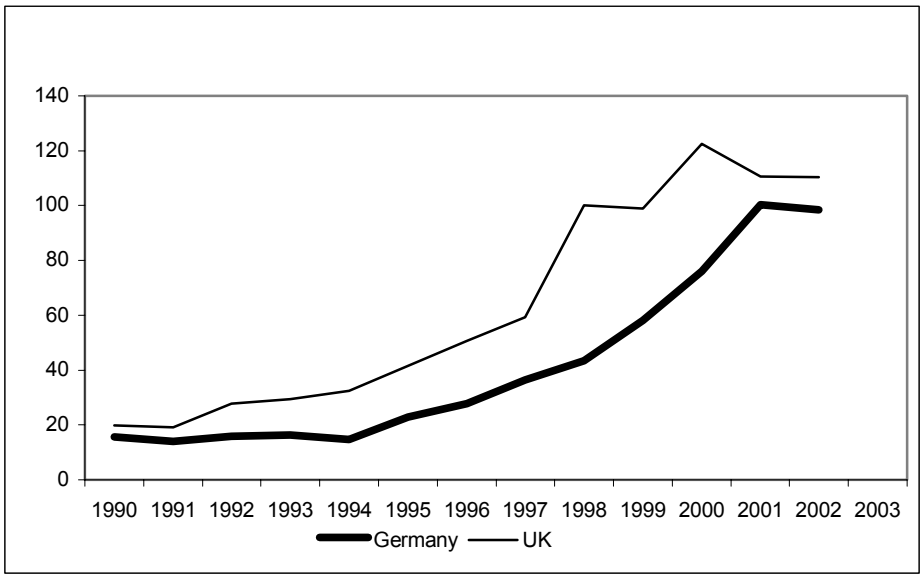
Later in the development of the sector, the composition, attachment strategies and structural properties of the networks change to a stronger focus on DBF-DBF partnerships and to the growth of financing as a tie between firms, in addition to R&D links (for a description of a similar evolution of network dynamics in the US biotech industries, see Powell et al. 2005). The

Table 4: Examples of international LDF-DBF networks

LDF	AHP	Bayer	Boeh. Ingel.	Dupont Merck	Eli Lilly	Glaxo Wellc.	Hoechst	Roche	Merck & Co	Novartis	Pfizer	SKB	Warn. Lamb.	Zeneca
DBF														
Affymax	2					1	1		1	2				
Affymetrix	1							2						
ArQule	2							1						
British Biotech.	1					2				1	1	2		
Celltech			1						2					2
Chiron							1	1		1			1	
CoCensys	1									1			1	
Human Genome Scie.								1				3		
Incyte Pharma		1			1		1			1	1	1		
Millenium Bio Therap.	1				2			1						
Neurogen	1										3			
Onyx		1			1								2	
Repligen					1	1			2	1	2			
Scios				1	1		1	1			1			
Sequana Therap.			1			1		1					1	
SIBIA					1	1				1				
Xenova													2	

Source: Pyka/Saviotti 2000: 28

Figure 13: Biotechnology patents (UK and D) with foreign partners



Source: OECD Corporate Data Environment and own estimations

trend towards international network formation also increases. Figure 13 shows the co-patenting activity of German and UK biotech firms with foreign partners.

UK firms have a higher proportion of co-patents but have less patents in total, which means that the two curves converge, providing yet more evidence of the similarities of the industries in the two countries, noted above.

Another factor leading to network formation and internationalisation is the biopharmaceutical industry's need for capital. To develop a new drug, capital of about 600 Mill. EUR must typically be available and the development will need a period of about 10-12 years until the point when commercialisation is a possibility. The immense resources required for R&D, clinical testing and marketing exceed the capabilities of single firms. The risks and uncertainty inherent in new drug development are indicated by the high exit rate of projects and firms.

When Germany is stated in the VoC and NIS literature to be at a disadvantage in the area of radical innovations such as drug development or in successfully establishing knowledge-based industries as a whole, it is the capital requirements and risks that are mainly considered. Summarising, it is argued (Casper/Kettler, 2001: 16f.) that the national institutional framework in Germany makes money scarce for risk-intensive and expensive projects (see above). However, this is true – at least in these dimensions – for any national economy, including the UK. To overcome the problem, network formation is the strategy of choice in both Germany and the UK. The missing resources are gained within globally-oriented innovation networks (international VC-DBF partnerships; international DBF-LDF partnerships, cross-border mergers and acquisitions). In addition we have shown in section 3.2 that foreign direct investment is important for the biotechnology-based industries as an external source for financing innovation.

4 Conclusions

National frameworks alone cannot provide the necessary knowledge stocks and financial resources to produce innovation in knowledge-

intensive industries. Complementing the collaborative activity on the national and regional level which is already significant, we observe increasing international network formation as the main organisational feature of research and production. These collaborations are intended to alleviate the disadvantages stemming from the restrictions of national institutional infrastructures.

While heterogeneity persists at the level of institutional frameworks and path-dependent innovation environments, the differences are of decreasing relevance in knowledge-intensive industries, where networks dominate industrial organisation and lead to convergence and alignment. In knowledge-intensive sectors such as the biopharmaceutical industry, the necessities of knowledge exchange, transfer, co-operation and diffusion between firms leads to a strong structural and dynamic alignment of national industries. Inter-organisational networks seem to offer a kind of "second order co-ordination" alongside institutional frameworks shaping economic action. Commonalities and differences of different "capitalisms" (as proposed by the VoC approach) or national institutional frameworks (the NIS approach) must be re-considered for modern knowledge societies.

Research is necessary to show how networks perform this alignment process and which network features qualify for what organisational reflexes. Social network analysis (e.g. Granovetter/Swedberg 2001; Kadushin 2004) suggests that dense networks (e.g. those now being established in the knowledge-based industries) tend to show the alignment of members and processes as a typical effect due to knowledge distribution in networks. The network members become more similar not only in their knowledge but also in their intentions and strategic behaviour. Agent-based modelling of network formation in knowledge-based industries (Gilbert et al 2001, Ahrweiler/Pyka/Gilbert 2004) sheds some light on the procedural aspects of these issues. Nevertheless, further theoretical, empirical and modelling efforts are required to work on the complex features of innovation dynamics and industrial organisation in knowledge-based economies.

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Promoting Legitimacy in Technical Standardization[1]

Raymund Werle (Max Planck Institute for the Study of Societies, Cologne)
Eric J. Iversen (NIFU STEP – Studies in Innovation, Research and Education, Oslo)

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Abstract

In this article we examine the legitimacy of committee standardization as an alternative to pure market processes of technical standardization of information and communication technology (ICT). We argue that not only mandatory (regulative) but also voluntary (coordinative) standards require some kind of democratic legitimacy. While the question of how to achieve this legitimacy has become central to today's changing world of standards, this situation is not adequately reflected in how the mounting legitimacy-deficit is treated. We note here that there remains a tendency to think of the legitimacy-deficit primarily in terms of "input legitimacy" criteria. At the same time we observe a tendency for standardization organizations (SDO) to orient efforts towards achieving "output legitimacy" by developing standards that are regarded by diverse groups of (legitimizing) stakeholders as constituting "good standards". This article therefore applies the distinction between input and output legitimacy to the rapidly evolving standardization landscape, arguing that it is necessary to expand the analysis of the legitimacy-deficit in the formal bodies responsible for ICT standards. We address what democratic legitimacy means in terms of standards and standardization, discuss why it is particularly important here, and explore how it has been addressed. Current examples indicate that in order to arrive at "good" standards SDO extend and redefine the cognitive and normative frame of standardization. This frame change helps to include non-technical and non-commercial interests and values without directly involving the growing variety of stakeholders and civil society advocates in the process.

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1 Introduction

Legitimacy of standards and the standardization process has become absolutely central to today's changing world of standards. Yet there remains a tendency to think of the legitimacy-deficit in standards primarily in terms of "input legitimacy" criteria, especially in terms of representation of different stakeholders during the standardization process. This focus on input legitimacy alone however inevitably falls short of the expectations of the theory of democratic representation which it attempts to live up to. Legitimacy based on this form of representation is extremely difficult if not impossible to accomplish in standardization. This has increasingly been recognized by the standardization organizations (SDO) which have started to work around the limitations of the engrained focus on input legitimacy alone.

A starting point for the article is thus the observable trend for SDO to re-orient their quest for increased legitimacy around efforts to achieve "output legitimacy" by developing standards that are regarded by diverse groups of (legitimizing) stakeholders as constituting "good standards". Here we observe that SDO increasingly attempt to provide for the consideration of interests and values of groups such as environmentalists, consumers or employees. Recently civil society groups have tried to establish more general public policy interests as the basis for deliberation in some SDO. This reinforces efforts of the SDO to avoid overloaded processes that attempt to directly involve too many stakeholders and advocates but to draw attention to their interests and values through modifying the cognitive and normative frame in which standard setting takes place.

In this light the article applies the distinction between input and output legitimacy to the evolving standardization landscape on the premise that effectively addressing the legitimacy-deficit requires coordinating both input and output based legitimacy approaches that are appropriate to different standards settings. We particularly address the area of voluntary ICT standards because these directly affect core aspects of the network society. We discuss whether different types of standards involve different legitimacy requirements, distinguish between input and output legitimacy, and look at the cognitive and normative frame of the committee deliberations in order to more precisely analyze the strategies of the standardization organizations to meet the legitimacy requirements. Some illustrations of more recent output-oriented measures are also presented.

2 Standards and legitimacy

2.1 Focus on ICT standards

Standards are acknowledged to be building-blocks for the information society. What these blocks are, how and why they come about, and what they achieve are matters the literature has, somewhat curiously, found difficult to provide uniform answers. The heterogeneity of concepts and definitions of standards and standardization testifies to the heterogeneity of the phenomenon. But it also reflects the fact that standards and the standardization landscape in which they are set continue to undergo profound change as a function of the brisk dynamics of the industry and changing power relations.

To a large extent the dynamics of the ICT industry are responsible for this change in institutional, organizational and process aspects of standardization. These are reflected in:

- The formal setting in which the process takes place (on markets, among firms, by committees).
- the rationale that initiated the process (e.g. to establish technical compatibility, to promote competi-

tive advantage, to minimize negative externalities),
- the mechanisms employed to involve the relevant stakeholders and allow them to help shape the standard (membership conditions, intellectual property rights, regulatory requirements, etc.),
- as well as characteristics of the outcome (public-good, private good content) and the forces that shape the expectancy to adopt or otherwise comply with the output.

How a standard comes into being and according to which mode it diffuses are crucial dimensions which affect the democratic legitimacy of the standard. This applies to all kinds of standards – product and process standards, measurement standards but also newer types of management standards. They all carry a cognitive or normative expectation to comply. Despite many commonalities there are also crucial differences between standards groups.

The argument here focuses on the legitimacy of committee standardization as an alternative to pure market standards processes. Our attention is concentrated on standards in ICT since this technological area brings together a pronounced reliance on standards on the one hand, with a central societal importance as the core of the network society on the other. Information and communication technology accelerates the diffusion of inter-organisational networks and intensifies communication and collaboration between organizations and individuals (Castells 2001). ICT facilitates e-business and e-government if standards are available and complied with. They ensure the compatibility of components and the accuracy of technical operations and they guide the use of the systems. The standards impinge on the benefit and risk which the utilization of technology entails for users and third parties as well. It has been argued that standards might even have an effect on the "democratic quality" of ICT (cf. Iversen et al. 2004).

2.2 Important distinctions in the world of standards

Concerning the legitimacy of standards it is important to distinguish between standards set on markets and those that involve formal standardization procedures. In the first case, individual commercial interests can manage to promulgate ICT solutions on the market where they become de-facto standards. The market is the ultimate selection environment for technologies and this is the default situation for the diffusion of standards incorporated in the technology. The diffusion of de-facto standards is based on market leadership or on bandwagon and imitation processes, in which the number of actors attracted by a standard increases with the number of those who have already adopted the standard.

Other standards are developed and agreed on in committees. Such committees, generally called standards developing organizations (SDO), are dedicated to the joint elaboration of standards. The SDO differ with respect to their degree of explicit institutionalization – some have a more official others a more informal character – but they share many procedural elements and rules of collaborative committee standardization. We will focus on these in section 3.

The distinction between market standards and committee standards arises from the circumstances of their emergence. Equally important from the perspective of the legitimacy of standards is the degree to which their compliance takes on an obligatory nature. Standards differ in this respect. Some are regulative others coordinative (Diagram 1).[2] Regulative standards – often in the form of maximum or minimum requirements and limits – aim at preventing negative external-

[2] This distinction serves an analytical purpose. Many standards blend coordinative and regulative elements.

ities through internalization, i.e. imposing the externalities on those who have induced them. These standards depend on governments or other political authorities to become effective within their area of jurisdiction. Thus, regulative standards for, say, environmental protection, have the normative character of a legal rule or an ordinance mandated by hierarchical political governance.

Coordinative standards, such as protocol and interface specifications, on the other hand, frequently aim at promoting interoperability and compatibility of technology in order to reduce transaction costs and to generate positive externalities. These standards cover economic sectors (industries) or markets for the respective technology, and they ignore political frontiers. Coordinative standards, say, a specific modulation procedure, emerge in markets or result from voluntary agreements. They are similar to conventions and tend to be self-enforcing, i.e. they enjoy a considerable likelihood of compliance (Schmidt/Werle 1998: 119, 120).

Put in game-theoretic terms, coordination is often akin to the "battle of the sexes". Here actors strive for a common solution but initially disagree as to which particular solution to choose. Regulation, on the other hand, shows features of a "prisoners' dilemma" where incentives to cooperate are so weak that, as a rule, no common socially beneficial solution is achieved voluntarily (Snidal 1985). The latter problem can only be overcome in a "collaborative regime" which is based on enforceable agreements secured by hierarchical political governance. Coordination in contrast can be achieved on a voluntary basis. In this case a "coordinative regime" facilitates institutionalized self-coordination by providing opportunities to communicate and to negotiate a common solution (Stein 1990).[3]

The two types of standards require different levels of democratic legitimacy. It is clear that standards that are imposed and that thus become mandatory need strong democratic backing.

Diagram 1: Two types of standards: An analytical distinction

	Coordinative	Regulative
Aim	Interoperability, compatibility	Prevention of negative externalities of technology
Mode of generation	Negotiation of agreements among "interested" actors, emergence in markets	Hierarchical political governance
Normative character	Convention, voluntary	Legal rule, mandatory
Area of validity	Industries, markets (techno-economic units)	States (political units)
Economic effects	Reduction of transaction costs, positive externalities	Internalization of negative externalities

(Source: Werle 2002: 246)

[3] This distinction of coordination and regulation looks at costs and benefits from a rational perspective focusing on interest and utility. But regulation, often taking the form of legal rules or law, also engages normative considerations and touches upon social values which are symbolized and reinforced by these rules. "Content" regulation – for instance, focusing on what is communicated or broadcasted via the channels of a telecommunications network – is usually based on normative as well as economic or commercial criteria.

Actors who benefit from the provision and use of a product or service will not be inclined to bear costs or other burdens which, as a side effect of their activities, are incurred by third parties. These actors, who may not even be aware of the negative externalities, are compelled by regulative standards to internalize the externalities. Thus, at first glance, these standards appear to be extremely precarious from the perspective of legitimacy. But if they are included in legal regulations, they derive their legitimacy from the national governments or the intergovernmental regimes which promulgate the standards. Accordingly, legitimacy is not so much contingent on how and by whom a regulative standard has been developed (e.g. by a bureaucracy or by an expert committee) but rather on the authority of the government or intergovernmental organization which adopts the standard.

The situation is different if political authorities have de-facto delegated regulatory power to an SDO. The "New Approach to Technical Harmonization" directive of the EU provides a case in point. According to this directive, European harmonized standards which include regulatory elements ("essential requirements") are developed by European SDO and de-facto binding without further endorsement by the political authorities. Similar patterns have evolved in national standardization. But as European and national SDO do not have the legal status of independent regulatory agencies (Thatcher 2002) political authorities must be concerned about the legitimacy of the standardization process: its openness, transparency, and democratic pluralism (Daelemans 1997; Egan 1998; Tamm Hallström 2004: 11-15).

Voluntary (coordinative) standards – no matter whether they were developed by an SDO or emerged in a market – seem to be less problematic than technical regulations as regards the requirement of democratic legitimacy. Formally nobody can be compelled to comply with a coordinative standard. But this view would be too narrow. Some standards may be indirectly promulgated by governments or courts referencing them in legal regulations or judicial decisions. Equally important is that particularly in network industries such as telecommunications and information technology coordinative standards can attain a quasi-mandatory status as a consequence of network effects (Shapiro/Varian 1999). If a standard becomes prevalent in such an industry, it may eventually lock in (Hawkins 1999). That means that producers and users of a specific product or service may be compelled to conform to the prevailing standard even if they have implemented a different one and face high switching costs. In this way, a coordinative standard developed by an SDO may require legitimacy comparable to a regulation despite being imposed through a market process.[4]

3 Deliberation in standardization organizations

Technical standards are never purely technical but can obscure commercial interests, political preferences, moral evaluations etc. at the same time that these underlying interests and choices are brought to bear. This ambiguity is again why the democratic legitimacy of all standards is at issue as a matter of principle. Following the above argument, legitimacy requirements can be said to differ depending on the type of standard in question. Regulative standards need a strong democratic legitimacy which they often derive from the political authority mandating the standard. The "burden" of achieving legitimacy rests on those who

[4] Tamm Hallström (2004) deals with issues closely related to legitimacy of voluntary standardization in her analysis of the strategies of two SDO to establish authority and achieve compliance with standards.

impose the standard and not on the standard's source, no matter if it is an SDO, a single expert or a government department. Only if regulatory authority is delegated to an SDO the organization has to deal with legitimacy requirements directly.

