SELF-REGULATION AND THE FUTURE OF THE REGULATORY STATE

International and Interdisciplinary Perspectives

editors:
Marc Hertogh
&
Pauline Westerman
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INTRODUCTION:
The Regulatory State at the Crossroads

Marc Hertogh & Pauline Westerman

1 Introduction

If there has ever been a time in which regulation, or more specifically, legislation could be seen as the exclusive product of a sovereign legislator, the legendary Rex, issuing orders, commands, decrees and laws to be received and obeyed by his subjects, this time is over. Conversely, if there has ever been a time in which citizens and institutions could be regarded only as 'norm-addresses', as the passive receivers of law, who played no significant role in the way the law is framed, interpreted, applied, and received, that time is over too.

In recent history, the face of government has undergone several dramatic changes (cf. Braithwaite 2000, 223). The Nightwatchman State of classical liberal theory had functions more or less limited to protecting its citizens from violence, theft, fraud and promulgating a law of contract. However, this model of government changed significantly with the New Deal and similar policies in Europe, which assumed a large degree of central state control of formerly unregulated activity. This, of course, marked a shift from the Nightwatchman State to the Welfare State (or: the Keynesian State). ‘[T]he mentality of the Keynesian state was general belief that the state could do the job’ (Braithwaite 2000, 224) At the end of the period of reconstruction of the national economies shattered by World War II, redistribution and discretionary macroeconomic management emerged as the top policy priorities of most Western European governments. The market was relegated to the role of providing the resources to pay for government largesse, and any evidence of market failure was deemed sufficient to justify state intervention. ‘Indeed, centralisation and unfettered policy discretion came to be regarded as prerequisites of effective governance.’(Majone 1997, 141)

However, the consensus about the beneficial role of the state – as planner, direct producer of goods and services, and employers of last resort – began to crumble in the 1970s and 80s. Rising unemployment, rising rates of inflation, discretionary public expenditure and generous welfare policies were increasingly seen as part of the problem of poor economic performance. Following the lead of the Thatcher government in Britain, during the 1980s and 90s thousands of privatisations of public organizations occurred around the world. Moreover, this period was characterized by a ‘regulatory crisis’, which included a growing disillusionment with state regulation and calls for a dismantling or ‘rolling back’ of the state. Both in the United States and Europe there was a strong deregulatory rhetoric, centering on claims of overregulation, and legalism (Hutter 2006, 1). From the mid 1990s onwards this eventually lead to the development of a new, third model of government which a number of scholars have
described as the rise of the (New) Regulatory State (Majone 1994; Loughlin and Scott 1997; Moran 2002; Levi-Flaur and Gilad 2004).

According to Majone (1997), three major functions are ascribed to the modern state: redistribution; stabilization (for example, in the form associated with Keynesianism); and regulation (meaning promoting efficiency by remedying market failure). The rise of the regulatory state consists of the rise of this third function at the expense of the other two (Moran 2002, 402). This new model of governance has a number of characteristics, prominent amongst them is the decentering of the state (Hutter 2006, 1). This involves a move from public ownership and centralised control to privatised institutions and the encouragement of market competition. It also involves a move to state reliance on new forms of fragmented regulation, increasingly involving self-regulatory organizations and independent regulatory agencies operating at arm’s length from central government. During the last two decades all Western European governments have adopted these strategies, though the timing, speed, and determination of their choices varied a great deal from country to country (Majone 1997, 148). The rise of the regulatory state was partly European catch-up with the New Deal, partly a fresh phenomenon shaped by the adaptation of domestic policies and institutions to deepen European integration (Majone 1997; Braithwaite 2000, 224).

What does this past imply for the future? What will be the dominant face of government in the decades to come? Will it be a continuation of the Regulatory State, or will this mode of governance be replaced by yet another approach? Although most authors agree that the practice of governance is constantly evolving, and that it is therefore unlikely that the Regulatory State will remain unchanged in the coming years, there is no consensus on what this state of the future will look like. The answer, of course, also depends on one’s attitude towards the present Regulatory State. Although this concept has become increasingly important both in academic writings and policy documents, the international literature also reflects a growing number of critiques. In general terms, this criticism can be divided into both normative and empirical concerns about the concept. While the normative concerns primarily focus on the question whether the present Regulatory State (still) sufficiently meets the public interest, the empirical concerns question whether the concept of the Regulatory State (still) captures the most recent developments in the regulatory landscape. Based on both types of concerns, we may now construct three potential scenarios for the future of the Regulatory State. In all three scenario’s empirical observations are accompanied with or inspired by theoretical/normative concerns.

Scenario 1: The Re-Instated State
In the scenario of the Re-Instated State the central state regains its central position. Contrary to the Regulatory State, this scenario is characterized by a re-installment of the state. Self-regulation is a prominent feature of the present Regulatory State. However, according to those authors who promote the scenario of the ‘Re-Instated State’, self-regulation should be considered the ‘end point of regulatory capture and incompatible with the public interest’ (Bartle and Vass 2007, 886). This type of argument has been most clearly voiced against the background of the recent worldwide banking crisis. Starting in 2008, major banks and other financial corporations in the US and elsewhere have suffered major losses or even gone bankrupt. Moreover, this financial crisis has also lead to considerable problems in the ‘real’ economy and has prompted an international recession. In response to these dramatic events,
national governments have stepped in, buying out bad loans and bailing out banks. In some countries banks have also been nationalized by their governments. According to a number of authors, this illustrates that self-regulation (and with it the concept of the Regulatory State) is no longer able to meet the public interests (see, eg., Vonk 2008; Levi-Faur 2009). In their view, this argument is not limited to the financial sector but also applies to, for instance, public health, public transportation, the energy sector, etc. Consequently, the Regulatory State should be transferred (back) into the Re-Instated State, in which (not unlike the Welfare State) the process of privatization is stopped and the national state reclaims direct control of all vital sectors of the economy.

Scenario 2: The Post-Regulatory State

The scenario of the Post-Regulatory State focuses on a further de-centring of the national state. This is the exact opposite of the first scenario. According to this scenario, future governance will be increasingly governance beyond the nation-state. According to several authors, the Regulatory State concept fails to capture the characteristics of the current (and future) regime because it neglects well established and growing trends to enlist non-state actors in regulatory governance (Grabosky 1994; Black 2001; Scott 2003; Hutter 2006). In their view, regulation can no longer be regarded as the exclusive domain of the state and governments. Instead they point at the increasing role of ‘civil society sources of regulation’ (Hutter 2006, 7) such as (international) NGOs, standards organizations (like the National Standards Body of the UK), and professional organizations (like the Law Society and the Pharmaceutical Society in the UK). Moreover, there are important sources of regulation in the economic sector which include (self-regulation in) companies themselves, industry or trade organizations, insurance companies and auditors (see Hutter 2006). Based on a review of the literature – in particular the legal theory of autopoiesis (Teubner 1993; 1998), the governmentality literature (Foucault 1991) and the theory of responsive regulation (Ayres and Braithwaite 1992) – Scott (2003, 21) concludes that the Regulatory State concept needs to be amended in three major ways. In the scenario of the Post-Regulatory State the law is less concerned with setting down rules and powers, but it focuses more on several types of ‘Meta-Regulation’ instead. Moreover, there is greater recognition to other types of legal and non-legal norms in processes of control. And finally, the hierarchical control dimension to regulation is displaced by control processes built on community, competition and design. In this scenario there is a shift from regulation based on hierarchies towards regulation based on networks.

Scenario 3: The Hybrid State

The third and final scenario of the Hybrid State is a combination of the two previous scenarios. Typical for this scenario is a ‘loosening of the sharp distinction between states and markets and between the public and the private’(Scott 2003, 3). It focuses on the increasing significance of a ‘regulatory mix’ (Hutter 2006, 14), embracing both state and non-state sources of regulation, to maximise the potentials of each sector. On the one hand, this scenario recognizes that future state regulation is only likely to be effective when linked to other ordering processes. On the other hand, it stresses that regulation beyond the state will often take place in the shadow of state activity (Hutter 2006, 15).
2  A Continuum of Governmental Interference

In order to assess the quality of the three scenarios, it is however of the utmost importance to study and to characterize first the features of the regulatory landscape that exists in the current Regulatory State. As we noted above this landscape is marked by a variety of new forms of regulation. Commonly, these forms are brought under the banner of ‘self-regulation’, a term which sounds both sympathetic and clear, but which is in fact an umbrella-term for very different kinds of regulatory arrangements.

This book sets out to study, from various angles, at least some of these intermediate and mixed forms of regulation, that can be identified. Although initially the group of contributors to this volume, most of them based at the department of legal theory at the University of Groningen, planned to publish a joint volume on ‘pure’ self-regulation, we soon stumbled upon ambiguous forms of regulation such as ‘conditional self-regulation’, ‘co-regulation’, or ‘commissioned self-regulation’. To analyze these and other regulatory forms, a continuum can be construed between traditional regulation and self-regulation, depending on the degree in which the central legislator is involved, and the degree in which it is left to the field to regulate itself.

Following Black’s (1996, 27) definition, self-regulation may be described as ‘the situation of a group of persons or bodies, acting together, performing a regulatory function in respect of themselves and others who accept their authority’ (Black 1996, 27). As Black notes, no particular relationship with the state is implied by the term self-regulation. Outside traditional regulation, Black (1996, 27) broadly identifies four types of possible relationships between the state and the ‘self’. In mandated self-regulation, a collective group (an industry or profession for example) is required or designated by the government to formulate and enforce norms within a framework defined by the government, usually in broad terms.

Especially in the European context, this is also referred to as ‘co-regulation’. The term ‘co’ suggests a joint enterprise which invites us to investigate what exactly is done by whom. It should be noted however that this ‘co’ does not always imply voluntary cooperation. In some cases norm-addressees are told that if they refuse to take measures and to report on what has been achieved, central government will resume its traditional task and will regulate matters in a traditional top-down manner. This is what Black refers to as ‘sanctioned’ and ‘coerced’ self-regulation.

In cases of sanctioned self-regulation, the collective group itself formulates the rules, which is then subjected to government approval. Coerced self-regulation refers to a case in which the industry itself formulates and imposes regulation, but in response to threats by the government that if it omits to do so the government will impose statutory regulation instead.

Finally, in cases of voluntary self-regulation there is no active state involvement, direct or indirect, in promoting or mandating self-regulation. As Black (1996, 27, fn. 21) points out, however, this does not mean that the government may not implicitly or explicitly rely on the body’s regulatory function. Yet the key is that the collective group itself takes the initiative in the formation and operation of the regulatory system.
If we want to locate a given example of regulatory activity on our continuum between ‘pure’ (traditional) regulation and ‘pure’ (voluntary) self-regulation, we should also keep in mind that the amount of governmental interference often depends on the degree of abstraction of the aims that are issued from a central level. If these aims are phrased in very abstract terms (e.g. ‘provide for a healthy environment’), there is some room for the addressees to shape them as they see fit. The activity in which they engage is concretisation of abstract aims into more workable and more concrete ones and there is some room of choice between different ways to concretise these abstract aims. If, however, the aim of the legislator is more concrete, the field can only hope to fill in the details. Their job is then merely to implement the requirements of the central regulator.

3 Dimensions of Regulation

For an analysis of the various forms of regulation it is not sufficient to analyse them in terms of ‘more’ or ‘less’ central steering or ‘more’ or ‘less’ room for self-regulation. It is equally important to determine the kind of activities and tasks that are involved. In this introduction, we will focus on three dimensions of regulation drawn from Hood et al’s (2001) work on regulatory regimes, namely the three control components of information gathering, standard setting and behaviour modification (see also Hutter 2006, 3).