In the case of coordinative standards the legitimacy requirement diverges according to their source. If they evolve in markets in an uncontrolled process of spontaneous adoption by producers and users of technology nobody can be held responsible for the economic and social effects and the standards are taken for granted. If a dominant firm pushes a standard, this company may be blamed morally (rather than legally), but it will usually not be expected to endow the standard with legitimacy. Only if the coordinative standard has been developed by an SDO and exerts some pressure of compliance the question of legitimacy of the standard, respectively the organization accountable for its development, arises.

Hence, the issue of legitimacy primarily surfaces in committee processes in SDO. Technical standardization in a SDO is essentially a deliberative process. It sets out to address a recognized need for collective decision-making. Stakeholders may allude to a need for improved coordination between different parts of the value chain to reduce transaction costs, for a modular decomposition of a technical system to provide more choices for the consumer, or for new safety features to reduce accidents. Participants in the standards committee legitimize their preferences in collective interaction with other group members. Technical issues are always involved in the discussions and technical reasoning often guides decision-making. But from the angle of democratic legitimacy of the process and its outcome, the plurality of less technical concerns – ranging from the commercial to the moral – may play an equally important role in collective deliberations. A standard adopted by a committee exerts pressure to comply not only on the committee members but also on non-participants. In addition to this direct effect the standard usually has indirect or external effects. The direct and indirect effects will only be accepted or tolerated if the standardization process is regarded as legitimate.

How do SDO cope with the requirement of democratic legitimacy? If we look at the landscape of SDO we find different types of organizations which vary according to the geographical scope of their jurisdiction, their formal status, as well as to other features.

SDO can be national, regional or international in scope and they are official or unofficial (informal) organizations. The latter distinction is continuous rather than discrete. Furthermore, some of the national SDO have a regional or global significance.

The most prominent official international SDO (with national membership) are the standardization branch of the intergovernmental International Telecommunication Union (ITU-T), the international non-governmental International Standardization Organization (ISO) and its sister body, the International Electrotechnical Commission (IEC). Also at the regional level we have official SDO such as the European Telecommunications Standards Institute (ETSI), the European Committee for Standardization (CEN) and the one for Electrotechnical Standardization (CENELEC). The spectrum of official organizations is completed by national SDO which we find in all industrialized countries. Organizations such as the British Standards Institution (BSI), the Deutsches Institut für Normung (DIN), or the Association Francaise de Normalisation (AFNOR), are politically independent and formally non-governmental organizations, but they are accredited or recognized by governments. To some

extent governmental recognition lends legitimacy to an SDO.[5]

The majority of SDO are informal. They include national or international trade associations and professional organizations which, besides other more central activities, discuss and occasionally develop standards. The prevalence of informal standardization is most visibly indicated by the ever growing number of private consortia. Most of them are vendor-driven and many disappear once a particular standardization task has been finished. Few informal SDO have had such a continuous significance as the Internet Engineering Task Force (IETF) and the World Wide Web Consortium (W3C) in the area of Internet standardization. Participation in the IETF and its numerous working groups is open to anyone and a broad and unrestricted discussion of proposals via electronic mailing lists is possible. W3C is a member organization which develops basically all standards for the web. Members are companies from the industry and service sectors as well as research and education institutions.

The number of SDO is still growing and the landscape is steadily changing. The headline-trend can be summarized as a move from regulative to coordinative standards, from national to regional and international standardization and from intergovernmental and other official organizations to private consortia of standardization.[6] The proliferation of bodies has led to a degree of overlapping standardization activities which vie with one another for members and for getting their standards adopted. This competition between standards and standards bodies tends to heighten the importance of legitimacy where it might set apart a standard which is perceived to cater to a narrow set of proponent interests from a competing standard which lays claim to serve wider interests.

The proliferation trends indicate that despite undisputable diversity the SDO

Diagram 2: Prevailing institutional rules of standardization organizations

1. Participation is within certain membership rules open to those being substantially interested in the standards.
2. Usually members are organizations rather than individuals. Individuals are regarded as "delegates" of organizations.
3. The work is committee-based, cooperative and consensus-oriented. It follows formalized rules and procedures.
4. Organization and working procedures are impartial, unsponsored and politically independent ("due process"). The organizations are non-profit organizations.
5. The work is based on technological knowledge. It is not remunerated (voluntary).
6. Most standards are non-mandatory and public goods. However, they are not necessarily provided to the public free of charge (but on equal terms).

(Source: Werle 2001: 397)

[5] Usually SDO are accredited on the condition that they provide for the representation of consumer, labour and other interests.

[6] Mattli argues that the trend toward private consortia, he calls it "private governance" of standardization, has revealed limits and failings, including a lack of legitimacy, which have triggered moves toward "joint private-public governance" (Mattli 2003: 210).

show remarkable similarity concerning central institutional features (Diagram 2).[7] Apparently new organizations are designed according to the model of existing ones with respect to these features. This process of imitation and copying of organizational models, designated "mimetic isomorphism" by DiMaggio and Powell (1991), includes the bylaws and charters of many consortia, as well as the internal organization of work (Werle 2001).

The status of the standards which are developed by SDO is ambivalent as far as their legitimacy is concerned. Firms and users may not differentiate according to which organization a standard was adopted by as long as they regard a standard as beneficial and in this sense as "good". It is when the standard leads to detrimental effects that the legitimacy of the standard will be questioned. In this context the standard's origin and the democratic quality of the process of its development can be decisive.

Most institutional features included in Diagram 2 conform to the principles of a democratic decision-making process but they do not guarantee that they are fulfilled. Openness to participation for substantially interested actors (1), for instance, implicitly suggests that they do have access to standardization. But in most SDO work is not remunerated (5) and participants incur membership fees and travel expenses. Thus, engaging in standardization requires substantial financial resources and time.

4 Input and output legitimacy

Current changes of the landscape of SDO, mainly driven by the increasing number of consortia and the prominent role standards play in the changing regulatory environment, have triggered what can be called a competitive "market" for standards. This has repercussions for the strategies of SDO to achieve legitimacy for their products. We introduce the distinction between input and output legitimacy to address such strategies.

In the literature we find different variants of this distinction.

- Neo-institutional organization theory highlights two basic strategies to achieve legitimacy (Meyer/ Rowan 1991). Organizations either put emphasis on the input and internal "production" side demonstrating the involvement of a variety of actors working in accordance with impartial and fair procedural rules in an open technical discourse. Or the organizations focus on the "quality" of their products (output) designed to the benefit of the addressees or the general public.
- A distinction introduced in the debates about deliberative democracy points in a similar direction. Institutions can involve more "aggregative" or more "deliberative" arrangements. The first are mainly based on aggregating interests through direct representation in the decision making process, while the latter put more emphasis on the justifications of collective choices (Cohen 1998: 186). Here organizations are required to provide the basis for inclusion of a pluralism of preferences and values.
- Institutional political theory most explicitly draws on the distinction between input and output elements in terms of achieving legitimacy (Scharpf 1999). It is argued that central pillars on which input legitimacy rests are direct participation of all affected by a rule (standard) and decision-making based on consensus. Output legitimacy, on the other hand, is achieved by

[7] In a recent report it is maintained that in particular the larger long-standing consortia resemble the official SDO in many respects (NO-REST 2005: 75 ff.). Schoechle takes up a more sceptical position concerning the institutional similarity of official and informal SDO and the implications for legitimacy (2004: 149-214).

successfully dealing with problems which can only be collectively resolved. Among other things, that requires all interests to be considered (but not represented) in the definition of the collective interest. Thus, what is aimed at from the output perspective can be called "good" governance[8] or, regarding standardization, "good" standards. Ideally, such standards would be beneficial or acceptable to all who are affected by them regardless of their participation in the rule-setting process (Diagram 3).

the regional or global level – in international standardization where most committee standards with a global significance are adopted – only a minority of those interested or affected will be able to participate directly.[9] The question is whether this minority represents all those who cannot but, from an input perspective, should be present in a standardization committee.

The official international or regional SDO follow the principle of territorial representation with national SDO or other national representatives being

Diagram 3: Modes of achieving legitimacy in standardization

Input legitimacy Focus on the "production" (standardization process) • Openness to and direct representation (participation) of all actors interested in or potentially affected by a standard • Work in accordance to impartial and fair procedural rules • Decision-making based on consensus
Output legitimacy Focus on the "product" (standard) • All "interests" are considered (but not directly represented) in the standardization process • External tracking and monitoring of standardization by stakeholder and advocacy groups • Decision-making in an open inclusive discourse (arguing) to the benefit of all standards addressees ("good" standards)

SDO blend input and output criteria in their institutional design and in their operations. But particularly official SDO have traditionally put more emphasis on input legitimacy. A crucial principle here is openness. It requires that all affected individuals and organizations have the opportunity to get involved in the decision-making process. But this appears feasible only in a local (maybe national) context. At

their members. The national "delegations" are regarded as the voices and representatives of the aggregated and streamlined interests of all interested actors in the respective country. In principle, the international SDO adhere to the one-nation, one-vote decision rule which assures that every country (every national delegation) has a vote. If the question of legitimacy is limited to the aspect of territorial representation through national delegations and

[8] This concept has gained popularity in view of the European Union's "comitology" and the adoption of regulations by this committee system through a "deliberative" process in which "technical" expertise plays an important role (Joerges 1999).

[9] As indicated earlier, the prohibitive costs incurred by those being involved in international standardization in effect exclude interested parties from participating in standardization.

if the fiction is upheld that all affected interests are covered by these delegations the most significant requirements concerning input legitimacy of official international SDO are met. At the same time the burden assuring the involvement of diverse interests is shifted to the national organizations.[10]

Thus, national SDO have been the first to be confronted by the fact that many organizations and individuals with a legitimate interest in a standard usually do not participate in standardization despite their formal openness. Lack of resources, the collective action dilemma and other factors account for this deficit. This collides with the claim of the official SDO to develop standards which are dedicated to the public benefit. Early on many SDO tried to mitigate this deficit by involving different interests. Initially they stimulated user participation. But most users were big companies from industries such as media, finance, aerospace or defense and not small enterprises or consumers. In the 1970s, the SDO started efforts to promote the involvement of consumer, labor and later also environmental interests in standardization. Since the early 1990s, consumers have been represented in practically all national SDO in the industrialized world (Schepel/Falke 2000: 101ff). In many countries consumer representation is directly or indirectly financially supported by governments and also stipulated if the SDO want to be officially recognized. Typically special consumer councils or consumer committees are established which monitor consumer relevant standardization work, investigate consumer concerns and develop standards proposals on this basis. That means on the other hand that representatives of consumer interests usually do not directly participate in the deliberations of a standards committee.

Compared to consumer interests the representation of other non-industry interests is less well institutionalized. The northern European countries as well as Germany and France who to some extent share a corporatist tradition, provide arrangements for the involvement of trade unions in standardization while such arrangements are lacking in other countries (Schepel/Falke 2000: 123). Mainly in Germany where, in 1975, the Trade Union Federation (DGB) called for a "democratic" process of standards development "some major progress" can be observed concerning labor interests representation especially if occupational health and safety issues are at stake. But out of some 26,000 experts involved in standards committees of the German DIN only one tenth of a percent represent employees (Bamberg 2003). Without financial support by the German government, representation would be even weaker.

Yet less favorable is the situation at the national level to environmental interests. In a few countries officials from environmental offices or ministries participate in standardization. In rare cases representatives of environmental groups are involved in the work of technical committees. The German DIN set up a coordination office for environmental protection. This office, funded by the government, examines standards at the draft stage (Schepel/Falke 2000: 126).

This illustration indicates that issues of territorial representation are irrelevant at the national level. Rather a kind of functional representation with

[10] An official "Statement on Consumer Participation in Standardization Work" issued by ISO/IEC in 2001 illustrates this tendency to shift responsibility to the national level. ISO/IEC recognizes that "the interests of governments, manufacturers, all categories of users and consumers, and any others concerned, should be taken into account" and stipulates that "delegations to technical committee meetings should be in a position to represent all interests within their respective countries." <www.iso.org/iso/en/prods-services/otherpubs/pdf/copolcoparticipation_2001-en.pdf>

an origin in corporatist thinking is seen to facilitate achieving legitimacy (Voelzkow 1996). The involvement in standardization of a variety of non-industry interests, in the first place consumer, to some degree also labour interests, has gained importance, whereas environmentalists have to struggle to create awareness in standardization. Other interests and perspectives play an even weaker role.

Given these asymmetries at the national level one cannot expect national SDO to provide regional or international SDO with unbiased input. But these organizations have increasingly ceased to rely on national input anyway. In particular in ICT, the traditional bottom-up process of feeding national standards into supranational committees which then negotiate an international standard on this basis has been undermined by the shift of generic standardization to regional and international SDO (Büthe/Witte 2004). At the same time standardization has moved towards the early stages of technological design (ex-ante standardization). At the working level – where standards are developed, tested and negotiated – the regional and international SDO have abolished the principle of territorial representation and are open to direct membership of firms, R&D institutes, business associations, government departments and other corporate actors. National SDO only transpose into national standards what has been developed internationally. As a consequence the regional and international SDO have to respond to legitimacy requirements of the same type as the national SDO and they do so in the same way emphasizing functional representation and openness. But the barriers to including non-industry interests are even higher at the supranational than at the national level.

Again consumers' interests are more effectively represented than other non-industry interests. In Europe where the European Commission has traditionally mandated many standards and tried to shape the institutional landscape of standardization the Commission contributes to funding the European Association for the Co-ordination of Consumer Representation in Standardization (ANEC) which is based on a network of more than 200 consumer representatives across Europe. ANEC is an associated member of the European Committee for Standardization (CEN). At the international level the ISO set up the Committee on Consumer Policy (COPOLCO) in 1978 "to ensure that the voice of the consumer is heard in the development of standards" by selecting areas that are of priority to consumers and coordinating participation of consumer representatives in the technical committees developing standards in these areas.[11]

Labour interests in standardization are often represented by trade unions. At the European level unions mainly focus on health and safety standards which are often mandated by the European Commission and have the character of binding regulations. In 1989, the European Trade Union Confederation (ETUC) set up a Technical Bureau for Health and Safety (TUTB) which became an associated member of CEN in 1993.[12]

Participation of environmental groups in European standardization has a rather short history. Early efforts of the European Environmental Bureau (EEB), a Federation of Environmental Citizens Organizations, to get involved in standardization failed, partly due to a lack of funding by the European Commission of a technical bureau which was designed to organize direct

[11] <www.iso.org/iso/en/comms-markets/consumers/iso+theconsumer-04.html>

[12] In April 2005, the TUTB merged with the European Trade Union Institute (ETUI) and the European Trade Union College (ETUCO) – to become the European Trade Union Institute for Research, Education and Health and Safety (ETUI-REHS). Now this new organization is an associated member of CEN.

involvement of environmentalists in standardization. Instead, the European Environmental Citizens Organisations for Standardisation (ECOS) were awarded an EU contract, starting on November 1, 2002, which facilitates the coordination of input of environmental organizations into standards work. ECOS is a membership organization, open to non governmental organizations (NGO) active at a European or a national level. Assisted by the EEB, ECOS sends experts to technical committees and working groups of the European SDO. It is associated member of CEN and cooperating partner of CENELEC.[13] At the international level we find, for instance, IEC's Advisory Committee on Environmental Aspects (ACEA) which was created in 1994. In a recently published document ACEA draws the attention of the designers of electrotechnical products to the need to integrate environmental aspects into the product design. Another document concerning the inclusion of environmental aspects into product standards explicitly addresses the technical committees which develop them.[14]

5 Toward output legitimacy

Different formats have been chosen by the SDO to facilitate participation of consumer, employee, and environmental groups in standardization. In some instances, group representatives have direct access to the committees in which the detailed standardization work is done. In other cases special committees have been set up in the SDO to monitor and track the standardization work and to provide input into the working committee process if and when it appears necessary. Again in other cases, experts from consumer, employee or environmental groups are members of the boards of standardization organizations where they have the opportunity to draw attention to the interests and values they represent but cannot feed them directly into the standardization work.

But consumer groups and, to a greater degree, the other groups stress the lack of funds and other resources as a continuing obstacle to effective participation in standardization (Schepel/Falke 2000: 111-127). Another problem is the narrow focus of expertise of most experts who are delegated by a consumer, environmental or employee group into a standardization committee. Usually not all aspects of a standard are covered by a single expert. More serious is the issue of appropriate representation of the groups' interests and perspectives because it is difficult to establish that the view presented by the expert who represents a group is in fact the collective view (Hawkins 1995). As a consequence direct involvement of experts from consumer, employee and environmental groups in the SDO often fails to meet the expectations these groups associate with it.

Direct participation in the process of standards development and, if possible, also proportional representation by the participants of the plurality of non-industry interests and values would perfectly meet the requirements of input legitimacy. There is broad consensus that without public funding and other support, non-industry interests would not be represented in the standardization process at all. But one can have doubts that further efforts to "pro-actively support participation of relevant stakeholders in standardisation work at the national, European, and international levels" will really have the effect

[13] <www.ecostandard.org/about_who_we_are.php>

[14] IEC Guide 114: "Environmentally conscious design – Integrating environmental aspects into design and development of electrotechnical products" (Geneva, 2005) and IEC Guide 109: "Environmental aspects – Inclusion in electrotechnical product standards" (Geneva, 2003).

expected by the European Commission and other political authorities.[15] A look at standards development for the Internet confirms this view. Internet standardization has established itself completely detached from the official SDO as well as from the prevailing industry standards for networks (David/Werle 2000). The Internet Engineering Task Force (IETF) is more open and inclusive than any other official or informal SDO (Froomkin 2003). Only individuals (and not firms or other organizations) can be "members" of the IETF and most of the work is done via inexpensive electronic means of communication. But the expectation that these features attract many individuals with non-technical and non-industry interests and concerns has been disappointed. "By and large, vendors, service providers, and to a lesser extent, academia dominate the lists and the meetings" while users, for instance, "are as under-represented on the distribution lists and at the meetings as they are on ITU-T and OSI committees" (Jakobs 2000: 157).