Information gathering involves the collation and provision of information about policy issues and problem areas. In the legislative process, for example, representatives of the norm-addressees are consulted at different stages. They may be consulted long before bills are drafted, or they may be consulted about the effects of law long after the act has been passed.

Standard setting refers to the process of setting goals through standards and targets. Sometimes, experts or other groups of professionals are not merely required to draft the rules in order to meet a given aim. Rather, they are required to determine, on a case to case basis, the applicable norms. Their job can more appropriately be compared to that of a (common law) judge: by applying some rough standards to concrete cases it is hoped that more specific and more refined norms can be developed. An additional way to develop rules and standards is by negotiation. The social dialogue that takes place at the European level is an example in point. Here, the rules are not the product of some kind of legislation nor of some kind of case-to-case (judge-like) decision-making, but can be more aptly compared to the kind of rules that are established by contract. Finally, we should not forget that rules can be developed in order to facilitate control and supervision. In order to develop criteria by means of which performances can be judged and assessed, extensive lists of performance-indicators as well as minimum-standards have to be drawn up. These activities can be delegated to supervisory boards but they can also be entrusted to the field of norm-addressees itself, as is the case with a system of peer-review amongst professionals.

Finally, behaviour modification refers to changing individual or organizational behaviour, for example, through compliance, deterrence or hybrid enforcement approaches.

In all these activities, the government can adopt a more interventionist attitude or it can practice abstinence. In order to bring some clarity in our mixed bag of regulatory arrange-
ments, we thought it useful to draw a preliminary regulation matrix, capturing the various theoretical possibilities (Table 1). It combines both Black’s (1996) typology of self-regulation and Hood et al’s (2001) typology of different dimensions of regulation.

Table 1. The Regulation Matrix

<table>
<thead>
<tr>
<th>Information Gathering</th>
<th>Standard Setting</th>
<th>Behavior Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mandated Self-Regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sanctioned Self-Regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coerced Self-Regulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voluntary Self-Regulation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4 Complex Entities

A survey of the many possibilities suggested by the matrix above makes clear that relations cannot be characterized as pertaining between ‘legislators’ and ‘norm-addressees’. Although the practices of self-regulation studied by Sally Moore (1978) were less equivocal than the many intermediate forms that can be witnessed today, and although the groups that engaged in these practices (the garment-industry is an example in point) were closely knit together, one of the advantages of Moore’s concept of semi-autonomous social fields is that it is a functional term. It is not demarcated by organisational characteristics but by its ability to make rules and to enforce compliance. As such, the social fields that are engaged in the various activities listed above can also be constituted in different ways. More ‘voluntary’ forms of self-regulation are often produced by groups that have emerged relatively independently from governmental interference. But just as such ‘pure’ self-regulation is frequently a rather marginal phenomenon compared to all the intermediate and mixed forms of regulation, such ‘indigenous’ and closely knit groups are rare in comparison to the many social fields that engage in some of the above-mentioned regulatory roles.

This is not surprising. In view of the fact that many forms of co-regulation or conditional regulation are prescribed by central government, groups are either actively constituted by the government to that very end, or they are formed in reaction to the governmental obligation to self-regulation. So we find representative bodies of single groups (e.g. representatives of fishermen, or of museum-directors), we may come across more or less permanent combinations of (different) representative groups (e.g. a committee consisting of a representative of the trade-union together with a representative of a professional body as well as a cluster of companies) or we may find that a temporary committee has been instituted by the government with no other aim than to draft a specific code or protocol (e.g. Code Tabaksblat in the Netherlands). In virtually all such semi-autonomous social fields, the hand of the central legislator is visible. In the case of special committees this hand is very clear, but also in cases where a certain set of institutions and / or representatives have gathered themselves, this is often done as response to a certain piece of (imminent) legislation and in these instances we
may regard the composition of the social field a direct consequence of the way the central legislator has ordered and categorized the state of affairs to be regulated. The composition of the group then mirrors the constitution of regulatory reality. Perhaps an exception to this is formed by the groups who regulate the Internet. The group that has access to all kinds of open source software is literally unlimited and cannot be said to be constituted by any more central regulator.

Terms like 'central legislator' or 'regulator' are equally misleading by their simplicity. The central government of a nation-state is only a central government in relation to the citizens of such a nation-state. But in relation to the European Commission the same legislator may equally be regarded as a field of norm-addressees who are obliged to take measures and adopt legislation in order to meet the aims of the European Commission. Conversely, a committee consisting of social partners who develop rules while negotiating on the terms of adequate working conditions may decide to agree on just some main targets, and to delegate further rule-making to individual employers.

All this may suggest that regulation can be captured as a chain of delegation and may evoke a hierarchical picture in which higher echelons delegate further rulemaking to lower echelons. Such a hierarchical picture is, however, a distortion. In reality, also the European Commission is informed by experts and influenced by lobby-groups. The topics on the agenda, the ordering of the regulating landscape may therefore very well and to a large extent be determined by the very people that one expects to find at work at the bottom-end of such a hierarchical picture.

5 Overview of the Book

Most previous publications on self-regulation depart from one disciplinary or theoretical angle. They draw from theoretical insights developed in studies of public administration, public management or political science. This volume is different in its attempt to bring together not only different forms of regulation, but also different perspectives. Sociological investigations (Hertogh, Weyers) are combined with philosophical and conceptual analysis of regulation (Westerman). Political analysis (Hoogen/Nowak and Zeegers) is accompanied by analysis of information technology (Dijkstra and Mifsud Bonnici) and finally the academic perspective is complemented with a more practical point of view (Van Beuningen). This leads to a highly diverse picture, if not to eclecticism. In our view, however, eclecticism is not a vice but a virtue. In the many discussions that preceded the publication of this book, we usually felt that we had learned more of each other than we had expected.