Thus, achieving legitimacy through direct participation in standards committees is not only contingent on the openness of an SDO and the availability of public funding but also on the prevailing rules and principles governing the process of the development of standards. Of special interest in this context is the consensus principle which guides decision-making at the working level of standardization and is shared by virtually all official and informal SDO (see above Diagram 2). Consensus, essential for input legitimacy, is difficult to accomplish. Although it is not the same as unanimity and practices have evolved in many SDO to arrive at consensus this principle affords veto power to every individual involved. Thus, a tension between legitimacy through consensus and efficiency in terms of adopting many standards quickly is undisputable (Rada 2000).[16] The more diverse the interests involved in a standards committee are the more difficult it is to forge consensus. This is one reason why several informal SDO, consortia in particular, target industrial parties but hesitate to involve other stakeholders and participants as they might increase diversity (Werle 2001). But also in this respect the difference between official and informal SDO is one of degree rather than principle (Egyedi 2001).

The obstacles to direct participation of non-industry interests are multiplied if not only stakeholders such as consumers or labor but also civil liberties organizations and public interest groups are to be involved in standardization – a requirement that suggests itself from the point of view of the legitimacy of standards.[17] More than consumer or employee groups these organizations strive for technical solutions including standards which secure openness of technical systems, help protect privacy and provide for "democratic" elements in the design of technical systems in particular in ICT. Adding public interests groups to the circle of actors actively involved in

[15] General guidelines for the cooperation between CEN, CENELEC AND ETSI and the European Commission and The European Free Trade Association 28 March 2003. Official Journal of the EU 2003/c 91/04: 7-11, p. 10.

[16] New participants in the working groups of the IETF read the following instructions: "The general rule on disputed topics is that the Working Group has to come to 'rough consensus', meaning that a very large majority of those who care must agree. The exact method of determining rough consensus varies from Working Group to Working Group. The lack of voting has caused some very long delays for some proposals, but most IETF participants who have witnessed rough consensus after acrimonious debates feel that the delays often result in better protocols." (<www.ietf.org/tao.html#9.1>)

[17] Stakeholders are understood here as persons or groups with a direct *economic* interest, involvement, or investment in something, for example, the employees, shareholders, and customers of a company.

standardization increases the inclusiveness and the democratic quality of the process. The heterogeneity of interests and values is appreciated from a legitimacy perspective but if they are directly involved in standardization the result may be inefficiency, delay and deadlock of the process. Also, affected companies may try to bypass the respective SDO and turn to more exclusive ones.

A response of many SDO to this problem has been to put more emphasis on output than on input legitimacy of standardization. What counts at the end of the day is to issue standards which are accepted by the addressees or the general public as beneficial or at least as not harmful no matter how the details of the standardization process have been shaped. However, considering the possible positive and negative externalities of a standard, the "market test" (diffusion in the market) is not sufficient to establish its benefit. Developing a "good" standard requires facilitating access to SDO of as many diverse interests and values as necessary to assure that all relevant technical, commercial, socio-economic and socio-political aspects are appropriately taken into account. But it does not require that they are directly and proportionally represented in the standardization process by advocates and other representatives of these interests and values.

Although we claim here to observe tendencies of many SDO to put emphasis on achieving output legitimacy, we are not arguing that this indicates an encompassing general trend. It would also be misleading to infer that the SDO acknowledge a kind of functional imperative if they shift emphasis into this direction. Rather external pressure originating from three sources has been exerted on them, especially on the official SDO, to more explicitly consider the legitimacy of their standards and search for an adequate strategy to cope with this requirement.

1. In the first place policymakers and regulators have called for strengthening the legitimacy of standards. One step has been that many countries require formal public inquiries during the adoption of national standards by the official SDO. Also, in particular in the EU – resulting from the New Approach to Technical Harmonisation (in 1985) which spelled out that harmonized standards virtually always include regulatory components – the official SDO had to formally recognize the need to involve public interests into the standard setting process. As early as 1984, this was put forth in a joint memorandum between the political authorities and CEN and CENELEC. But the way of how to involve "public authorities, manufacturers, users, consumers, trade unions" and other groups effectively in the drawing up of European standards was left open.[18]
2. More general pressures can be associated with the dynamic market for standards.[19] The efficiency argument traditionally made to legitimize streamlining the standardization process by circumventing "superfluous" interests has to a certain degree been turned around. Initially competitive pressures have made a standard in line with consumer preferences more successful on this market than one that reflects the narrower commercial interests of business. Recent developments in ICT suggest that standards which have been adopted in a

[18] General Guidelines for Cooperation between the European Commission and CEN and CENELEC, agreed on 13 November 1984, and published as CEN/CENELEC Memorandum No 4. <www.cenorm.be/boss/production/production+processes+-+index/candidate+harmonized+standards/cclcgd004.pdf>

[19] A qualified indication is that there are around 400 standards bodies currently in operation. See the Consortium and Standards List at <www.consortiuminfo.org/links/>

more pluralist environment are perceived as equitable and therefore more appealing on this market.

3. A third set of pressures involves the activities of advocacy and interest groups. The advent of such grassroot civil liberties and public interest groups is linked to the emergence of ICT systems and their potential opportunities and risks. They have directed attention to technical standards which coordinate and regulate the development and use of the systems. These groups and their interests and values could no longer be ignored by the SDO which organizationally responded in various ways to these new pressures.

6 Reframing standardization

Achieving output legitimacy requires successfully integrating a great plurality of interests and values in the standardization process without necessarily requiring the direct participation of the respective stakeholders and advocates. This means that in effect the cognitive and normative frame in which the deliberations on standards take place must be broadened.

That the cognitive and normative frame of a collective decision-making process has an influence on the outcome has been shown in many experimental and "real world" studies in different traditions of social theory. In Goffman's seminal analysis frames are defined as basic cognitive structures which guide the perception of reality. They are adopted in a communicative process (cf. Goffman 1974). Frames promote particular problem definitions, causal interpretations and moral evaluations and they influence individual and collective decisions. Tversky and Kahneman (1985) demonstrate the behavioral effects of different frames in experiments which show that economic choices are controlled by the formulation of a problem as well as by habits, norms and values. In the early 1990s, frame analysis made inroads in policy studies. Frames are seen as constituting policy issues and at the same time providing guideposts for analyzing, persuading and acting on them (Rein/Schön 1993). Frames can change in discursive deliberations but in a stable institutional setting a new dominant frame does not replace previously legitimate frames (cf. Surel 2000).

For a long time, the cognitive frame of the standards developing process was a technical one. Standardization was perceived as a search process aiming at finding the technically optimal solution which then was easy to agree upon. The technical discourse among engineers prevailed and non-technical arguments tended to be considered illegitimate. Since the 1970s, this discourse has increasingly been supplemented in some and marginalized in other SDO by a business oriented commercial discourse.[20] Strategic commercial interests are argued in light of firm-level capabilities, complementary assets, any installed consumer-base, and of course the prospect of new customers. Thus, competitive concerns and profit interests are generally regarded as legitimate by the actors participating in standardization (Schmidt/Werle 1998). This shows that it is possible, in principle, to change the cognitive and normative frame of the standardization discourse and it has encouraged SDO to try to include other elements which direct the standards committees' attention toward non-technical and non-commercial issues.

The SDO gathered some experience with environmental implications of

[20] An indication that the technical discourse has still some relevance is provided by the IETF's widely cited philosophy: "We reject kings, presidents, and voting; we believe in rough consensus and running code." In this reading standardization is about finding not necessarily the best but a technically reasonable ("running") solution.

standards which, if at all, are usually revealed in a late stage of the development of a standard – too late to intervene in the process. As a consequence SDO such as the DIN in Germany or the European Committee for Standardization (CEN) established an Environmental Helpdesk with the task to advice and support the standardization committees considering environmental aspects. CEN has issued "Environmental Guidelines" to ensure the best possible incorporation of environmental aspects.[21] It is emphasized by CEN that the integration of environmental aspects in standards is a voluntary instrument to achieve environmental goals. But at the same time CEN requests that "every work item should include an assessment of the environmental aspects as early as possible in the process. It should preferably be done between the stage of approval of a work item and the stage of circulation of a first document at the latest, in order to avoid delays in standardization process."[22] We already mentioned comparable developments at the international level but what we want to emphasize here is that SDO continuously try to feed environmental aspects into the cognitive and normative frame of the standardization process. These efforts are reinforced by a significantly growing public interest for the environment.

Another notable attempt – initiated by public policy agents – aims at integrating the specific needs of "minorities" such as handicapped people in the standardization process. Traditional design of technology in effect excludes the handicapped. On the other hand the group of the handicapped and their needs are very heterogeneous, because this category spans a wide range of individuals from those with impaired vision, to those with different types of other functional disabilities. For that reason direct participation of handicapped in standardization would always imply selective rather than encompassing representation.

In several countries public agencies support relevant research and development and influence companies to consider these needs in the design and standardization of technology. One case in point is Norway which launched the "Information Technology for the Disabled (IT Funk)" program. This long term attempt shall affect standardization at the national and the supranational level in order to improve the conditions for the disabled mainly in terms of accessibility to ICT systems and services.[23] The other Scandinavian countries are involved in similar actions. The "Danish Centre for Assistive Technology" provides input into ETSI, CEN and ISO and tracks standardization processes from the angle of the needs of handicapped people. All Nordic countries run laboratories which test products but also propose European standards from this angle and provide feedback into standardization.[24]

Official SDO, in particular, have reacted to the emerging initiatives and pressures by either issuing guidelines for standard-makers on how to take into account the needs of disabled people[25] or setting up a special committee which is responsible for guidelines and standards that deal with requirements of disabled people (ETSI HF).

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[21] The CEN "Guide for the inclusion of environmental aspects in product standards" (Guide 4) was issued in 1998 and revised in 2004.

[22] CEN: Guidance – Consideration of environmental aspects in standards, version 1 (January 2005) <www.cenorm.be/boss/supporting/guidance+documents/gd050+-+environmental+aspects+in+standards/index.asp>

[23] <www.itfunk.org/docs/engpres.html>

[24] <www.hmi.dk/index.asp?id=482>

[25] See Guidelines for standards developers to address the needs of older persons and persons with disabilities (ISO/IEC Guide 71, 2001) and the European equivalent issued by CEN/CENELEC (Guide 6, 2001).

More recent developments indicate that awareness creation has shifted to the encompassing issue of how the interests and needs of all types of minority groups linked to the use of technology can be considered in standardization. Efforts in this direction emphasize the "design for all" principle. If this principle is taken into account in the standards development process the likelihood increases that the resulting standards are acceptable to all who are directly or indirectly affected by them. They may even help avoiding problems such as computer illiteracy and the "digital divide". The idea to influence the design of technology by promoting design for all principles in standardization emerged in the USA in the 1960s. The American National Standards Institute (ANSI) adopted "universal design" principles in 1961. In the following decades the idea slowly diffused to Europe and South-East Asia. A new bibliography on design for all principles indicates that more than 50 documents of different types produced by official supranational SDO address ways to include such principles in the deliberation on standards (Olsson/Lyhne 2005).

ANEC and other consumer associations strongly support design for all priorities. These principles have a root in consumerism but they are also rooted in the US civil rights movement. Based on the tradition of these movements new civil society and public interests groups have emerged which have become aware of the societal significance of technical standards. The Internet, in particular, has stimulated a broad debate regarding the democratic legitimacy of standardization in the Internet Engineering Task Force (IETF) and the World Wide Web Consortium (W3C) (Froomkin 2003; Russell 2003). More than in other contexts of standardization, general aspects of democracy rather than special consumer, employee or environmental interests are emphasized in this debate. Among the few public interests and civil society groups which highlight the significance of standardization is the Center for Democracy and Technology (CDT). This advocacy group has most actively struggled for the consideration of individual civil rights and civil society values in Internet standardization. In 1996, the CDT set up the Internet Privacy Working Group which initiated the development of technical privacy specifications in the W3C. Some members of the working group participated in developing the Platform for Privacy Preferences (P3P) standard.[26]

In an analysis of the experience gathered during this activity – but also in several cases in the IETF – the CDT points to the limitations of direct participation of public interest advocates in standardization (Davidson et al. 2002; Morris/Davidson 2003). Direct ongoing participation is regarded to be most effective, as in the case of P3P, but extremely time and resource intensive and, thus, not feasible as a standard operating procedure. But also the less resource-consuming ad hoc mode of participation is considered to be of limited usefulness because the public interest advocates retain the role of an outsider whose suggestions can easily be dismissed by the committee. An alternative to direct participation is seen in monitoring and tracking the work of standards committees by the public interest community. The CDT developed instructions ("ritualized public policy impact assessments") to be followed if standardization processes are monitored. This and other documents – characteristic of the efforts to broaden the cognitive and normative frame of standardization – aim at creating awareness of potential policy impacts of standards. They address different areas of public policy

[26] This standardized technology communicates the privacy policies of web sites to the users that connect to them (Cranor 2002).

concern, ranging from "Content Censorship and Control" to "Personal Privacy."[27] They shall be addressed by the standard developers when they design new technologies.

Taken together, these illustrations indicate that broadening the cognitive and normative frame of standardization is a promising option for SDO in a situation in which they have started to stress output legitimacy in response to the pressure to strengthen the legitimacy of standards. Reshaping the normative and cognitive frame of standardization is in itself a deliberative process in which ideally individuals with diverse interests, preferences and values should be involved (Hamlett 2003: 132). But this appears unfeasible in standardization, especially at the European and international level. Strategies to create advisory groups which monitor and occasionally intervene into the work of standardization committees and to issue guidelines which draw attention to issues usually not considered by these committees are at least one step toward reframing standardization. A broadened cognitive and normative frame makes it possible – but by no means guarantees – that non-industry interests and values are considered. They are not directly represented in the standardization committees but may be "invoked" by the members (cf. Feng 2005).

7 Conclusion

Adopting technical standards makes up a crucial step in the process of developing technology. It often takes place in company labs hidden from the public. A significant number of standards are developed in SDO. Company standards provide input into this process. They are voluntarily disclosed because the companies expect to benefit from the agreement on a common standard in the SDO. Participation in standards development is time-consuming, resource-intensive and requires technical expertise. Taken together it is not surprising that the majority of participants in standardization are agents of firms. Given the plurality of interests and values in society these agents are definitely not representative. The bias towards industry interest representation is – with few exceptions – strongest at the international level, where even small and medium-sized enterprises are absent, not to mention non-industry interests and values. The SDO are aware that this bias calls the legitimacy of standards into question – regulative (mandatory) and coordinative (voluntary) standards alike.

The institutional rules of committee standardization, in particular the relative openness and transparency of the process, in principle, attract participation by actors and groups interested in or affected by a standard. But without public funding and without pressure on the SDO consumer, employee and environmental as well as minority, civil society and public policy interests would usually not be considered in standardization.

Two (not mutually exclusive) options are available to achieve legitimacy of standardization by including non-industry interest and values. One option is to put emphasis on the input side of the process trying to balance interest and value representation through direct participation of all affected or interested groups. Apart from the high costs, direct participation would likely result in complexity overload and deadlock in the committees which are expected to decide on the basis of consensus. The overloaded SDO would be bypassed by industry and standardization would migrate from official and de-facto recognized informal SDO such as the World Wide Web Consortium into exclusive private consortia.

[27] Concerning the work of the IETF: Public Policy Considerations for Internet Design Decisions <www.cdt.org/standards/draft-morris-policy-considerations-00.pdf>

Partly because of these problems – but also partly as a consequence of an increasing number of interest and advocacy groups which claim to be directly or indirectly affected by the standards – the SDO have started to shift emphasis toward output legitimacy. The efforts to arrive at standards beneficial or acceptable to all affected vary with regard to their specific starting-point. But they share the aim to stimulate participants in standards developing processes to consider potential non-market and non-technical impacts of standards. They aim at broadening the cognitive and normative frame of the standardization discourse and creating awareness of a standard's implications without requiring direct participation of advocates and representatives of non-industry interests and values. This is mainly facilitated by guidelines for standards committees which promote the inclusion of non-market interests and values into the standardization discourse. In addition, special committees from outside or special boards within the SDO monitor and review the work of the standards committees and return an assessment to them. The ultimate aim of all these measures is creating good standards endowed with some form of democratic legitimacy.

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Inescapable Decisions. Implications of New Developments in Prenatal Testing

Bernhard Wieser (IFZ – Interuniversitäres Forschungszentrum für Technik, Arbeit und Kultur, Graz)

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Abstract

The main ethical principle in prenatal testing is the autonomous decision of the pregnant woman concerned. However, recent developments in prenatal testing undermine this model. The overall number of invasive* prenatal examinations has dropped significantly. Yet, the amount of pathologic results has increased. Due to the improvement in ultrasound diagnostics the predictability of possible disabilities or diseases of the unborn child has increased substantially. As a result of this pregnant women can take the decision whether or not to undergo invasive prenatal examinations on the basis of personal risk "evidence" produced earlier on by means of non-invasive* screening. It can be questioned, how autonomous decisions can be if they are increasingly pre-informed through upstream risk-assessments on the basis of non-invasive screening. Particularly ultrasound screening is often carried out without thorough counselling and sometimes even without consent. The concept of autonomy is difficult to uphold if women do not deliberately decide whether to undergo non-invasive screening, but the moment of such a deliberate decision comes only after positive screening results. Taking into account that public discourses have rather focused on other aspects of genetic or reproductive technologies such as stem cell research or pre-implantation diagnosis it is important to analyse how technological innovations transform medical practices without a re-articulation on a discursive level as I will try to show in this paper for the case of prenatal testing.[1]

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* Medical terms are explained in the glossary and marked with a * sign when first used in the text.

[1] Acknowledgement: The issues discussed in this paper were investigated in a research project called "Prenatal Testing: Individual Decision or Distributed Action" that was carried out by the author and his colleagues within the accompanying research programme (ELSA) within the Austrian Genome Research Programme (GEN-AU) funded by the Austrian Federal Ministry for Education, Science and Culture.

1 Introduction

It is generally assumed that in the current medical practice, prenatal testing requires *genetic* counselling*. In particular this is true for so called invasive (or diagnostic) methods such as amniocentesis* and chorionic villus sampling (CVS)*. This counselling is to secure the individual and autonomous decision of the pregnant women concerned. It is she and only she who should decide matters of prenatal testing. Not least for that reason, genetic counselling plays a key role in prenatal testing and has become an obligatory requirement in the procedure. The main task for the counsellor is now to give proper information on the subject. This is to inform the client's decision and to provide medical knowledge that a pregnant woman may not possess. A counsellor will be keen to talk about the implications of available examinations, possible risks they include and their potential outcomes. Experienced counsellors emphasise the importance of stressing that prenatal testing is not a guarantee for a healthy child and that there are certain limits to such examinations that anybody who undergoes them must be aware of.[2] Furthermore, it has become a standard that prenatal testing will only be performed if a pregnant woman has given her explicit agreement to the procedure, confirming that she has received comprehensive information and has decided after thorough consideration thereof.

This framework of prenatal testing refers to specific ethical standards, which are largely shared among counsellors and physicians in the field (c.f. Wertz/Fletcher 1989: 28 and 2004: 36-43).[3] These principles aim to give highest priority to the woman's right to decide for herself. There are certain measures to ensure that all decisions are left to the client. Most importantly this is through so-called "non-directiveness" in counselling. In short this means that the physician should serve as an informant, but must not influence or prejudge decisions in one way or another. This way "informed consent"* should be achieved. All together: "The counsellor-client relationship is based on values of care and respect for the client's autonomy, identity, welfare and freedom" (NSGC 1991).

It has been argued elsewhere (c.f. Clarke 1991: 1000; Marini et al. 2002: 171; Wertz/Fletcher 2004: 38) that in practice it is not so easy to actually come close to this ideal. But despite all the difficulties in applying these ethical standards, they still remain the dominant reference point for physicians and counsellors in prenatal testing. However, some have taken a critical view of the underlying individualism. Elisabeth Beck-Gernsheim for example has argued that the opportunity to decide is also an obligation to do so. In fact the possibility to not decide no longer exists (Beck-Gernsheim 1990: 157; Beck 1990: 52). A personal decision becomes inescapable. But, whoever decides is responsible for what follows from that decision. It can be argued that there is a specific coupling between individual decision and personal responsibility.

Undoubtedly the guiding vision of an "autonomous decision" in prenatal testing is a powerful driving force that shapes clinical practice to the present day. However, in this article I will

[2] Based on interview data as conducted by the author.

[3] Non-directiveness in genetic counselling is a concept that reaches highest acceptance among counsellors. In a survey on geneticists in 19 nations more than 75% of those surveyed agreed to this standard in more than 75% of the investigated countries (c.f. Wertz/Fletcher 1989: 28). Having investigated 36 nations in 1993-95 Wertz and Fletcher point to the fact that "unbiased information" is a guiding norm for English-speaking nations in particular and similarly important for northern and western European countries (c.f. Wertz/Fletcher 2004: 36-43).

argue that medical practice is not *exclusively* a matter of social constructions. In particular I will question how independent such a decision or informed consent actually is. For that reason it is the role of the medical technologies that is examined more carefully. To what extent do the testing methods applied exercise an influence on prenatal testing? In providing an answer to this question it can be shown how technological innovations contribute to the re-organization of medical practices.

2 Methodology

The argument presented in this paper is based on an empirical study carried out by the author and his colleagues. The study aims to examine the individual character of decisions in the course of prenatal testing and focuses on processes that contribute to an individualization of responsibility for decisions in the context of prenatal examinations. Among other research methods we have carried out expert interviews with physicians (geneticists and gynaecologists) who perform prenatal testing.

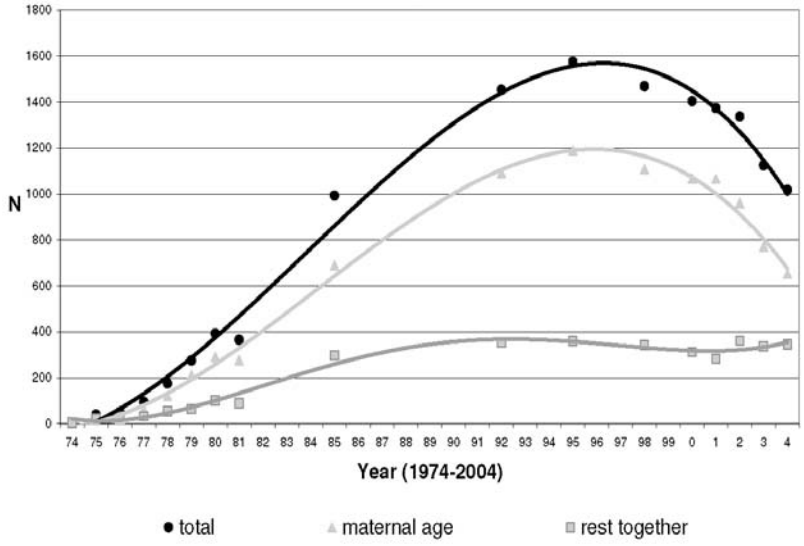
Purposive sampling was used to obtain a sample of 15 experts in prenatal testing. We have chosen interviewees who work in the major centres for prenatal testing in Austria. With one exception we could carry out interviews with physicians from all the centres for prenatal testing who run a cytogenetic* laboratory. In addition we interviewed physicians from a province which does not have a cytogenetic laboratory on its own, but send there samples elsewhere for analysis. One geneticist was interviewed who does not carry out prenatal testing anymore, but has done so previously. Ten of our interviewees are gynaecologists who carry out the prenatal tests in cooperation with one of the cytogenetic laboratories or have one in their own department.

Semi-structured guideline based interviews were carried out by members of the research team and were audio-taped and transcribed. The interviews were carried out in the offices of the interviewees and were typically one to one hour and a half long. All interviewees were informed about the purpose of the interview and asked for consent to using the material for our study. For the qualitative analysis we used a software for data management and analysis (atlas.ti).

In the course of the interviews our interviewees provided us with data of the tests they have performed. In this paper I will analyse these data on the frequency of the tests, the indications* they were induced, and the number of positive results. The analysis is informed by the expertise of the interviewees who explained the data to the interviewer. However, it needs to be mentioned that there are no consistent data on the *total* number of prenatal tests on a national level. Data are only available from the centres which offer such tests and willing to open up to social scientists. The figures presented in this paper are data of a particular centre, which can be regarded as a typical case. The centre is of national importance and one of the largest in the country. Our interviewees of the other centres observe a similar picture in their own context and confirm the trend we present here in the interviews we have taken. On this basis it is claimed that the presented findings give an appropriate account of prenatal testing in Austria.

The developments described in this paper can also be observed in other countries (e.g. Wray et al. 2005, Benn/Fang/Egan 2005 for the USA). However, it is difficult to generalize the practice of prenatal testing. The national health care systems are different and they provide different circumstances for antenatal care accordingly. Diffusion patterns of medical technologies vary from one country to another and also legal frameworks are

Figure 1 - Total number of invasive prenatal tests



Total: total number of all women who have undergone invasive prenatal tests (according to various indications).
Maternal age: tested women of advanced age
Rest together: tested women of all other indications

unlike to name a few parameters, which make it difficult to compare or even generalize. For that reason this paper does only claim to provide an analysis for Austria. On the other hand, medical science is highly internationalised and medical technologies are commercialised on a global market. Several of the Austrian specialists in prenatal testing have worked in other countries and learned from their colleagues abroad. For that reason developments in prenatal testing take place on an international scale, but they are situated in specific national or even regional contexts. This paper will bring together both dimensions and thereby exemplary show how international developments in diagnostic technologies are integrated in a national medical practice.

3 Medical background on the developments of testing methods

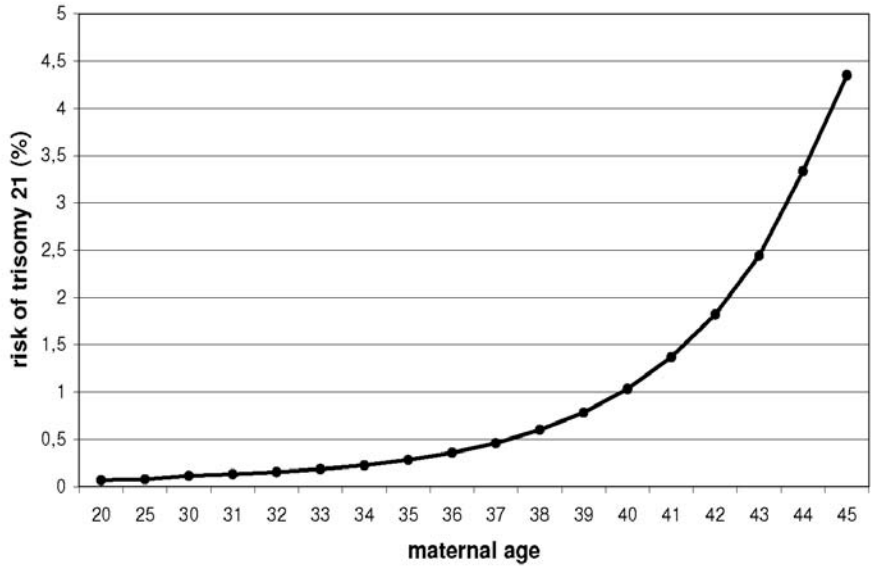
During the last ten years, quite a remarkable development can be observed in prenatal testing. The overall number of prenatal testing by means of amniocentesis and CVS is declining dramatically. In certain Austrian hospitals the total number has decreased by one third of its peak in 1995. Geneticists report that in Germany a decline of 50 percent can be observed[4] and a recent studies refers to a similar change in the USA (c.f. Wray et al. 2005: 353; Benn/Fang/Egan 2005: 328, Benn et al. 2004). In order to offer an explanation for the dramatic change in the frequency of invasive prenatal testing it is argued that the medical technologies applied play a major role. Decisions of pregnant women and

[4] Based on interview data as conducted by the author.

related counselling processes cannot be understood appropriately if technologies and the medical data they produce are seen as neutral or even negligible as an influence.

age. Women of 35 years and older show a higher risk of chromosome aberrations* (trisomies* or translocations*). As one can see from the diagram above (figure 1) up to three

Figure 2 - Maternal age and trisomy 21



Source: Snijders et al. (1999:169)

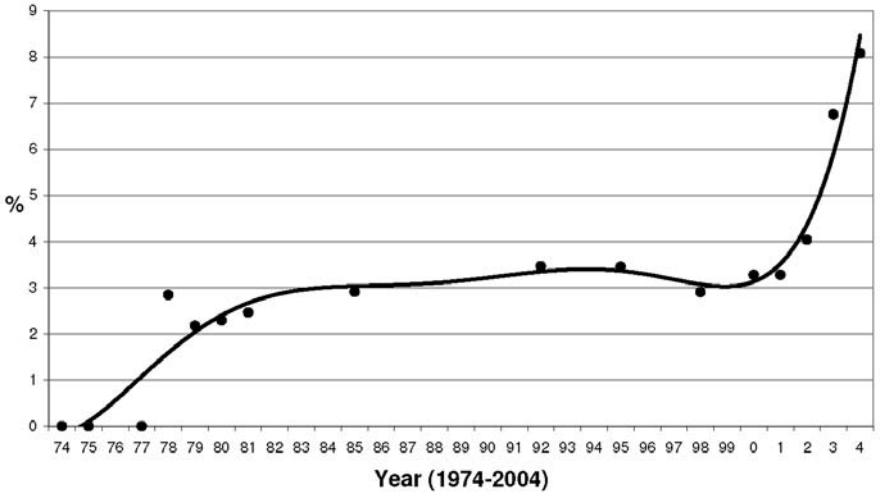
Taking a closer look on the diagram above (figure 1)[5], it becomes obvious that the dynamic of the total number of invasive prenatal testing is determined chiefly by just one factor: maternal age. Any test has a justification why it is undertaken and if the justification is "only" that a particular woman wants to have it. But most of the time there is a medical justification, i.e. a higher risk of foetal anomalies compared with that on average. If this is the case and there actually is such a higher risk, in medical terms this is called an "indication". For example a prenatal test could be indicated because a woman has previously given birth to a disabled child. Yet, in most cases the indication for a subsequent prenatal test is maternal

quarters of all invasive prenatal tests have been undertaken for that very reason (between 1978 and 2003 the ratio did not drop below 68% and reached its peak in 2001 at 77.6% in the presented case). Advanced maternal age is regarded as an indicator because of the correlation as described here: "Generally the probability of a birth of a child with Down's syndrome (and many other chromosome anomalies) increases with the age of the mother. The so-called age indication following from the fact that this is the most frequent reason for a prenatal chromosome analysis" (Sancken et al. 2003, my translation). A diagram (figure 2) shows the correlation between birth giving age of the mother and a higher rate of chromosome aberration; trisomy 21 in this case.

Generally it is true that women of advanced maternal age do have a higher risk. But for some reason this

[5] The figures refer to empirical data from a specific clinic, which remains anonymous here.

Figure 3 - Chromosome aberration in relation to invasive prenatal tests performed



Pathologic results with chromosome aberration in percent of all women tested with invasive methods.

correlation no longer plays such a significant role in the management of antenatal care. Advanced maternal age is not indicating an invasive prenatal test to the extent that it did only a few years ago. This becomes clear when considering the dramatic decline in the number of examinations indicated by advanced maternal age. At this point the question arises: why is that the case?

The first point to mention is that, if age is the chief indicator for a higher risk, many pregnant women will be tested. In Austria the proportion of women who are of advanced age (35 years and older) and give birth to a child is 15% (Statistik Austria 2004: 68).[6] This equates to 11,856 women in the whole country in 2002. However, even if, theoretically, all pregnant women of advanced age would be tested, the majority of trisomy 21 pregnancies will not be detected that way. This argument was already made at the time when maternal age was sharply on the rise. Wald et al. explained that "in practice fewer than 15% of affected pregnancies are detected because fewer than half of these older women actually have amniocentesis" (Wald et al. 1988: 883).[7]

Equally Saller and Canick pointed out in the mid 1990s, when age indication reached its peak: "by only offering amniocentesis to women older than age 35 only approximately 20% of foetal Down's syndrome will be detected" in practice, and furthermore they conclude: "This approach results in failure to detect the approximately 80% of babies with Down syndrome born to women younger than age 35." (Saller/Canick 1996: 784) Meanwhile the proportion of women who have babies at a later stage of their life has increased. Consequently the percentage of possible detection* with age as

[6] Only in 1981 the proportion of women giving birth to a child at the age of 35 or older was 6,4%; a total of 6.016 women (Statistik Austria 2004: 68). According to a recent publication in Germany the proportion of pregnant women of advanced maternal age is about 13%" (c.f. Sancken et al. 2003).

[7] This has been claimed for the UK where 5% of women are aged 36 or greater when being pregnant (Wald et al. 1988: 883).

an indicator has increased and is estimated at about 30 to 40 percent if all women 35 and older would be tested (c.f. Sancken et al. 2003). Despite the fact that maternal age has increased on average the majority of trisomy 21 pregnancies are still conceived by women younger than 35. Some have concluded on the basis of this that "with regard to the total population of pregnant women age indication is neither particularly sensitive nor very specific" (Sancken et al. 2003). In short, from a medical point of view maternal age is an indicator, but it is not a very good one. One could even say that it is not much more than a qualified guess that about four out of a thousand 35 year old pregnant women are carrying foetuses with Down's syndrome.

Following the described logic a more accurate indicator than maternal age is desirable. The point now is, that meanwhile there are better indicators that help to identify for an amniocentesis or CVS those women who have more reasons to undergo such examinations than simply being of advanced age.

When looking at the data one can observe that even though the total number of invasive prenatal tests has gone down by about 40%, the number of foetuses diagnosed with chromosome aberration is still going up.[8] Figure 3[9] shows how significant this development is by relating the number of test results with chromosome aberrations to performed examinations. If this development is a result of the availability of better indicators, so what are these better indicators? The answer to this question is: non-invasive prenatal testing is a better indicator for subsequent invasive examinations than simply maternal age alone.

Historically it was the so-called triple-test* that first provided a better judgement of the likelihood that a foetus would show anomalies. The problem with this triple-test is that it produces a relatively high number of false results as Babbur et al. point out in a recent publication: "For the screened population, to achieve an 88% detection rate using the triple test alone, the predicted FPR [false-positive rate*] would be 20%. Conversely, for an FPR of 4,8% using the triple test alone, the detection rate would be only 60%" (Babbur et al. 2005: 465). For that reason, the triple-test was controversial among physicians, and some Austrian hospitals decided not to use it any longer.

Also in the literature the triple-test is contested: "The original age indication limiting prenatal diagnosis to women over 35 has now largely disappeared in practice, so that every pregnant woman is notified of the possibility of PD [prenatal diagnosis] by her gynaecologist. The expansion of the use of PD has been driven by the so-called 'triple test', which makes it possible to identify an increased risk of chromosomal anomalies in a foetus from an examination of the mother's blood. Although this test is under severe criticism from human geneticists for its lack of validation and frequent false positive (and negative) results, it is offered by many gynaecologists as a 'safety first' test, which is often followed by a (frequently unnecessary) amniocentesis" (Hennen et al. 2000: 9).[10]

At first maternal serum* screening was offered as an alternative option for those women who did not accept the

[8] 46 chromosome aberrations out of 1067 tested women of age indication in 2000; 76 chromosome aberrations out 771 tested women of age indication of 2003.

[9] The figures refer to empirical data from a specific clinic, which remains anonymous here.