[Brief introduction of all chapters to follow]
WHO IS REGULATING THE SELF?
Self-Regulation as Outsourced Rule-Making

Pauline Westerman

Introduction

Self-regulation has become the buzzword of any modern and enlightened legislator. It is generally assumed that it has become impossible to steer society from one central point. Some sixty years after Hayek\(^2\) wrote down his doubts concerning the possibility to acquire the knowledge which is necessary for central steering and planning, legislators of welfare-states have come to agree on the wisdom of his insights. Rather than trying to do the impossible and to get a bird’s eye’s view of society as a whole, it is said that governments should rely on self-regulating bodies, fields or networks. Multilevel governance is the banner, delegation of powers is the practice.

Sympathetic as all this may sound, we should not be misled by terms. Self-governance or self-regulation are terms that in this context acquire a specific meaning. In multilevel governance, the pleasantly pluralist sounding prefix ‘multi’ tends to obscure the question how these different layers and levels precisely relate and who decides on what. It is not my intention here to advocate a return to the situation in which central steering was an unquestioned practice. My aim is rather to elucidate the relations between the different levels. By investigating these relations, it will be possible to characterize the type of rules that are made by all these self-regulating bodies, and the functions they acquire in these new contexts.

In this contribution I will not analyse these relations empirically but try to relate this specific meaning of self-regulation to the style of regulation currently in vogue and practiced by both the European legislator as well as the legislators of the member-states. I will call this style goal-regulation.\(^3\) In forms of goal-regulation rules do not prescribe specific manners by means of which goals can be obtained, but prescribe the goals themselves in a straightforward manner. Norm-addressees are required to ensure the ‘protection of the environment’, to ‘improve health and safety’, or to further an ‘innovative knowledge economy’. They are furthermore required to draft the rules and regulations necessary to obtain those ends and to report on that. The kind of self-regulation which figures in this form of goal-regulation differs

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1 I would like to thank Steven Hartkamp for his inspiring comments and insights.
in a number of respects from the classical more 'spontaneous' forms of self-regulation as they were identified and studied mainly in the sixties and seventies of the previous century.\footnote{Moore, S.F., “The semi-autonomous social field as an appropriate subject of study”, in: Law & Society Review 7, 719-746, 1973.} In section 1, I will sketch the style of goal-regulation. In section 2, I will analyse its implications for the specific concept of self-regulation that is used, in terms of the Principle-Agent (P-A) model. In the next two sections I will contrast the kinds of rules most likely to be developed by 'spontaneous' self-regulation (section 3) with the kinds of rules that emerge in a goal-regulative context dominated by P-A relations (section 4). In section 5, I will touch upon organisational implications, followed by some concluding remarks in section 6.

1 Goal-regulation

In a system of goal-regulation central bodies often abstain from prescribing in a detailed manner the means and ways by which certain aims can be achieved.\footnote{Goal-regulation is sometimes referred to as discretion-based regulation. See D.G. Hawkins et al. Delegation under Anarchy: States, International Organizations and PA Theory, in Delegation and Agency in International Organizations 3, p. 7 (2005). The disadvantage of this term is that it leaves unspecified what is exactly the scope for discretion. The term 'principles based regulation' as used by J. Black in her article Forms and Paradoxes of Principles Based Regulation (LSE Working Papers 13/2008) is much better, but obscures the distinction between principles and goals which is in my view fundamental and which I explored in ‘Het nastrevenwaardige gefixeerd’, in: De grenzen van het goede leven: Rechtsgeleerde opstellen aangeboden aan Prof. Mr. A. Soeteman, Olaf Tans et al. (red.) Ars Aequi Libri, Nijmegen 2009, pp. 73-83} They do not require employers to allow a lunch-break of one hour, but tell them to alleviate unnecessary work-stress.

Examples of such goal-prescriptions are the framework directives issued by the European legislator. Precise rules that indicate the manner by which certain goals can be realized are supplanted by general duties of care, indicating a certain interest, value or goal to be reached. The general duties of care that figure in these directives are imposed on private parties or public bodies alike and are owed not just to some specified others but to the world at large.

It should be noted that such general duties of care are never presented in isolation. They are always accompanied by two other requirements:

1. an implementation norm requiring norm addressees to devise the means and to draft the rules that are necessary to achieve the imposed aims, and

2. an accountability norm: the requirement to report on the measures taken, the rules drafted or, generally, the progress that is made towards the imposed goal. In the Council Directive on Health and Safety at Work\footnote{89/391/EEC, 12 June 1989}, for instance, member-states are required to communicate the text of the provisions of national law to the Commission and to report every five years on their practical implementation. The accountability norm, therefore, requires norm addressees to prove that they complied with the first two requirements: the requirement to further a certain goal and the requirement to draft the necessary rules.

The strategy to impose goals in a direct manner is not only adopted at the European level, but is mirrored by the national legislatures. Also here, a general duty of care is formulated, although often that duty of care is more concrete than the abstract one issued at the more central level. And also here, the duty of care is accompanied by both an implementation and an accountability norm. Further down the chain, at the level where institutions or inspection
boards are confronted with these duties of care, the strategy is reproduced again. Goals are analysed in even smaller component parts and even here, lower organs are required to draft regulation and report on the progress made.

Schematically speaking, we might sketch this goal-regulative chain as follows:

1a) Further the protection of the environment. (aspirational norm)
1b) Make sure that you take the necessary precautions, draft the necessary legislation. (implementation norm)
1c) Report on the progress you made. (accountability norm)

2a) The emission of toxics should be as low as reasonably achievable.
2b) Make sure you carry out a feasibility study, take the necessary measures, including rule-making.
2c) Report on the progress you made.

3a) Within two years emission of toxics should be reduced by 10%.
3b) Inquire into the 'best available techniques'.
3c) Report on the progress you made.

At each successive stage, we see that the aim under a) acquires a more concrete shape. It specifies the component parts of aims (e.g. at 2a) and it specifies the degree in which these ingredients should be realized (see 3a). This means that at each level of norm-addressees, their rule-making activities mainly consist in two kinds of concretization: the analysis of the more abstract aim into component parts and the specification of the extent to which these component aims should be realized.

In a goal-regulative system, the term ‘self-regulation’ is used to refer to this twofold concretization. It is often called ‘conditional self-regulation’ in order to make clear that the self should regulate itself within an imposed frame of desirable goals and end-states. If in such a system, regulators extol the virtues of self-regulation, they simply say that they would rather like to outsource the business of rulemaking. If those to whom this activity is outsourced, repeat this strategy, they in turn simply outsource further rulemaking (read: concretisation) to more local levels. At each successive stage, norm addressees are told that they should engage in self-regulation.

2 Self-regulation of agents

A suitable and appropriate way to conceptualise the relations between the layers and levels that come into play in a goal-regulative chain is furnished by the model of Principals (P) and Agents (A) in which a Principal hires an Agent to perform a certain task. Goal-regulation being nothing more than a system in which rulemaking is outsourced, the P here indeed orders A to draft legislation.

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The paradigmatic example of a P-A relationship is that of a newly arrived visitor who hires a cab in order to bring him to the hotel. The visitor, foreign to the city, is obviously utterly dependent on the cab driver’s knowledge of the city plan. Unable to check whether the cab driver is taking unnecessary and costly detours, the P has to rely on the reports of others, or on certificates, proving that the taxi company is trustworthy or other such means to make up for the intrinsic information asymmetry between P and A.

This knowledge-asymmetry is also characteristic for the relationship between parties in multi-level governance. As we have seen, this asymmetry is the very reason why central bodies are keen on outsourcing rule-making. It is assumed that local knowledge can remedy the insufficiencies of the central bird’s eye view. Outsourcing rule-making, however, exposes the more central level to the risk that this knowledge is not used in order to draft the right rules, or that it is even used in order to achieve other objectives than those imposed. In order to make up for this form of uncertainty the P will ask proofs of trustworthiness. That is the rationale behind the duty to report: the accountability norms that pervade the goal-regulative scene.

In an important respect, however, the relationship between the more central and the more local level seems to escape from the P-A scheme. The more central level usually does not pay for these rule-making activities. The P here is simply not a paying customer but one with a gun under his coat. Institutions which refuse to make the necessary rules are often told that if they persist in their unwillingness to cooperate, they will be confronted with less benevolent regulations, issued by the central body. Euphemistically, this scheme is called ‘substitutive self-regulation’. Substitutive self-regulation can be phrased as: ‘if you don’t make rules, we do’.

Fortunately, the literature on the P-A model is not entirely dependent on the customer-example. A rival and more widespread exemplar is in use, which stresses the fact that P is always owner. Here P is not customer, but employer. Like in the cab-driver example, there is information asymmetry, but by virtue of his ownership P has a ‘right’ to control A which is not completely dependent on his ability to pay. Curiously enough, both the customer version and the employer version of P are used simultaneously, which is a source of confusion that pervades the entire literature on P-A relationships. Whereas any cabdriver is ready to point out to you the difference between his boss and his clients, the P-A literature is less clear on this matter. In order to analyse the goal-regulative chain in terms borrowed from the P-A model, it seems that we are more helped by the ‘owner’ metaphor than by that of the customer simply by the fact that the P here is not paying customer.

However, by doing so, we run into a third difficulty. The owner-metaphor is namely also present in yet another usage of the P-A model, namely where it serves to analyse the relationship between the electorate as P and representative government as the A. Here, P is ‘owner’ in the sense of ‘sovereign’. This usage of the P-A model is widespread but, I believe, highly

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9 Ibid.
problematic. In order to clarify and defend my own usage of the P-A model it is important to identify these problems.

In my view, there is a crucial difference between the P-as-electorate on the one hand and the P-as-boss/customer on the other. If we think of customers and bosses, they both issue *specific* directions and orders as to what should be executed by the A.\(^{12}\) This does not apply to the electorate. The electorate cannot be said to have identified a *specific task* that can be outsourced to the government. There is no easily identifiable goal that the citizen/voter wants to reach.\(^{13}\) If we could speak of a goal or task at all it can only be described in highly abstract terms (‘we the people’ want you to take care of the ‘common good’). That means that representative government can hardly be understood as an A. It is not an agent commissioned to execute a certain well-defined task (‘bring me to the hotel’; ‘paint that door’). Rather, it is entrusted to strike a balance between *different* competing perspectives and interests and by being representative of all the interests and values involved, the government is much more than an A. The current attempt to squeeze the traditional relationship between voter and government in a P-A model is ill-guided since it rests on the mistaken assumption that the voter has a specific objective in mind, which can be reached by expert knowledge.\(^{14}\)

But although the P-A model is hardly suitable to describe and analyse traditional relationships between electorate and government, it lends itself more easily to describe the relationship in the multilevel regulatory landscape of today. The central body who outsources rulemaking has indeed a rather clear idea in mind concerning the goals and objectives that should be reached. It is true that they are more abstractly formulated at the more central levels, allowing for more scope for reasoning and deliberation than at lower levels, but the end-state that should be reached is defined. The ends that should be pursued are not left free to be determined by the A. The ‘self-regulating’ bodies that are addressed here are real agents. They execute the tasks entrusted to them *within* the parameters proposed and according to the conditions laid out by the P. It is the P who decides on *what* should be achieved, whereas the A is asked to deliberate on *how* these can be reached.\(^{15}\)

It is important to note that objectives are formulated and defined by the P, since that affects the nature of the process in which the A should account for his performance. In the traditional relationship of the citizens versus representative government, the mandate is global. It does not specify which objectives should be reached and therefore there are no fixed criteria, determined beforehand, which can be applied in an evaluation of the performance. If representative government is held accountable to the public it is only accountable in general terms and they are evaluated in no less general terms. Since governments are required to pursue the ‘common good’, their conduct is judged in equally abstract terms. Gross breaches of trust may be reason for dismissal, not defectiveness in pursuing a definite goal.