[10] Translated by the authors in an English summary of their working report (www.tab.fzk.de/en/projekt/zusammenfassung/ab66.htm; last access 07. Mar. 2006).

risk of amniocentesis or CVS. Yet, once these tests became available, they also gained the function of providing a more profound risk assessment for those women who wanted to have additional information prior to making a decision about having amniocentesis (c.f. Newberger 2000). Indeed maternal serum screening is still advocated as a useful means to reduce the number of amniocenteses (c.f. Rosen et al. 2002).

Meanwhile, ultrasound has also become more important, largely due to recent improvements. Initially, ultrasound was not precise enough to detect Down's syndrome foetuses (or other chromosome aberrations), but this has changed with technological advancements in the picture quality. At first, ultrasound was used at a later stage of the pregnancy and it was used for Down's screening only in cases where an indication was already given. Second-trimester* ultrasound assessment (15-23 weeks) was offered to women with increased risk "for trisomy 21 based on advanced maternal age or abnormal maternal serum biochemical marker screening, who either had declined amniocentesis or chose to have a sonogram before deciding whether to undergo amniocentesis" (Vintzileos et al. 1996: 949). In this case ultrasound serves as a second step to provide further evidence in an already ongoing risk assessment.

But, there is a tendency to turn this upside down. Ultrasound increasingly becomes the first step. "Increased fetal nuchal translucency is associated with chromosomal abnormalities, many fetal defects and genetic syndromes" (Souka et al. 2001: 9). Ultrasound measurement of nuchal translucency* is therefore used as a first-trimester screening test. Nuchal translucency first-trimester screening has a detection rate of about 76,8% at a false-positive rate of 4,2% (c.f. Krampl 2005: 86). In other words, three quarters of all foetuses with trisomy 21 can be identified that way, but this rate can be increased if other biochemical tests are performed additionally (called the combined test*). Together with an analysis of maternal serum (ß-HCG[11], PAPP A[12]) the detection is as high as 87% with a false-positive rate of 5% (c.f. Krampl 2005: 86). This can be further increased if an ultrasound of the nose bone is also performed.[13] Geneticists claim that it can be as high as 95 to 97%.[14]

Not only are there several alternatives in prenatal testing, they are also linked together: "Women who are screen-positive in the first trimester can elect to receive cytogenetic testing of a chorionic villius biopsy. The first trimester test could also, theoretically, be combined with the second trimester maternal serum screening test (integrated screening) to obtain even higher levels of efficacy" (Benn 2002: 1).

The point now is that pregnant women older than 35 do not need to decide whether or not to undergo an amniocentesis or CVS just on the basis of an anonymous statistical probability. Now they can take this decision on the basis of personal risk "evidence" provided by non-invasive testing. And if this is the case – that such a non-invasive screening produces a higher risk factor – results of the screening would justify a subsequent amniocentesis or CVS.

Currently there is a trend in invasive prenatal testing that such tests are performed less often just because of a

[11] Human Chorion Gonadotrophin

[12] Pregnancy Associated Plasmaprotein-A

[13] In case the result of an ultrasound examination between 11 and 14 weeks is the absence of the nasal bone (broad nosal bridge syndrome) this is understood to be an indicator for foetal abnormalities. "Research results indicate that including this marker along with the mother's age, baby's age, nuchal fold measurement, and blood tests can bring the accuracy of the risk assessment up to 97 percent." (BabyCenter 1997-2004b)

[14] According to interview data conducted by the author.

higher risk due to maternal age (an indirect guess based on statistics), but increasingly because of a higher risk due to risk "evidence" (based on previous tests). And this is a significant difference. Such "evidence" is still no proof, but from a medical point of view it is a much better risk assessment than a "guess" based on maternal age alone. The decline of invasive prenatal testing indicated by maternal age (figure 1) shows how outdated the latter has become as an indicator for invasive prenatal testing. The observed tendency can be related to the increased application of non-invasive screening tests. Taken together a shift can be observed. This includes a shift from maternal age indication to testing as a result of prior screening, but a series of other changes are evident, too.

1. Increasingly there has already been some sort of examination – on the basis of which a higher risk is determined – before invasive testing is carried out. Maternal age, on the other hand, is a presumption without more specific empirical evidence for the specific case. Now that maternal age has lost its importance as an indication for invasive prenatal testing, other indicators have become more important.
2. These other indicators which have become more important are produced by means of non-invasive screening methods, mostly ultrasonic tests (and the combined maternal blood test) as already mentioned. And because non-invasive tests have become more important and more reliable, the total number of amniocentesis and CVS has gone down dramatically.
   "*For many years, research on maternal blood tests has been performed. A tendency towards preselection on the basis of non-invasive methods can be noted. This way, an earlier start, higher effectiveness and higher acceptance can be achieved as well as a distribution of prenatal testing across all stages of age*" *(Arbeitsstelle Pränataldiagnostik/Reproduktionsmedizin 2004).*
3. As mentioned in the previous quote, the current shift in prenatal testing represents also a shift towards testing at a much earlier stage, from second to first trimester of the pregnancy. Time is in fact a major factor in prenatal testing and many have argued (c.f. Katz-Rothman 1989) that the earlier the testing the better it will be. Not only does the time a women has to wait for the result matter (which is a major disadvantage of amniocentesis), but also the advancement in the pregnancy makes a difference. If an abortion is to be considered, this is easier to cope with before the 24 week of the pregnancy when a curettage* can still be performed.
4. The tendency is noted that non-invasive techniques lead to an expansion in prenatal testing. A growth in participation can be concluded since the number of invasive tests has gone down but the number of pathologic results has increased significantly at the same time (see figure 3.). Most likely this is explained by more young women deciding in favour of a non-invasive screening.
5. Another reason for the expansion of prenatal testing can also be related to the fact that invasive tests require a specialized laboratory that is able to carry out the analysis. In Austria there are only a few of such laboratories.[15] Non-invasive techniques, however, already have a much higher dis-

[15] In fact the common practice in invasive testing is that the sample was taken not only in clinics which had a cytogenetic laboratory. Those who did not have a laboratory on their own would send it to one of these institutions for the analysis.

semination and can be performed in a number of clinics.

6. Non-invasive screening tests also lead to "inescapable decisions". Generally, all couples are at risk of conceiving a child with chromosome aberrations or other anomalies, but a statistical probability does not tell who will and who will not. Advanced maternal age is a hint that the probability increases with age, but it does not tell who will actually give birth to a child with chromosomal anomalies. Only an invasive test can answer this question. But now non-invasive screenings provide an individual risk figure. By these means, decisions are increasingly taken on the basis of individually determined risk and not any longer on an anonymous statistical correlation, which could distinguish a certain age group at best. In this sense, one could say that invasive tests have become more medicalized, because decisions no longer start from zero.
7. Finally a last shift can be noted. The decision-making process is divided into a number of small decisions. There is no such thing as "one" decision, where everything is decided at once. In other words, decisions are by no means a-priori, i.e. without pre-conditions. On the contrary, decisions are taken step by step with one leading to another: first the individual risk is determined, then a definite diagnosis is produced and only then does the question arise about whether or not to abort the pregnancy.

As the presented data show the shift described has only come about only recently. In the second half of the 1990s a stagnation of performed invasive prenatal tests can be noted. However, that this development would turn into a decline became clear only after 2001 when tests induced by age indication significantly dropped.

Obviously the technologies which have lead to the mentioned changes in prenatal medicine have been developed several years earlier. Nuchal translucency measurement was developed in the 1990s and combined with maternal serum markers thereafter (c.f. Nicolaides et al. 1992; Brizot et al. 1994). Until the innovation could exercise its full impact in Austria, physicians had to be trained (in London at King's College), but also the knowledge about the existence of the new method and who is able to perform it had to be communicated. Furthermore it takes some time to change the regime of antenatal care in which pregnant women are informed about diagnostic possibilities and referred to respective specialists. However, meanwhile the shift has become evident. One of our interviewees explained that they have a participation rate of 99% of all women who give birth in their hospital. A physician from a centre in another province of the country said: Yes, we offer non-invasive screening to all pregnant women. They only come to me after the screen. And from a third centre for prenatal testing we know that the number of chromosome aberrations diagnosed (with invasive methods) has doubled since 2000. This means that also the number of tested women has at least doubled taking into account that more and more young women are screened with nuchal translucensy measurement. Although comprehensive data of the entire country on the participation of pregnant women in antenatal screening programmes are not available there is clear evidence for a substantial diffusion of non-invasive screening methods.

4 Discussion

It is argued that the observed shift in prenatal testing leads to an individualization process. From a medical point of view it might be desirable to have a more accurate risk assessment, which allows for a better management of invasive prenatal testing (decisions

seem to be evidence based and therefore more rational). But on the other hand the determination of an individual risk can also be seen from a sociological point of view.

The notion individualization was prominently introduced by Ulrich Beck in his book "Die Risikogesellschaft" (Beck 1986) and Elisabeth Beck-Gernsheim (1990) has discussed individualization in the context of reproduction. Already when the concept was introduced it was argued that individualization does not only lead to an increased freedom of choice, but that it would also lead to a pressure to take decisions. Furthermore Beck argued that individualization is paradoxical and includes what he has called "control" or "reintegration dimension" (1992: 128). From this point of view prenatal testing means the integration of pregnant women into a control regime. Indeed, with the expansion of ultrasound screening more and more pregnant women are integrated into a medical network, which determines their individual risk for foetal anomalies. In his Book "Discipline and Punish" (1975) the French philosopher Michel Foucault has defined individualization as the identifiability of the individual. Following this understanding of individualization it can be argued that the prenatal regime aims to differentiate pregnant women and this differentiation is predominantly carried out in terms of risk. The place they are allocated to is derived from a sophisticated risk-assessment.

Nevertheless, this does certainly not mean that pregnant women are not free to decide. It is essential for prenatal testing that it is the women concerned who decide about their own pregnancies. This results in a fundamental paradox: There are more and more possible decisions, but these possibilities are produced in a systematic way. Thomas Lemke has argued that decisions become increasingly choices between options, but the options are pre-given beforehand and structured by pre-decisions (c.f. Lemke 2000: 243). It is increasingly impossible *not* to choose because it is harder and harder to escape the risk assessment by means of ultrasound screening. Choices promise freedom, but the confrontation with one's individual risk demands a decision which takes the screening results into account.

Whether a chromosome anomaly is actually given or not can only be clarified through an invasive diagnostic step (cytogenetic methods are not based on statistical methods, but they provide definite results at a very low rate of false results). However, such invasive tests are bound to a risk of miscarriage (c.f. Evans/Wapner 2005). For this reason many women want to avoid an invasive examination. But as it has been argued in this paper such decisions whether or not to undergo an amniocentesis or CVS are increasingly bound to an upstream risk assessment. Hence these decisions are *not* taken without conditions, they are taken under consideration of medically generated data.

The point now is that these risk-data are produced in a framework which substantially differs from invasive testing. Our interviews suggest that increasingly genetic counselling is only performed in cases of positive screening results (prior to invasive testing). Decision autonomy is still the central ethical orientation in prenatal testing, but the consent procedure prior to non-invasive screening is largely formalized and often women don't realize the significance of the examination. Women are still asked to decide and they are explained that it is their own personal decision, but the moment of such a deliberate decision comes only after positive screening results. It is questionable if such decisions can be accounted "autonomous" if they are taken against the backdrop of a risk-assessment produced by medical examinations.

Apparently the described technological transformation in prenatal testing goes along with significant changes in the practice of its application. However, the assumption that "technical change causes social change" is usually labelled as technological determinism (MacKenzie/Wajcman 1985: 5). Günter Ropohl talks about "consequential technological determinism" (1991: 193). The criticism is, that technology is nothing original, but technology itself is socially created.

Nevertheless, one may ask, why it is possible to carry out non-invasive testing in a different organizational framework than invasive testing: Why is it possible for gynaecologists to perform nuchal translucency measurement without thorough conversation about the significance of the examination, whereas geneticists still insist on profound genetic counselling prior to amniocentesis? Both test methods are predictive malformation diagnostics. Thus the differences in the practice of their application require an explanation.

The risk of miscarriage caused by the examination is a substantial difference between invasive and non-invasive testing that can be related to the technology. Bettelheim et al. specify the risk of miscarriage (including intrauterine foetal death) to be 0.44 for Amniocentesis and 0.99% for CVS (2002: 119). Not least for liability reasons an essential task of the counselling interview is to inform the pregnant women about the risks and limitations of the examinations themselves. But if the risk that the performed examination may cause a miscarriage can be precluded there is no need to seek for "informed consent" for *that* reason.

There are certainly more reasons for counselling prior to prenatal testing. Doubtlessly the ethical model of decision autonomy needs to be understood in its historical context, namely as a possibility to overcome classical eugenics and the catastrophe of Nazism. Nevertheless, against the backdrop of the changes in the current practice of prenatal testing, it is also important not to disregard the efficacy of the technology applied.

5 Conclusion

The aim of this paper was to highlight the significance of the emergence of new prenatal screening technologies and to show their impact on medical practices. The role these screening technologies play, becomes evident when relating their development and dissemination to the frequency of the total number of invasive prenatal tests. By emphasising the role of technology the question arises: how autonomous can a decision be? To what extent can a decision about whether or not to have amniocentesis (or CVS) be regarded as autonomous if it is taken on the basis of previous risk assessments determined by screening. The concept of autonomy is difficult to uphold if diagnostic technologies apparently have such a strong impact.

The decision about whether or not to undergo invasive tests increasingly depends on medical evidence. Such medical evidence is produced from the first moment a woman learns about her pregnancy. It is largely through improvements in ultrasound screening and other non-invasive tests that maternal age loses its importance as the chief indicator for an invasive test. The corresponding decline of amniocenteses or CVS shows that non-invasive screening methods serve as a means of risk assessment further upstream. But it is not only pregnant women of advanced age who can now decide on the basis of a previous risk assessment. More and more pregnant women undergo such a "pre-test" in screening programmes. It has been argued that the new diagnostic technologies contribute to an expansion of prenatal testing even though invasive tests are performed less frequent. This

way the character of prenatal testing becomes quite different; it can be argued that ultrasound changes the function of invasive tests. Amniocenteses and CVS are increasingly carried out to confirm a qualified suspicion produced by a risk assessment upstream.

In the introductory section of this paper it was stated that the highest priority is given to the autonomy of the patient, and that the goal of counselling is to ensure this for individual decision made by pregnant women. Having argued that decisions are increasingly "pre-informed" through upstream risk assessments on the basis of non-invasive screening, the question arises as to how patient autonomy and individual decisions go together with current developments in prenatal testing. Is the philosophical concept of an autonomous subject still appropriate for the problem at stake, and if not, are there alternatives? What does all of this mean for the concept of informed consent? And last but not least, what does the current development mean for counselling practices? As a matter of fact there is not much counselling involved prior to ultrasound or maternal serum screening. In many European countries prenatal screening is offered routinely,[16] but increasingly genetic counselling is only performed in cases of positive screening results (prior to invasive tests). The practice of prenatal testing has changed considerably since such new screening methods as described above are available. Despite its significance this transformation has not received much public recognition in Austria to this point. Public discourses have rather focused on other aspects of genetic or reproductive technologies such as stem cell research, human cloning or pre-implantation diagnosis. Taking this into account it is even more important to analyse how technological innovations transform medical practices without a re-articulation on a discursive level as it was tried to show in this paper for the case of prenatal testing.

[16] A remarkable exception to this rule are the Netherlands.

6 Glossary

Aberration (chromosomal): the medical term for an abnormal set of chromosomes. Humans have 46 chromosomes in each cell. Too many or to few chromosomes in the cells are associated with particular disabilities and diseases. This is also the case if the chromosomes are damaged, a piece is missing or to much in the set of chromosomes. See also chromosome, translocation, and trisomy.

Amniocentesis: a diagnostic test, usually carried out between 14 - 17 weeks of pregnancy, in which a needle is inserted through the abdomen to remove a sample of amniotic fluid containing cells from the developing baby for testing. Either the chromosomes of the cells are examined for prenatal diagnosis of genetic abnormality or DNA is prepared for analysis. Ultrasound is used to guide the needle. The procedure carries a risk of miscarriage of about 0.5%.

Chorionic villus sampling (CVS): a diagnostic test normally performed between 9 - 11 weeks of pregnancy. A needle is inserted through the mother's abdomen or cervix and is used to remove a small amount of placental tissue (afterbirth). Foetal chromosomes or DNA can then be examined similar to amniocentesis. The procedure carries a risk of miscarriage of about 1%.

Chromosome: a piece of densely packed DNA containing hereditary information of the organism. See also aberration, translocation, and trisomy.

Combinet test: a non-invasive screening method, which combines nuchal translucency measurement and maternal serum test. In such a way the predictability of chromosomal anomalies can be increased up to 87%. If an ultrasound of the nose bone is also performed, the predictability can be further increased to 95-97%.

Curettage: a surgical abortion refers to the procedure performed by a doctor to remove the pregnancy from the uterus. In early pregnancy the surgical abortion is called a vacuum aspiration or a suction curettage.

Cytogenetics (cytogenetic testing): the study of the structure, function, and

abnormalities of human chromosomes and chromosomal anomalies. For prenatal testing a sample of foetal cells is required, gained either by amniocentesis or chorionic villus sampling (CVS).

Detection (rate): it is not possible to identify all chromosome anomalies with non-invasive screening methods. The detection rate indicates the ratio of the cases that are identified by means of a particular test in relation to all cases that are actually given.

False negative: test results which suggest that a foetus does not have a condition which it later turns out to have.

False positive: test results which suggest that a foetus has a condition which it later turns out not to have.

Genetic counselling: A process by which information is imparted to those affected by or at risk of a genetic disorder. It includes information on the nature of the disorder, the size and extent of genetic risks, the options, including genetic testing, that may help clarify the risks, and the available preventative, supportive and therapeutic measures. In the context of genetic testing it may include responding to the concerns of individuals referred and their families, discussing the consequences of a test, and help choose the optimal decision for themselves, but not determining a particular course of action.

Indication: the reason or justification for carrying out a diagnostic or therapeutic measure.

Informed consent: permission given by an individual to proceed with a specific test or procedure, with an understanding of the risks, benefits, limitations, and potential implications of the procedure itself and its results.

Invasive methods: amniocentesis, chorionic villus sampling (CVS) or other procedures to take a sample of foetal cells. Such invasive methods of sample taking are necessary for diagnostic testing, i.e. the analysis of the chromosomes or sequences of the DNA.

Maternal serum: refers to maternal blood in the context of prenatal testing. "Maternal Serum (Screening) Tests" are blood tests performed to determine the risk of foetal anomalies (such as neural tube defects and chromosomal anomalies). The calculation is based on the levels of alpha-fetoprotein, estriol, and human chorionic gonadotropin in the mother's blood during pregnancy. These indicators can be measured alone (triple test) or together with a nuchal translucency measurement (combined test).

Neural tube: a structure in early foetal life that develops into the brain, spinal cord, spinal nerves and spine. Defects of the neural tube are severe conditions and sometimes lethal. To the present knowledge, they are not genetic, although it is assumed that they might be.

Non-invasive methods: ultrasound examinations or maternal serum tests where no foetal cells are taken. Such non-invasive methods allow for probabilistic tests in order to determine the risk of foetal anomalies (such as neural tube defects and chromosomal anomalies). This form of prenatal testing is also referred to as screening. See also maternal serum and nuchal translucency measurement.

Nuchal translucency (measurement): the nuchal translucency test is used to determine if a woman is at high risk of having a baby with a chromosomal anomaly.

Translocation: an anomaly, which has moved one piece of a chromosome to a different position. Translocations can be balanced (the set of chromosomes is complete, but does not have the proper form) or unbalanced (a piece of a chromosome is missing or too much in the set of chromosomes).

Trimester (first, second or third): any of the three 3-month periods into which pregnancy is divided.

Triple test: a maternal serum test used to determine the risk of foetal anomalies (such as neural tube defects and chromosomal anomalies). The calculation is based on the levels of alpha-fetoprotein, estriol, and human chorionic gonadotropin in the mother's blood during pregnancy. Also called "Multiple Marker Test".

Trisomy: three copies of a single chromosome in the cells. The most common form is trisomy 21, the so called Down's syndrome.

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On the Potential Social Impact of RFID-Containing Everyday Objects

Kerstin von Locquenghien

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Abstract

Radio Frequency Identification (RFID) is a rapidly evolving technology. While industrialists hope that the use of RFID will bring about great benefits, civil rights activists warn against the dangers. Since RFID pervades everyday life more and more, this paper deals with its potential impact on individuals. Currently private persons are least included in the public debate, although perhaps they will be affected the most by potential negative effects.

Critics are especially concerned about the potential violation of privacy. Due to its informational infrastructure RFID could be used for surveillance purposes. Many people therefore fear a surveillance state. Looking at the use of RFID on the product level, completely dynamic pricing and business models could be developed. If everyday objects record and send context sensitive information via embedded RFID tags, this might strongly influence our perception of these objects and our emotional attitude towards them. This relationship between man and RFID containing smart objects is expected to differ from the relationship between man and machines as well as man and computers, as a new function as well as a new significance are added to already well-known objects.

Last but not least, this paper also points out RFID's potential impact on health and environment, which has barely been discussed in public so far.

The analysis shows that, apart from certain opportunities, considerable risks have to be dealt with. However, panic, as suggested by some critics, seems unreasonable as the development is still wide open. This should rather be considered a great chance: it offers the possibility to play an active role in the shaping of RFID within a legal democratic process. In this process all members of society are likewise responsible for future developments.

1 Introduction

Today Radio Frequency Identification (RFID) is a rapidly evolving technology and at the same time it is strongly disputed among experts. Some companies already use RFID while others plan its implementation in the near future (SOREON 2004). Enormous progress is predicted for the miniaturisation of chips, by lower costs, an increase of storage capacity and developments in materials sciences (Mattern 2003: 11). Thus, numerous innovative applications of RFID will become possible. Even today industry is highly committed to this technology, because it reckons with more efficient processing conditions in the long run.[1] Yet civil rights activists draw the attention to the risks of RFID concerning data protection and privacy.[2] Some even draw the attention to a possible fall of the democratic constitutional state regarding RFID (Brust 2004). Specifically alarming is the fact that the general public – especially in Germany – hardly knows anything about RFID (Capgemini 2005), while it pervades everyday life, continually and unnoticed by many people.

This paper wants to present a survey of some potential effects of RFID on everyday life with a special focus on questions and consequences from the individual's point of view. Furthermore, the different positions in the debate will be discussed as well as the question of accountability concerning the development of this technology.

[1] One of the most important publications in this field is the RFID-Journal. It presents a survey of the latest technological developments and pilot projects, www.rfidjournal.com [as at 28.12.2005].

[2] Among the main critics are, for example, Katherine Albrecht, chairperson of the Organisation CASPIAN (USA), www.spychips.org [as at 28.12.2005], Rena Tangens and padeluun, chairperson of FoeBud e.V. (Germany), www.foebud.org/rfid [as at 28.12.2005].

2 RFID: technological basis and examples of usage

2.1 Technological basis

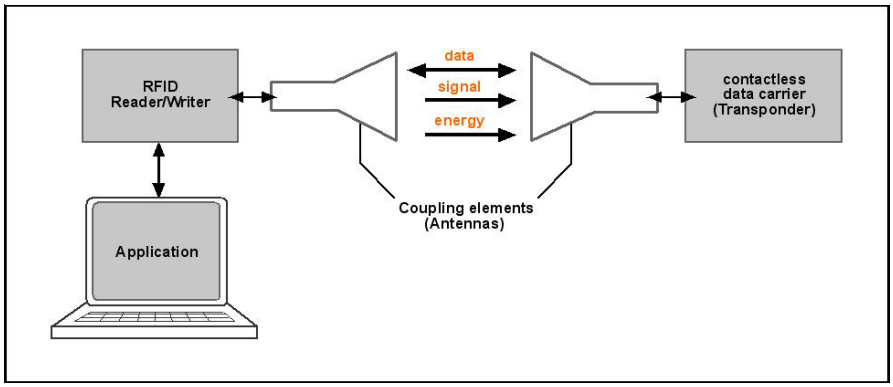
RFID technology is an automated identification technology. By means of RFID objects, animals or persons can be clearly identified over a certain distance. RFID systems always consist of two components: a transponder and a reader. The reader consists of a reading and possibly a writing unit[3] and an antenna. It transmits energy to the transponder, scans its data and possibly makes the transponder store additional data. A transponder only sends data if it is near a corresponding reader ("on call"). The transponder, also called 'tag', is the actual data carrier, consisting of an antenna and a chip. On this chip a unique identification number is stored. Between 16 and 64 kb of additional data can be stored, depending on the kind of transponder (Finkenzeller 2002: 8).

RFID tags exist in different sizes and shapes: as self-adhesive labels (so-called *smart labels*), as glass cylinder transponders, as plastic transponders, as watches, keychain pendants, or as plastic cards *(*so-called *smart cards).* There are numerous other types which can be adjusted according to usage (Finkenzeller 2002: 14-22). The forgery-proof nature of RFID tags is commonly considered as very high (Finkenzeller 2002: 8; Oertel et al. 2004: 90). RFID systems differ on frequency bands, transmission ranges, storing technologies, security systems[4] and means of power supply. All these factors together constitute the qualities of the system. Therefore one cannot speak of *the* RFID system. Transmission ranges often appear to

[3] Not every RFID system contains a writing unit, because not all kinds of transponders are rewritable and allow the storage of additional data on top of an unique identification number.

[4] There are different procedures for authentification and codification available.

Chart 1- Basic components of an RFID system
(based on: Finkenzeller 2002: 7)



be unclear. In exceptional cases a transmission range of up to one kilometre can be reached. However, the systems that are used in Europe only reach a few centimetres – because of legal restrictions on the one hand and the development status on the other hand – *smart labels* for instance which are applied to the product level, or 1.2 to 4 metres for applications in the logistics branch (RF-ID 2004; IDTechEx 2004; Oertel et al. 2004: 29).[5]

RFID systems still have technical deficiencies. Among them are

- the high costs,
- the low degree of standardisation concerning the compatibility of products from different manufacturers or of different frequency ranges,[6]
- gaps in the security systems used,[7]
- performance problems in the vicinity of metal and certain liquids
- as well as a lack of globally standardised regulations for radio frequencies.

All these problems have hindered global usage so far (Oertel et al. 2004: 101-111).

However, experts believe that the present technical problems will be largely overcome by 2010 (Oertel et al. 2004: 106) and they expect a further exponential increase in performance, according to Moore's law (Moore 1965).[8] For the European market a strong growth of the RFID sector has been predicted for the following years (SOREON 2004; Oertel et al. 2004: 104-111). Germany is even expected to become market leader by the year 2008 (SOREON 2004).

2.2 Examples of usage

In the following paragraph a few examples of today's usage will be presented to show how RFID works and can be used, also to start reflections on potential future usage. They are just examples, because the tech-

[5] The technical information of this chapter largely follows Klaus Finkenzeller`s "RFID-Handbuch" (2002), which I would like to recommend for further technical details.

[6] The use of multiple frequency readers could be a big step forward. One of the first of its kind was presented at the end of 2005, cf. http://ubiks.net/local/blog/jmt/archives3/004561.html [as at 28.12.2005]

[7] These are discussed in detail in the essay on "Risiken und Chancen des Einsatzes von RFID-Systemen", published by the Bundesamt für Sicherheit in der Informationstechnik (Oertel et al. 2004: 41-65).

[8] In summary Moore`s law from 1965 says that a computer`s CPU capacity will roughly double every 18 months. So far this prediction has also been confirmed in the field of storage capacity and communication range. Simultaneously prices for microelectronic components will fall radically while the CPU capacity remains the same. These facts facilitate a widespread use of a technology.

nology is rapidly evolving at present; consequently the number of pilot projects and new applications is constantly increasing.

Identification of animals, objects and people

The identification of animals belongs to one of the traditional applications of RFID. Especially cattle, sheep and goats are tagged with electronic ear chips or implanted transponders. If an animal passes a reader, it can be clearly identified and additional data on origin, diseases, sex and previous whereabouts can be read. According to a regulation by the EU all goat and sheep populations from a certain size are to be electronically tagged and all the data is to be stored in a central database by 2008 (Press releases 2003).

Similarly RFID is already being used for the identification of containers in transportation, of garbage containers and for the unique identification of products (Oertel et al. 2004: 67). Gradually, it is also used to identify people. In Japan RFID is used for the surveillance of school children, for example (Heise 2004). In a pilot project of the New York Jacobi Medical Center patients are kept under surveillance with an RFID wrist band. This application also enables hospital staff to access medical records directly on the patient (Fiutak 2004).

Protection against counterfeiting of documents

Since the end of 2005 Germany just like other countries has started introducing passports containing biometric data such as fingerprints. They are encoded in an RFID tag and when passports are controlled they can be scanned and compared with the features of the passport holder. This is supposed to increase the forgery-proof nature of the document (Die Welt 2004). The implementation of RFID in banknotes is also being discussed (Hascher 2003; Krempl 2004).

Protection against theft

Retail has already been using 1-bit transponders for the last 40 years. Transponders are attached to products and readers are installed in security gates near the exit. When a product is bought, the transponder is removed or re-set to "0".[9] The security gates can be passed with paid-for products, but a stolen article sets off an alarm. Libraries or electronic immobilisers make use of RFID in a similar way (Oertel et al. 2004: 81-82).

Access control

RFID has already been firmly established in the field of access control. Many companies use transponders in the form of cards or keychain pendants as electronic identification to control building access and record the working hours. In many holiday regions transponders replace hotel keys, ski passes or local credit cards. They also play a growing part in the sale of tickets for public transport or cultural events (Oertel et al. 2004: 76-80). Since the beginning of 2004 the Baja Beach Club in Barcelona, Spain, has offered guests a small, implantable glass cylinder chip to identify them. They in turn use it to pay for food and drinks (Gossett 2004).

Tracking and tracing

RFID is used more and more to track baggage and parcels, and for toll collection (Oertel et al. 2004: 76-80). However, from the industry's point of view the supply chain management is considered most important. The production and distribution of goods requires complex partner networks. RFID tags on the product mean that it can be individually tracked in real time as it moves from location to location. The supply chain management becomes transparent and can be organ-

[9] Which is not to be confused with "turned off" as the tags technically cannot be turned off in a reliable and safe manner, yet.

ised more efficiently in the future due to increasing automation. Today mainly car industries use this technology during the production process. In preliminary pilot projects it is also tested to track products until they are in the consumer's hands, for example in the Metro-Future-Store in Rheinberg, Germany (Oertel et al. 2004: 84-89).[10]

3 Potential impact of RFID on everyday life

All participants of the discussion seem to agree that huge changes will be brought about by new RFID applications. However, the quality of these changes and their intensity are widely disputed. In the following chapter some potential effects will be described.

3.1 Protection of the private sphere

Critics regard the invasion of privacy as one of the most crucial potential effects (Aspekte 2005; CASPIAN et al. 2005; Oertel et al. 2004: 110). Discussing this issue it is necessary to understand what the term *private sphere* means and why it is considered to be indispensable in a free democratic system. More over, it is equally necessary to establish criteria for the protection of privacy.

Description and value of the private sphere

The discussion about the effects of RFID applications is based on Beate Rössler's definition of *privacy* (2001; 2003). The term *informational privacy* refers to all data about a person, in general everything other people know about a person (Rössler 2003: 17). *Informational privacy* especially includes individual-related data.

In 1995 the European Union (EU) laid down a privacy policy which also says that the term *individual-related* refers to those data of a person which can directly or indirectly be used to clearly identify a person (Europäisches Parlament 1995).

Gary T. Marx offers a different approach by defining certain limits of privacy (Marx quoted by Bohn et al. 2003: 205-206):

- "natural limits" refer to the physical limits of observability;
- "social limits" refer to the basic confidence that social groups have in other people's attitude towards private data;
- "physical or temporal limits" refer to the fact that different areas of life can exist in isolation without influencing each other;
- "situational limits" refer to the fact that what is said or done unthinkingly may be forgotten after some time.

Accordingly a person's privacy is violated if one of these limits is crossed.

The protection of the private sphere is valuable, because it protects the individual's liberty and autonomy (Rössler 2003: 18). The protection of privacy is therefore founded on everyone's right to lead a free and autonomous life. This statement is also reflected in the argumentation of the Bundesverfassungsgericht (German Constitutional Court) concerning the so-called Census Verdict. The term "*informationelle Selbstbestimmung*" (control over one's personal data) and its value are expressed most clearly here:

"*If somebody cannot overlook with sufficient certainty which information concerning certain areas is known to his social environment (…) he can be significantly hindered from planning and deciding in a self-determined way. (…) If somebody has to reckon with the registration of his participation in a meeting or a citizens' initiative by the*

[10] More information on this project can be found online at www.future-store.org.[as at 06.11.2005]

authorities and with the danger that risks for him are involved, he will perhaps not exercise his corresponding basic rights (German Constitutional Law, Article 8, Paragraph 9)." *(Krisch 2005: 9)*

Therefore the *control over one's personal data* is a basic principle of the free democratic constitutional state. It is as important for the individual's chances for development according to the German Constitution as for the free democratic state which is based on the active participation of its citizens (Krisch 2005: 9).

Criteria for the protection of the private sphere

From the explanations above criteria for the protection of informational privacy and the use of personal data can be deduced. They were summarised and are internationally known as the "Principles of Fair Information Practice" (CASPIAN et al. 2003; OECD 2003). In principle personal data shall only be collected in a range as limited as possible, only if highly necessary and they shall only be used for fixed purposes ("collection limitation and purpose specification"). Personal data shall remain concealed as far as possible and only be passed on or published in a limited and selective way ("anonymity and pseudonymity"). It must be guaranteed that unauthorised persons do not have access to data which has been collected ("confidentiality"). Individuals have the right to know when and under which circumstances data is collected. This can be guaranteed by an obligation to obtain approval for example. Later on data subjects shall have access to their data as well as the possibility to correct or delete it and to object to its use ("transparency and access"). This means that the operators of RFID systems must be considered reliable in so far as they need to show a serious interest in keeping the data up-to-date, as well as complete and correct. They are also obliged to use only the amount of data agreed upon for the specific purpose agreed upon. There must be an entity to which individuals can complain in case of conflict ("confidence and security").

Example: RFID at retail

Many publications focus on the use of RFID at retail trade. The reason is perhaps that some companies plan on introducing RFID in the near future or they already test it (SOREON 2004). RFID in conjunction with the so-called Electronic Product Code (EPC) will be used for the globally unique identification and tracking of items from production to disposal (Krisch 2005: 4).[11] Apart from product-specific data, further information about the context of the product can be stored. The following paragraphs are to be understood as a demonstration of potential using possibilities.

The EPC system of tags in connection with so-called *smart shelves*, i.e. shelves equipped with readers, can record the shopping behaviour of a costumer without being noticed. In conjunction with the use of a personalised loyalty card, a credit card or surveillance cameras the data collected can be unmistakably be tied to the identity of this person. Classic "data mining"[12] methods allow the construction of detailed consumer profiles afterwards. It may contain information about a customer's habits, his potential spending capacity and his social environment. This information can be directly used for individual pricing as well as advertising measures.[13]

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[11] Further information: www.epcglobalinc.org (6.11.2005)

[12] "Data mining" describes the systematic detection and extraction of unknown information, mostly automatic or semi-automatic, from a great amount of data, to analyse among other things a consumer's shopping behaviour and to develop targeted marketing strategies (Wikipedia 2005).