\(^{13}\) Although it should be conceded that citizens tend to perceive themselves more and more as customers.

\(^{14}\) I should add that this distinction between specific directions and global mandates is one which allows for degrees. Even the proverbial taxi-driver, summoned to reach a specific destination, should drive with due care, and with reasonable speed, which means that he also has to strike a balance between these various requirements.

\(^{15}\) An important part of the P-A literature is devoted to the ‘trade-off between (a) the cost of measuring behavior and (b) the cost of measuring outcomes and transferring risk to the agent.’ See Kathleen M. Eisenhardt, ‘Agency-Theory: An Assessment and Review’, in: Theories of Corporate Governance: The philosophical foundations of corporate governance, ed. by Thomas Clarke, pp. 78-92, at p. 82.
This does not apply to the system of goal-regulation which is in use in multi-level governance. There, the central levels behave much more like the paradigmatic taxi customers and employers: they specify objectives and targets to be reached. This facilitates the formulation of criteria that should be met in order to judge whether the objectives are met. That is why parties in multilevel governance can without difficulty be understood and analysed as P’s and A’s.

The only thing we have to keep in mind is that P and A are relational terms. As such, the relations between P and A can be reversed, as can be seen in the regulative chain depicted above. The agent A that figures at stage 1 turns into principal P at stage 2. The A addressed at 2 is the P of stage 3. Each A will become a P in the successive stage. Each level of concretisation as indicated above marks a metamorphosis of an A into a P. Throughout the entire system it is the A who executes the plans of P and accounts to P for what has been achieved.

3 Rules for nurses who nurse

It is important to note that the fact that self-regulation is required and commissioned by a P adds two more tasks to be fulfilled by the A. It is not enough that the A
1. carries out the tasks for which it was instituted (to teach or to nurse) and
2. makes rules in order to perform these tasks.
But furthermore, the A is commissioned to
3. promote the aims imposed by P ('excellent education' and 'good health care')
4. draft rules or take measures in order to attain those goals
5. report on the progress that was made.

In order to understand the difference between the first set of tasks (1 and 2) and the second set (3-5) let us first analyse the tasks performed by a group of professionals which sets out to make rules (2) in order to carry out their daily work (1). Here, self-regulation can be called more or less 'spontaneous', i.e. not required by a P. In the next section I will proceed by discussing the additional tasks 3 to 5 that have to be performed if self-regulation is commissioned by a P. At the end of next section I will argue that the rules that are developed in spontaneous self-regulation (2) are different from those developed as a response to P (4) since they acquire a different function.

Which kinds of rules are likely to be developed by those who actually carry out the work, for instance nurses, in order to do what they are supposed to be doing: nursing? I propose to carry out a small thought-experiment. What kind of rules would a simple group of nurses develop who are working together in a hospital ward? In this –admittedly- idealtypical situation, we may distinguish five kinds of rules.

a) The first of these are coordinative rules. The nurses should know when they are assumed to bring patients to the X-ray department, when the doctor will pay his visit, at which times the family is permitted to visit, they should know the lunch hours of the haematology dept. And so on. Without a minimum of coordination, work is impossible.

b) But not only do nurses want to know when they are to perform certain acts; they also want to know what they should do. It is possible to act without rules and to act on the basis of insight, experience or intuition but in order to reduce the risk of mistakes made by people
without great insight or of short experience, it is helpful to have rules and protocols at one’s
disposal in order to decide on the kind of medical treatment that should be given to a patient
who exhibits such and such symptoms. These are heuristic rules. In any organisation such
rules of the thumb pertaining to the craft itself can be found.

c) A third variety of rules that would be convenient are rules that serve to distribute and allo-
cate time, energy, benefits, funds, and the like. They serve the allocation of (scarce) resources
and enable both the way nurses deal with the patients (’which patient do I treat first’) as well
as how they distribute scarce resources amongst themselves. Without such allocation-rules,
work is still possible, but again, deliberation on a case to case basis would be inefficient and
cumbersome.

d) A fourth variety would refer to how the ward would look like. These rules refer to how
clean the kitchen should be, the technical facilities that should be present, the way the ward
is furnished and the like. These rules do not tell anyone how to act but specify how the sur-
rounding workplace should look like. I will call these rules stage-setting rules. Of all four
varieties stage-setting rules are the least indispensable. There are many hospitals around the
world which are genuine hospitals but that do not in the least exhibit the characteristics that
are required by these rules. However, if we are to imagine what would happen in a ward
without stage-setting rules, we would probably come across some nurse suggesting rules as
to the minimum features of what should look a decent hospital, just in order to improve ef-
ficiency of the work that has to be done in such a ward.

e) Finally, if the group of nurses is big enough and has to deal with newcomers, pupils and
strangers, a type of rules would be developed that is similar to what Hart called secondary
rules: rules that stipulate who is competent to make and change rules if necessary and to solve
conflicts and how those tasks should be executed.16

All five varieties of rules (coordinative, heuristic, allocative, stage-setting and secondary ru-
les,) would be developed by this fictitious group of nurses in order to facilitate the work they
are doing. It should be noted that these rules are not primarily meant to advance a certain
interest or aim, although, if asked, nurses would acknowledge that the possibility of doing
deserves no implications that better health care is provided. But the rules are not devised in order
to advance such aims. They are primarily meant to guide and coordinate behaviour, and to
cut short deliberation on a case to case basis for reasons of efficiency.

A further characteristic of these rules is that most of them would probably go unnoticed.
They are developed in an implicit way, as a result of working together for some time. Their
existence is only noticed in case they are violated.