[13] This is demonstrated for example by a virtual tour through the Metro Future

As the tags remain functional after the products have been bought, they can be scanned by every reader which is equipped according to the same standards. As a result, without knowledge (or consent) someone can be identified via the products carried along. If a combination of data concerning place, time and identity of a person is automatically stored in a backend database, a person's movement from location to location can be retraced.

Moreover it is possible that alongside the global EPC network, more databases are set up by the operators for their own individual purposes. In general, this means: The more readers are installed in public space, the more detailed an individual can be profiled and tracked.

Potential restrictions on the private sphere

The example mentioned above shows that the afore-mentioned criteria which should guarantee the protection of the private sphere and the "Principles of Fair Information Practice" can all be easily violated.

The reason for this is mainly the technology's "invisibility", as the scanning and storing of data can go unnoticed by the person concerned. The readers can be placed invisibly. Tags can be incorporated into the packaging material or embedded in a way that goes unseen to the naked eye. Data transmission needs neither direct contact nor is it restricted to intervisibility, therefore it is virtually impossible for people to know when or where the reading process takes place and they are being identified.[14] Additionally the example of the Metro scandal at the beginning of 2004 shows that the use of RFID is not always disclosed to customers (FoeBuD 2004).[15] Hereby the criteria of reliability and security are also violated, as individuals cannot have confidence in unknown data processors and they cannot exercise their right to be informed about their data, to correct or cancel them, if they do not know who they are (cf. Krisch 2005: 15). Data processing is not transparent to private persons – this contributes to the "invisibility" of the technology. According to Krisch, the data collected can also be linked and retrieved without a directly known name. Thus the persons concerned do not have the opportunity to be informed about the storage of their data and check it, because they would have to know the product specificcodes. Yet this is impossible without special technical equipment (cf. Krisch 2005: 13).

Now and again cases are uncovered where the security systems of RFID operators fail when data is transmitted or stored in a backend machine. These cases can result in data abuse (Rentrop 2005). Yet experts believe that privacy is less put at risk by attacks on the RFID system, than by its normal operations (Oertel et al. 2004: 55).

Existing protection measures

The fact that RFID is being increasingly used on the product level may lead to a situation where nobody can escape the collection of personal data via RFID. In this case the simplest way to

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Store, where the use of RFID is tested in a pilot project. Metro Future Store Initiative: www.future-store.org/multimedia/virtual tour mpeg1.zip. (10.4.2005)

[14] In comparison, if a barcode system is in use the customer will always know because a contact between barcode and scanner is necessary to read the code. Besides, the barcode only contains the name of the product (e.g. Philadelphia Cream Cheese), while EPC contains a globally unique ID (e.g. Philadelphia cream Cheese Nr. 9388485DCo).

[15] Metro had integrated RFID tags into customer loyalty cards without informing the customers. This practice was stopped after the scandal had been uncovered by the civil rights organisation FoeBuD und Katherine Albrecht from the organisation CASPIAN, because Metro feared that negative publicity would continue to harm its image (FoeBud 2004).

protect oneself by not participating would no longer be an option.

So far there are no serious protection measures from the technical point of view. Although customers in the Metro Future Store's pilot projects are offered the possibility to deactivate the tags, they cannot check whether the tags have been completely deactivated or whether they have only been rendered temporarily inoperable and can be activated again at a later time without being noticed (FoeBuD 2004). A further protection means propagated by the industry is the use of "blocker tags". They behave like transponders and disrupt transmission. However, they cannot be looked upon as reliable as the closeness to the reader is mostly accidental. Neither the reliability, nor whether it functions correctly, can be controlled (cf. Oertel et al. 2004: 53; CASPIAN et al. 2003). The removal of a tag from a product cannot be rated as an acceptable solution as well as consumers might thus exclude themselves from services or even be suspected of theft or forgery. Presently the only reliable method to prevent data transmission between tag and reader is to keep the tag wrapped in aluminium foil (Langheinrich 2004: 24). But this is not an acceptable and long-lasting solution by which consumers can be protected. Critics of the present situation are therefore primarily concerned with the fact that producers and traders simply shift the responsibility to customers who themselves have to pay attention not to suffer from disadvantages (Langheinrich 2004: 29; CASPIAN et al. 2003).

Another way to solve the problem could be found by the introduction of new laws. Although data protection acts on a national and European level exist, there are concerns that it will become more and more difficult to control and maintain them because data processing technologies are getting increasingly complex and miniaturised (Oertel et al. 2004: 109). As we have already seen, the use of RFID might result in conflicts with present data protection regulations (Laschet/Brisch 2005: 84). The authors of the study on the "Modernisierung des bundesdeutschen Datenschutzgesetzes", commissioned by the German Ministry of the Interior, conclude that the data protection law is by no means prepared for the development of omnipresent data processing (Roßnagel et al. 2001). Therefore existing deficiencies in the laws are to be found and new laws must be created, which are especially suited to the use of RFID. While this has not been realised by many politicians (FoeBud 2005), today the first attempts are (being) made.[16]

Comparison with other technologies

To assess the effects of RFID on the *informational private sphere* RFID ought to be studied in the context of similar technologies. There are huge differences in the experts' evaluation of the situation. It ranges from the opinion that the new systems do not really offer anything that has not been possible so far, to the concern that tracking via RFID implies a new quality of surveillance (Oertel et al. 2004: 55).

There are already numerous possibilities to collect data or observe private persons via the internet, surveillance cameras, the storage of telephone calls or the use of credit or payback cards to name but a few. It is already widely known that especially the internet can be used for the purpose of data-mining (cf. Reischl 2001). Moreover it is common practice today to sell personal data to third parties (Leuthardt 1996: 146). In all these cases data can be collected without being noticed by the user and the actual purpose can rarely be checked.

[16] There are examples on the EU-level (cf. Article 29 Data Protection Working Party 2005) as well as in the Federal Republic: The Ministry for Consumer Protection held a conference on "Verbraucherpolitik in der digitalen Welt. Der gläserne Kunde", where RFID was directly dealt with (cf. FoeBud 2005).

Likewise the definite aim of numerous projects is the tracking of individuals (Reischl 2001: 175). Many suppliers of mobile phones and radio networks offer the localisation of mobile phones and their owners as standard equipment that goes with *Location Based Services* (Reischl 2001: 173). The Global Positioning System (GPS) which is used in navigation systems can locate objects even more exactly.

Therefore it has to be emphasised that the private sphere can also be violated in similar ways by other technologies. Yet RFID is different from some of the other technologies because of "always being on", which means that there is no possibility to switch it off voluntarily.

3.2 The discussion about a possible emergence of a surveillance state

RFID like no other technology of *Ubiquitous Computing*[17] has led to concerns about surveillance in the population (Langheinrich 2004). In the following chapter the questions if and how RFID can be used for governmental surveillance and which role surveillance plays in a democratic society will be dealt with, as well as the issues of how on the one hand the government, on the other hand the population cope with it and which consequences may result from it.

Surveillance in western democracies

Due to certain specific qualities RFID can be used to observe individuals. But the adoption of RFID does not necessarily lead to surveillance. However, the informational infrastructure provided by RFID can generally create the demand for further interpretation, and, consequently, for surveillance also by the government (Rössler 2001: 226; Oertel et al. 2004: 47).

Foucault (1976) analyses Bentham's principle of the *panoptic* and transfers it metaphorically to the disciplinary techniques of modern society. Foucault understands the principle of the *panoptic* as an important organisational principle of western liberal societies. The permanent possibility of surveillance hereby causes the individuals to discipline themselves almost without the need for any social control. Deleuze further develops Foucault's idea of the *disciplinary society* in his theory on the *controlling society* (Deleuze 1993: 255). While surveillance techniques in Foucault's sense are linked with institutions, Deleuze emphasises the penetration of society with flexible and permanent control and surveillance techniques. He sees the basis for the change in the means, i.e. in new forms of communication and surveillance techniques (Deleuze 1990: 259). From today's point of view RFID can be regarded as such a technique in many ways.

Mass media often deal with surveillance only in connection with totalitarian regimes. This leads to the impression that surveillance necessarily leads to a totalitarian regime, i.e. that only this kind of regime would use it. But surveillance is not absolutely negative and does not only exist in totalitarian regimes. It may have very different effects in different kinds of cultural contexts with different value systems (cf. Lyon 2001: 26). For example, it can also serve the protection of individuals and groups, as well as the safeguarding of liberty, equality and social justice. Moreover it is indispensable for the protection of the democratic constitutional laws (cf. Lyon 2001: 31).

But the abuse of surveillance by the government can never be excluded. Abuse occurs, if the government uses its power inadequately and does not

[17] *Ubiquitous Computing* describes the omnipresence of digital data processing and can be understood as the enhancement of the Internet Era. It contains the possibility to retrieve data anywhere at any time (Mattern 2001). Mark Weiser is looked upon as father of the *Ubiquitous Computing* theory. He decisively determined this term in his essay from 1991 (cf. Weiser 1991).

act in the interest of the majority of the population, or violates civil liberties. This would be the case if data were collected and used for controlling purposes secretly or against a person's free decision (cf. Rössler 2001: 226). Selection processes which are based on the scientific interpretation of data and which may result in the discrimination of entire groups of the population constitute another significant problem (cf. Peissl 2003: 13). Schulzki-Haddouti (2004: 170) mentions the example of the discrimination against religious minorities, for example after the terrorist attack of September 11, 2001 in the United States, which was caused by indistinctly defined computer search. This process is also called *social sorting* (Lyon quoted in Mattern 2003: 25). The protection of the population from crime and the protection of privacy both require a careful act of balancing. Furthermore, to which extent the preventive collection of data is regarded legitimate, also depends on the subjective impression of a threat posed by criminal attacks on the one hand or a violation of constitutional rights by the government on the other hand.

In the last few decades a gradual reversion of attitude towards law and order could be noticed. The original presumption of innocence has changed more and more into a general presumption of guilt (Leuthardt 1996: 110). This change of the searching principle can be realised when looking at the change of legal regulations in the last few years. While formerly unlawful behaviour had to precede the search, today preventive observation is commonly established in law (cf. Leuthardt 1996: 109). The most recent trend is the adoption of *profiling* methods. Therefore one might suppose that the data aggregation caused by RFID will also attract the government's attention.[18]

Citizens and surveillance

Citizens have become used to surveillance and do not reflect it very critically anymore, an attitude which might become dangerous. Especially the terrorist attacks on September 11, 2001 have raised awareness about issues of national security. For many people the individual's need for security seems to outweigh the interest in the protection of privacy. Therefore Greiner (2005) considers the population's need for security to be the actual "enemy of freedom". On the other hand many citizens are aware of surveillance but do not feel disturbed or restricted in their privacy (cf. Winsemann 2005).

The wide-spread acceptance of surveillance leads some authors to speak of a "nothing to hide mentality" (cf. Winsemann 2005).[19] This behaviour can obviously be attributed to the common concern to arouse suspicion by refusing observation measures. Jutta Limbach, former president of the German Constitutional Court, is worried that people will lose the pleasure of expressing their different opinions and committing themselves, if the government electronically observes its citizens in all domains of life (cf. Schulzki-Haddouti 2004: 159). Whether the

[18] This is exemplified by the latest legal changes, for example the abolition of confidentiality in banking in Germany on April 1, 2005 (Kaiser 2005), the demand for a prolongation of storage time for telephone data to three years by the German Minister of the Interior Otto Schily (cf. Deutschlandradio 2005), the demand for an extension of DNA analyses and the setting up of a nationwide gene database (cf. WDR 2005), or the decision of April 12, 2005, which permits police and public prosecutors to profile and track individuals via GPS (Bundesverfassungsgericht, 2005).

[19] Winsemann mentions as examples the widespread use of pay-back cards in spite of public information campaigns, web cams in discotheques and pubs or a chip implanted into the upper arm as a method of payment. She comes to the conclusion that these measures are rather looked upon as "fashionable accessories" and that the consequences concerning data protection and privacy are ignored (cf. Winsemann 2005).

individual citizens consider the purpose of observation to be legitimate *(positive observation)* or a restriction on their civil rights or even a threat *(negative observation)* depends on their respective threat assessment.

Historical context: Technologies and fears of surveillance

The debate about RFID and surveillance should be seen in historical context. Since the 1980s there has been a debate about fears of surveillance in context with technological development (Lyon 2001: 31). Leuthardt examines the historic development of surveillance methods and fears in correlation with electronic data processing strategies. He shows that from the first databases to the development of chip cards to the introduction of the internet the possibilities of data aggregation and interpretation have been continually improved and therefore also have been accompanied by fears of surveillance (Leuthardt 1996). During the last decades slogans like "electronic panoptic" or the "transparent citizen" or the "transparent society" were coined which also re-appear in today's debates. We already leave electronic data tracks permanently which can be used for observation and controlling purposes by interested parties (cf. Leuthardt 1996: 129). Therefore the question if RFID leads to a surveillance state is obsolete. More important is the question whether RFID and its embedding into a network of existing surveillance technologies will cause a new quality of surveillance. But this question could not be answered clearly so far.

3.3 RFID and consumer goods

Products equipped with RFID tags can, to a certain degree, be called "smart", because they offer the use of further functions and because there are processes which can be automated.[20] Especially in networks with other technologies RFID-"smart" objects can trigger far reaching changes in everyday life which have been hardly issued in the public media so far.

Dynamic pricing

The existence of highly automated networks of RFID equipped devices can lead to an economy in which the information about the "location and quality of goods, the means of production and people is available in real time and unprecedented accuracy" – a "*now-economy*" (Müller et al. 2003: 172).[21] This might result in an approximation to the so-called "*perfect market*" (ibid.). Besides, the pricing system can be controlled in a highly dynamic way in real time on the basis of analysis in supply and demand (Bohn et al. 2003: 212-213). In practice this could involve an automatic change of a product's price at very short intervals. This kind of pricing might mean in turn that the predictability of prices becomes more difficult or even gets impossible for customers who might become confused. Moreover, the question arises whether this model is fair. Will a dynamic pricing system discriminate against certain groups of consumers, maybe because their working hours do not allow them to go shopping at a favourable time? Or is it more likely that the shelves will always be refilled according to demand without the need for higher prices? Even

[20] "Smart" has become an in-term and is therefore insufficient for a clear definition of the qualities implied (von Locquenghien 2005: 4-10). In this paper "smart" only refers to the limited technical qualities and possibilities of RFID unless else specified.

[21] Three qualities identify a "perfect market" in the classic micro-economic theory: 1. the exchangeability of goods, 2. the complete overview of all market participants over the latest information and procedures and 3. the abolition of temporal or physical advantages for certain competitors. With this explanation Bohn et al. refer to David Krep's "A course in microeconomic theory" (cf. Bohn et al. 2003: 213).

today dynamic pricing models are used in other branches. Bohn et al. mention for example the hotel prices at the time of a fair, ski passes in the high season or on weekends, flight prices and internet auctions (2003: 213). But the acceptance of these examples cannot automatically be assumed for other products, as these mentioned goods could be considered luxury goods, which are dispensable if necessary. Basic food does not allow this option, however.

It has already been explained that prices can be established individually on the basis of customers' profiles. Here as well the question arises as to how far social inequalities might be strengthened or more justice can be created. In this case the retailers' attitude would be crucial.

Silent commerce

Objects which "purchase" certain things themselves because of their context sensitivity are called "*autonomous purchasing objects*" (Bohn et al. 2003: 216). A frequently cited example is the fridge that checks its contents and takes care of the refill according to the consumption behaviour of its owner. The term used for this procedure is "silent commerce" (ibid.). It shows that things happen in the background without a person directly being involved in the decision-making process. While on the one hand this passive way of shopping can be very comfortable, it might also lead to a feeling of loss of control. To avoid this danger, the procedures should be made as transparent and comprehensible for the user as possible. Another problem is the accountability issue. What happens if the fridge has ordered the wrong product? Who is responsible for the damage? There are fears that "the reasons for the damage which is done because components from computer hardware, programmes and network data working in combination can usually not be cleared up, because the complexity of these systems cannot be controlled, neither from a mathematical nor a legal point of view" (cf. Behrendt/Hilty/Erdmann 2003: 20-21). This is a basic problem of partly autonomous systems. However, considering the fact that up to now there are hardly any autonomous purchasing objects in private use, I consider exaggerated fears of this kind of risks to be wrong. The factors mentioned can still be taken into account when these products are designed and there is a realistic chance that most of them can be regulated by the functioning market itself.

Pay-per-use business models

Bohn et al. consider an extension of the pay-per-use business model onto all kinds of everyday objects possible via objects which would be uniquely identifiable and equipped with the latest communication technology (2003: 217). Thus the producer of a sofa might automatically get a transfer of a few cents when it is used., i.e. when sensors coupled with RFID tags and wireless internet connection would report this. Bohn et al. mention different examples of already working pay-per-use business models, e.g. charges for telephone, electric current and water as well as public transport and television. Before every use a conscious decision concerning the financial consequences is necessary.

While one might assume on the one hand that this leads to stress as these decisions about the use of everyday objects would have to be made very frequently, one has to keep in mind on the other hand that the conscious decision making concerning the consumption of electric current or water has also been shifted to the background. But simultaneously this example shows that the charges arising can hardly be checked afterwards. This could become a problem with everyday objects and increases the possibilities of abuse. Users might fall into a debt trap, a development which could be observed when mobile phones were

introduced on a large scale (cf. Schufa 2004: 172). Yet there is proof that the increase of information and the fact that people got used to the terms of payment resulted in a decrease of debts (ibid.). It might be possible that the wide-spread use of these terms of payment for everyday objects would also lead to this effect. Besides, the social consequences would be interesting: Will fewer guests be invited if each use of the sofa is charged? Will other seating habits be developed? Will this lead to a change in the cultural significance of property?

Specified services

If RFID tags are embedded into objects, it is possible to assign all the single parts of a machine to a producer. It is conceivable that a function could be incorporated into machines which would prevent spare parts from another firm being put in. This would severely restrict the free choice of spare parts and it would imply the exclusion of certain services for customers with lower incomes. This principle can also be transferred to other services like maintenance and repair. It is questionable, however, if companies would be interested in such a function at all, as they would risk a damage to their image if customers did not accept the principle. On the other hand the question would have to be studied whether the use of the prescribed parts would even increase the safety of the product significantly and thus bring about an advantage for the user.

Dynamic and personalised insurance models

Insurances might also be interested in personalised data which reflects the everyday behaviour of individuals (Bohn et al. 2003: 218). RFID and sensor containing objects can be able to record the individual consumption and behavioural habits of their owners, to transmit these to insurances that in turn could offer dynamic and highly personalised insurance bonuses. The smart refrigerator could transfer information about eating habits, the sensor-equipped car would be able to transmit detailed data about the driving habits of its owner to the insurance (cf. Langheinrich 2005). However, the question must be raised, if these data produce a true picture of reality and if this could lead to a fairer billing system. In general, problems could arise comparable to those in the previous examples concerning verifiability, abuse and financial calculability. Yet a positive effect based on individually measurable data could be an increased awareness for issues of health and risk in the population.

Digitally upgraded everyday objects

By means of RFID every object can be assigned specific information. This information can be retrieved automatically via the internet and transmitted by different media. So far mainly producers and operators can make use of data storage on the object, but in the future consumers might also reap the benefits. These could be operating instructions for electronic devices, recipes for cooking, information about the ingredients of food, instructions for care and maintenance, guarantee information, advertisements, bonus features or personal comments which can be scanned by privately owned readers. Presumably the additional digital features will increasingly influence the assessment of products' qualities.

"*What is displayed in every single case, may depend on the context, i.e. on the question whether the consumer is a long-time customer and has paid a lot for the product, whether he is over 18, which language he speaks, or his present whereabouts – maybe even on the question whether he belongs to the right party.*" *(Mattern 2003: 9)*

Mattern's statement shows that the information can be offered in a very flexible and personalised way, but at the same time he refers to the risks involved. He also raises the question of

who determines the contents of the object's statement, and who guarantees their objectivity and accuracy (Mattern 2003: 11). An objection would be that the contents of every mass media, e.g. television or internet, can be ideologically prejudiced just as well and in a certain respect are always shaped by subjective interests. Likewise the accuracy of information can rarely be completely guaranteed and proved. In this sense RFID containing objects are simply a new medium which will be affected by an already existing problem. Besides, this issue of acceptance of digitally upgraded objects will also depend on the influence a customer can exercise on the display of the data. An advertising film constantly showing on a display of the refrigerator would most likely be disapproved of, yet occasional requested information on a certain product might be welcomed.

3.4 RFID's influence on health and environment

Consequences for health and environment must also be considered a factor influencing everyday life. Little research has yet been done in this field. Generally speaking,

"*the influence on environmental aspects like disposal, consumption of resources and energy by a large scale implementation of ubiquitous computing technologies […] is hardly predictable, especially because a change of lifestyles, more dynamic economic circles and new consumer habits as a consequence of the new technology will react upon these parameters*" *(Bohn et al. 2003: 231).*

With good reason this statement can be transferred to RFID, as it is looked upon as one of the key technologies of ubiquitous computing.

Electromagnetic radiation

RFID being a radio technology is connected with electromagnetic radiation when operated. Health risks caused by radiation have been researched and debated in public so far only with reference to mobile phones and their effects. RFID's radiation effects on health have not been clarified as yet and long term effects in particular have not yet been researched (cf. Hilty et al. 2003: 240). Furthermore it is well-known that the distance between the source of radiation and the body has a strong influence on the intensity of the exposition. Future applications like the integration of RFID tags into clothes or their implantation into the human body may therefore raise the level of exposition to radiation. Advocates of RFID object that the radiation of RFID is lower than that of mobile phones and that it is not always active but only "on call", and therefore not or significantly less dangerous (cf. Cisco 2004). However, in workplaces where RFID systems are constantly in use, the radiation might have a much more negative effect than expected. This demonstrates the "urgent need for research" (Behrendt/Hilty/Erdmann 2003: 18).

Implantation of transponders

Medically, the implantation of RFID tags into a human body is already feasible, but it is not widespread yet. There are no accurate research results concerning harmful effects of RFID tags implanted into the body. First concepts for medical applications of RFID are now being developed, for example the implantation of a sensor and transponder to permanently measure and monitor the intraocular pressure of patients with glaucoma permanently (cf. IMS 2005). For chronically ill people, the monitoring of different physiologic parameters could mean a higher degree of safety and a better quality of life. Moreover, an implanted RFID chip could incorporate personal medical information, which might be life-saving especially in cases of emergency. However, there is a critical objection that the implanted medical information could create a problem concerning data protection laws. For chronically ill people the

advantages might outweigh the disadvantages, for many others, however, the dangers would be considerably higher than the advantages. Furthermore it has to be dealt with the issue that the implantation of RFID tags might lead to negative psychological consequences.[22] What does a person feel about an implanted and simultaneously linked tag which sends data from inside the body: would it be perceived as a prosthesis, as a foreign body, as an unwanted intruder or traitor? Or even as a fashionable accessory as can be seen in the case of the Baja Beach Club? The question if RFID tags are implanted voluntarily, is definitely one of the most crucial issues for their acceptance.

Health management

A tag on food and medicine containing detailed information on the product may help to promote applications which compare the ingredients automatically with individual incompatibilities and give warning signals in case of danger. Besides, a check could be kept on the correct taking of medicine. The first prototypes of smart medical cupboards reminding users of taking their medicine or informing them about medicine that expired have already been developed (cf. IMS 2003). Yet it has to be criticised that the devices for dispensing them are difficult to operate for the intended target group, i.e. mainly senior citizens. The interface would have to be improved and become better suited to the target groups.

The genuineness of medicines

The pharmaceutical industry in the United States plans to integrate RFID tags into the packaging of medicine in order to document their genuineness and location because many products are forged (cf. Computerwoche 2004). This could mean a higher security standard for patients as fakes can be distinguished from originals, if patients get the possibility to scan the tags. But the question remains if the problem of fakes will not simply be transferred. If criminals for example used empty original packaging and filled it with forged products then the possibility to distinguish this mediciation from originals would be considerably lower. The problem could only be solved by killing the tags after the consumption of the medicine. But this is technically not yet possible and it would probably not be easily implemented.

Stress

RFID has the potential to reduce stress in everyday life. Automated admission control might shorten waiting queues for example. If people were reminded of their everyday tasks they might carry them out more reliably. But, depending on the use of the technology, this might also lead to negative stimulus satiation (cf. Hilty et al. 2003: 245). It has to be emphasised that even the uncertainty of potential risks might result in a physical health risk. The feeling of being threatened can for example lead to insomnia, and correspondingly involve health problems (ibid.: 238). This feeling may be caused by fears of radiation, surveillance or of losing control likewise.

Electronic waste

During my research I did not find any plans for the disposal of RFID electronics. Today RFID applications are mainly confined to closed systems. "Disposable labels" in the form of *smart labels* on products at retail for example are not widely in use.

"*If smart labels were affixed to all supermarket products in the future, then billions of these chips would get into the household waste. Although a single chip weighs far less than a gram the total sum of all these chips would add up to several thousands of tons of*

[22] Paul Virilio (1999) extensively considers the relationship between technology and the body, yet without giving attention to a special technology (also see Misoch 2005).

electronic waste." *(Bohn et al. 2003: 231)*

Separate disposal could become a problem because tags can be integrated into packaging materials. On the other hand, RFID offers the possibility to optimise recycling processes because waste materials could be identified and separated more efficiently with the help of the data stored (ibid.). This might simplify waste disposal for the individual as machines could do the separating automatically. But up to today this concept cannot be technically realised yet.

Monitoring of the environment

In the future tiny sensors and RFID equipped devices might be able to monitor and document environmental phenomena in a so far unprecedented way. These data collections could lead to a potentially new understanding of certain processes in nature which in turn could enable scientists to find out about environmental disasters at an earlier date. Accordingly early warning systems could be used in a more targeted way. In the same way information about the populations of threatened species might be collected which could lead to new scientific findings. But apart from the tagging of animals there can hardly be found any applications in this sector until now (Oertel et al. 2004: 95).

3.5 The relationship to RFID containing objects

If embedded RFID tags can make everyday objects smart, then this can influence the perception of these objects as well as the individual's relationship to them. Psychologists and sociologists have only just gained interest in RFID. For a more detailed analysis the existing and future pilot projects would have to be studied extensively. The following chapter deals with the factors that might influence the relationship between man and RFID containing objects.

Recognition of RFID containing objects

It is important to know whether the individual can realise at all that an object has been changed i.e. that it represents more than its physical appearance and its conventionally known functions. Only then the difference in the relationship to an RFID containing object can be examined. The following factors are decisive:

- *The visibility of the technology*: many tags which are in use today are so small that they can hardly be noticed, and are placed invisibly or integrated into packaging material. The same can be said for readers, as well.
- *The visibility of the reaction to the reading process*: even if the technology itself is not visible, the reaction to the reading process can be noticed, for example when a ski pass automatically releases the turnstile.
- *Knowledge about the use of the technology*: this can be achieved by information about the use of smart labels on a shelf in the supermarket, on the packaging of products or by public notice, for example.

It can be assumed that those different ways of recognition will influence the individual realisation of the object and the emotional relationship to it. Yet if the object does not seem changed at all, RFID will probably neither directly influence the way the object is perceived nor the relationship between man and smart objects. It would also be necessary to study delayed or indirect effects which are not in first place linked with the visibility of the change.

Benefits of the application

Furthermore it is important to know whether the new quality is seen positively or negatively. Hereby a few elements might be of importance:

Personal advantage:[23] If the additional quality or function is seen as an advantage, it can be assumed that the object will be looked upon in a more positive and confident way than one without this technical upgrading. The degree of the positive realisation would grow accordingly if the function was used frequently and the positive result confirmed. It is different with applications which are complicated or do not function in the expected way and therefore lead to frustrations. The user might become mistrustful and finally see the object in a negative light (cf. Norman 1988: 11).

Advantage for others: Not every application implies a direct advantage for the user of the object. If a customer profile is created for marketing purposes the subjective advantage can only be perceived indirectly, if at all, or might even be seen solely on the operator's side. If users don't accept this kind of external benefit, they might feel to be at the mercy of the object or even feel threatened by it.

Impression of autonomy and aliveness

For different reasons electronically upgraded everyday objects are attributed the ability to act autonomously or being alive. On the one hand the way of communication about smart objects influences the perception of their qualities. In related literature human qualities are often used to describe so-called smart objects. This kind of rhetorical description produces the picture of a strongly emotional and socially aware autonomous acting object, which in reality simply executes certain pre-programmed functions without any reflection (Reeves/Nass 1996: 4).

Apart from the descriptive attribution of human qualities, observable features also contribute to the perception and evaluation of smart objects (Rammert/Schulz-Schaeffer 2002: 29). The impression of autonomy furthermore depends on the degree of context sensitivity and the actual autonomy of decision making behaviours, as has been briefly shown by the examples above. If the technological process is unknown, a person easily gets the impression that the object itself is "speaking" or "acting" and therefore appears to be "intelligent", because of the reaction caused by the object directly being attributed to the object itself.[24] In this context Adamowsky speaks of a re-emerging so-called "magic effect" (2003: 4), which is even emphasised by the "invisibility" and complexity of technologies such as RFID. Turkle (2004) also deals with the effects of "affective computing". Especially children tend to react emotionally to "intelligent" toys and clearly attribute to them a certain kind of "aliveness". More and more this effect can also be observed with grown-ups. However, the problem of grown-ups ascribing "aliveness" to "intelligent" artefacts is by no means new: it has already been noticed and analysed by Weizenbaum in the 1970s (cf. Weizenbaum 1977). From today's perspective the topic becomes even more relevant than ever before because of the development of new advanced technologies and their integration into highly complex systems.

The physical as well as the communication design can therefore be considered as one of the most influential factors for the relationship between man and RFID containing objects. When looking at today's applications, it becomes clear that the design options for RFID containing smart objects and their communication interfaces are still wide open.

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[23] Here I transfer Donald A. Norman's (1988) results from his psychopathologic study of everyday things to RFID containing everyday objects.

[24] For a detailed analysis of technical artefacts and their perception as acting objects, I would like to refer to the paper of Werner Rammert and Ingo Schulz-Schaeffer (2002) who extensively deal with relevant concepts.

A smart card implying the function of a key is most likely regarded as a new physical form of a key or a type of switch. The card would be looked upon as an instrument, which would not result in a closer emotional relationship (cf. Krämer 1998: 83-84).

If the object's physical or communication design gives the impression of being alive however, it would most likely lead to a greater emotional reaction of the user.

Therefore RFID containing objects should first be separated into different categories before being analysed. As a result it has to be taken into account, that the relationship between man and RFID containing smart objects can probably neither be treated like the man-machine-relationship nor like the man-robot or the man-computer-relationship. In these cases the function and the significance of newly introduced objects had been altogether new. Thus they could be perceived as a unity, and new ways of man-machine interaction could be acquired step-by-step. Comparatively, RFID applications are expected to lead to unfamiliar situations because of the fact that everyday objects with already well-known qualities will additionally gain one or more so far unknown qualities.

4 Conclusion

The consideration of potential future applications and their possible effects shows, that RFID has the power to bring about considerable changes. Apart from some chances, serious risks are to be expected. Today the extent of the changes can not yet be assessed as the future development of RFID technology and applications is still widely open.[25] It is exactly this openness as well as the awareness of potential risks which offer the chance to the people to deeply influence future developments and to actively take part in this process. A generalisation of concerns about RFID should be avoided, however, because of the diversity of existing technical systems and different applications in connection with their intentions. All members of society likewise have to take on the responsibility regarding the further development of RFID.

Developers: They can dictate, facilitate or exclude certain ways in which a technology can be used by creating the technical and organisational framework. "What is technically prevented, does not have to be outlawed." (Roßnagel/Lütge 2005) as soft- and hardware regulate the rules in cyberspace in a similar way as laws do in the real world (Lessig 1999: 6).

Operators:[26] Their attitude decisively determines the way RFID systems are deployed and how they treat those people who are affected by the applications. Operators should be greatly interested in maintaining the trust of customers and staff (cf. Capgemini 2005: 16). Therefore they should keep their specific application of RFID as transparent as possible and allow affected people to make a conscious decision about their participation as well as the option to permanently deactivate their tags. Operators should equally pass on some of the benefits resulting from the application of the RFID system (ibid.).

The government: It is the government's task to mediate between the different interest groups in society and to intervene if necessary. This includes the revision of existing laws in order to guarantee their applicability in the context of new technologies as well as

[25] In the TA-Swiss paper on the precautionary principle in the information society from the year 2003, this open potential for development is called "Januskopf chances" as the situation offers chances as well as risks (cf. Hilty et al. 2003: 265).

[26] The term shall include everybody who operates an RFID system and/or uses the data collections produced hereby for data mining purposes.

the establishment of new laws. Hereby the government should apply the methods of technology and risk assessment and include experts in their discussions. At the moment the impression that German data protection officials are not taken seriously is alarming.[27] Furthermore, globalisation processes lead to a legislation, which is tremendously under pressure due to international requirements or other internationally powerful states. Even though national governments oftentimes have an area of discretion concerning international laws, they rarely make use of it, but follow the general trend, without investing much time in a critical reflexion.[28] The close tie between politics and industries also state a severe influence on political decision making. Last but not least the responsibility of states also implies the protection of the individual's rights. A fact which nowadays sometimes seems to be eclipsed.

Citizens: They also bear part of the responsibility by their attitude towards new technological developments and applications, a fact which is often underrated. At present the population does not seem to be well informed about RFID. This might be due to a bad information policy on the part of the operators, but also due to a lack of interest on the part of the population. This attitude is alarming, because a passive behaviour neglects the chances of shaping the path of new technologies. However, this can lead to the dreaded imbalance in the consideration of different social interests. Civil rights activists, for instance, have already proved that and how the population can actively exercise its influence through various actions.[29]

"*While the analysis of a technology only answers the question of what the future can bring, the question of what the future may bring must be answered by a societal process.*" *(Mattern 2003: 29).*

Although controversies about risks and conflicts are often perceived as disturbances for society, economy and democracy, they should rather be seen as a learning process, as a productive element and a basis of democracy (cf. Petermann 2001: 7). Therefore the present discussion about the spreading of RFID should be regarded as an important occasion to re-negotiate the different interests occurring within a society and to discuss the fear of an omnipresent surveillance by the government. Basis for this process should be a balance of considering personal advantages as well as potential social costs. The democratic system is not a rigid structure; on the contrary it requires negotiation and must be understood as a never-ending permanent re-shaping process (cf. Marchart 2002: 296-297). Panic related to RFID technology, like some authors try to spread, is not justified at this time. However, they make an important contribution by bringing the topic to public attention and by taking part in the public debate.

The most important issues at stake should be to objectify the discussion, to inform and involve the public, to abolish existing myths about the technical potential of RFID, to intensify

[27] For example the data protection official of the Federal Republic, Peter Schaar, had criticised the Federal Government in his progress report published in April 2005. The Minister for the Interior, Otto Schily, countered that Schaar "had gone beyond his competence, and that it was not his task to assess technical questions and comment on political decisions" (DPA 2005).

[28] A good example is the quick implementation of biometric data in passports for example. (cf. DPA 2005; Die Welt 2004). Biometric data is stored on RFID tags integrated into the cover of the passport. The functionality of RFID tags as well as their potential health risks have not been assessed yet especially in long term use. Additionally they have been implemented regardless of emerging concerns about privacy issues.

[29] E.g. CASPIAN (www.spychips.com) or FoeBud e.V (www.foebud.org/rfid).

the interdisciplinary debate about potential effects of the technology as well as to commonly work on a stable societal solution.

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