Furthermore, it should be noted that there is only a need to make these rules explicit insofar
as they are used as a common point of reference, a shared standard, that should be transmitted
to newcomers in order to serve as a reason to question and to criticise people’s conduct, or as a
reason to be advanced in order to justify one’s behaviour. (As a result, the allocative rules will

(orig. 1961).
probably be the first to be made explicit). It is not for the sake of explicitness itself that rules are made explicit, but merely because they can only serve as workable normative standards for criticism and justification if they are reasonably explicit. I say ‘reasonably’ because such a justification need not be exhaustive. If asked by patients why they have to wait so long for their breakfast, it suffices to explicitize the rule that room 1 comes before room 2 but it is not always necessary to justify the choice of the rule that patients are to be treated according to the room they are in.

Finally, it should be noted that the five varieties just mentioned are all functional in the sense that someone is to gain by the rule.

ad a) In the case of coordinative rules, this advantage is clear. My freedom of action is obviously constrained by the rule that I have to be there at 7 PM, but the freedom of others with whom I deal is thereby enhanced. They are absolved from the need to wait for me interminably and can plan the rest of their day accordingly.

ad b) In the case of technical rules of the thumb, the advantage should mainly be sought in the time- and energy-saving nature of rules, which absolve me from the task of weighing all relevant pros and cons for and against a certain action. 17

ad c) The virtues of allocative rules are manifold. They serve to make life predictable and to minimize arbitrary exercise of power, they may enhance the legitimacy of the resulting distribution, while excluding favoritism and privilege. Whereas the virtues of allocative rules seem somehow intrinsic to them being rules at all (any allocative rule is better than no rule at all) this is not the case with

ad d) stage-setting rules, which somehow seem to depend more on their content and the balance between the benefits and burdens they impose. Clean hospital-floors may be in the interest of all, but the requirement that there should be a distance of 80 cm between two hospital-beds is already further removed from evident public interest and as such tends to become perceived as unnecessarily restrictive. Nurses who devise stage-setting rules will probably be keen on selecting only those which facilitate their job.

ad e) The secondary power-conferring rules, finally, are more evidently useful for the reasons adduced by Hart: without secondary rules which regulate how the other rules should operate, the potential virtues of these other rules are endangered.

Summarizing, if nurses would be left to regulate themselves, they would probably come up with rules that enable them to coordinate actions, to make their job easier and more efficient, that enable them to solve conflicts over resources and which are only made explicit if they are used as common standards facilitating justification and criticism. All these rules have a constraining as well as a liberating side to them.

4 Rules to advance P’s aims

In the context of multi-level goal-regulation, we have seen, however, that the image of self-regulation as rule-making by e.g. professionals in order to facilitate the execution of their job, is too simple. The norm-addressee is not only asked to do his job, but also to promote certain aims, to draft rules and to report on what has been done. So let me now proceed and

investigate the kind of rules developed in answer to these additional requirements: the duty to achieve the aims imposed by P and the duty to report on the progress made.

If we return to our fictitious group of nurses, it is easy to see that faced with these additional requirements, they will for a large part draw on the body of rules that were already developed over the years. However, since these rules should be presented in a report to outsiders (the P) and since, moreover, they should clearly be presented as advancing the desired aims proposed by P, they should be translated and modified. The duty to achieve aims and to report on the progress made, gives rise to three requirements that should be met by the rules at hand.

- First of all, in order to be presented in a report, the rules should be made explicit. Rules of the thumb should be formalised into elaborate protocols, that are analysed to such an extent that they can be followed step by step.
- Second, it should be shown that these rules advance the imposed aim. There should be a clear link between the rules and the aim.
- Third, it should be shown that the rules are followed. The P is not satisfied with dead letters. That implies that not only a set of rules should be presented but also compliance rates. This furthermore implies that rules should require a performance that is demonstrable and controllable.

It is not easy to meet these additional requirements. In fact, in order to establish a clear and demonstrable link between rule and aims, one will probably be compelled to work from both ends. At the one end, aims should be analysed and concretised into workable units. At the other end, rules should be adjusted so as to fulfill their new tasks. In fact, this is exactly the picture that emerges if we study more closely the kind of tasks undertaken in a goal-regulative landscape.

*Analysis of aims:

In order to make the abstract aims workable, they should be concretised and specified. Some will try to specify good health care by subdividing the aim into a number of desiderata to be met: short waiting times, adequate information, permanent assistance of qualified nurses, and so on. Others will busy themselves with the question how short a short waiting-time is; and how adequate the information that should be provided. They will feel the need to compare their own performance with that of other comparable units and wards. Both forms of concretisation of aims are accompanied by the need to make compliance controllable. This leads to an analysis of aims and targets into preferably tangible and measurable units of performance that can serve as criteria for the evaluation of achievements.

The rules that are derived from such analysis of aims are mainly imperatives that specify the targets to be reached. They are of the type: `by the year x waiting-times should be reduced by y%'. They specify what should be reached, but not how that should be done. They are not action-guiding rules, but rules that are very similar to what I called stage-setting rules: rules prescribing the *situation* that should be reached.

It should be noted, that all those engaged, however, in concretising the proposed aim and specifying this aim into targets to be reached will be compelled to adopt an outsider’s perspective to one’s job and ask themselves the question: what is it what we are aiming for?
While they are thus deliberating on the aim of good health care, the personnel of a given hospital or ward (to stick with this example) are confronted with other goals as well. Good labour-conditions is a case in point. Or the obligation to protect the environment. Also these aims should be concretised; and levels should be ascertained below which a certain performance is deemed unacceptable. To that effect special committees and commissions will probably be established, each devoted to the aim at hand and busy with the development of performance indicators.18

The enormous energy that goes into specifying aims and targets is hardly compensated for by any gain. Partly, this is due to the nature of such target-rules. They are a special variety of what I called stage-setting rules. We already noted that the advantage of stage-setting rules is dependent on their content. They are not intrinsically beneficial, such as allocative rules, which may be preferred above case-to-case reasoning in virtue of the fact that they are rules. This also applies to the target-rules that are developed in the process of goal-specification. A lack of target-rules does not render life unbearable or capricious or arbitrary. All one can say is that without target-rules, people are more easily satisfied with their own performance. Without target-rules, jobs are performed but without the zeal to aspire to higher levels of excellence.

Such lack of ambition may be deplored but should be offset against the burdens this new form of rule-making impose. Whereas the five types of rules discerned in the previous section to a large extent remove the inefficiency of case-oriented decision-making, these rules do exactly the reverse: they invite to engage in continuous deliberation. The ongoing reflection on the goals-to-be-reached may even cost more time and energy than deciding cases on their own merits.

* Adjustment of rules:

But not only new rules will be developed; also existing rules will be presented to the P in order to show that P’s aims are taken care of. Some of the existing rules lend themselves more easily to fulfill the three above-mentioned requirements than others. As is to be expected, stage-setting rules almost perfectly fit the job. The aim of good health care can be analysed as comprising ‘hygienic surroundings’ and all the rules pertaining to hygiene can be said to be conducive to hygiene and therefore to good health care. Compliance rates can be proved by inventing schemes of internal quality assessment and control. In fact, the rules pertaining to such control-systems are in themselves stage-setting rules: they prescribe a situation to be reached.

It should be noted that such stage-setting rules will be more abundant in a goal-regulative system than in ‘spontaneous’ self-regulation. We saw that in the simple setting of nurses working together, stage-setting rules will be selected in view of their usefulness in everyday life. But in a P-A context, they acquire a different function. They are presented to show that the imposed aims are to some extent realized. Here, these rules will not be judged to the extent they facilitate work, but in view of their usefulness as justificatory tool. Since the assessment of progress takes place by means of benchmarking, stage-setting rules tend to be uniformly imposed and adopted, regardless of the special features of the local context.

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18 A.R. Macken, Te meten, of niet te meten: dat is de vraag (oratie Rijksuniversiteit Groningen). Amsterdam: SWP, 2006
Heuristical rules, the rules that give information about how to execute the craft itself, can also be used. But again, in the new context of rules for the P they acquire an additional function. They are not merely useful devices in order to know and to discover some recommendable strategies to be used in the diagnosis and treatment of patients. The mere existence of the heuristical rules in itself will now serve as proof that the aim of the P has been taken seriously and has been aspired to. In order to be useful as such a justificatory tool the rules of the craft have to be explicitised and formalised in protocols.19 And since the absence of such protocol increases liability in case of accidents, these protocols have to be standardized as well.

What about coordinative rules; the rules which are genuinely indispensible in any daily context? Here, a problem arises. We have seen above that coordinative rules do not owe their usefulness to their content. They are advantageous because they are rules. Their content-independence is obvious from the paradigmatic example of coordinative rules: traffic rules. Whether one drives on the right or on the left is indifferent. What counts is only that there is a rule to that effect. This feature of coordinative rules makes them ill-fitted to figure as proofs to the P that they help to further the imposed aim. The problem is simply this: there is no direct link between rules of coordination and the aims to be advanced. The only way they can be presented in the annual report is that there is some scheme of coordination. In this respect they play a poorer role than heuristical and stage-setting rules. Heuristical rules are not useful just because they are rules, but they owe their merits to their content. Only those heuristic rules that are ultimately based on sufficient scientific evidence are able to advance the aim of good health care. The same applies to stage-setting rules. We already remarked that their usefulness depends on their content. The cleanliness of kitchen floors can be directly linked to the aim of good health care. All this cannot be said to coordinative rules. They do not owe their value to their content.20

Allocative and secondary rules are in the same bag as coordinative rules. Their virtues are mainly -though not exclusively- to be sought in their being rules. That means that their justificatory role -at least to the outside world- is limited, compared to heuristical and stage-setting rules. Although any health inspector knows that rules which confer competences, regulate the internal organisation of a ward or its internal distribution of burdens and benefits, are generally useful, and that their existence is usually a good sign, signaling an efficient or orderly hospital, it is not the content but the mere existence of these rules which alone can count as an argument in the annual report. It is enough to point out that there is some scheme for cooperation or for allocation. That means that the existence of documents containing codes, protocols and the like is presented as proof in itself. The content of these documents is less relevant. They are not the topic of extensive debate in the various committees who have to show that they made progress towards the desired aims. Whereas hours can be spent on determining the targets to be reached, the amounts of patients to be treated, the length of waiting hours or the amount of knee-operations, the rules that keep the organisation going are much less intensely


20 We should keep in mind, however, that content-independence is a quality that can be realized by degrees. Traffic-rules are to a large extent content-independent -they are indifferent as to whether one drives on the right or on the left side, but not completely so. It is still unwise to allow cars to drive in the middle. See also Schauer, F., Playing by the Rules: A Philosophical Examination of Rule-Based Decision-Making in Law and in Life, Clarendon Press, Oxford, 1991.
debated. Their existence is merely taken for granted as long there is some written document. And the rule that requires such a document is in itself, again, a stage-setting rule.

The context in which rules operate is therefore crucial. If they operate in the context of accounting to P, the rules lose the function they had for A. They lose their heuristic or coordinative powers and turn into justificatory tools. However, we should note that although they are perceived and presented by A as mere justificatory tools, they probably have a different function for P. For P they do not serve as justificatory tools. Rather, the P relies on the existence of such rules as helpful tools that help him decide whether the A is reliable, has reached P’s objectives, etc. So, it may be possible that one and the same rule changes function three times. The rule to regularly turn patients in their beds may originate as a heuristic rule for a nurse to prevent the patient from incurring decubitus. The same rule may be formalized (‘the patient should be turned around 4 times a day at regular intervals’) and presented as a sign that the hospital is well-organised, in which case the rule is turned into a justificatory tool for the A. But in becoming such a tool, it acquires again the function of a heuristic rule for the P, who relies on the existence of such rules in his effort to assess the quality of the health-care provided by that hospital.

It should be noted that the degree of content-independence can change as well during the time-span of such a rule. As heuristic rule for the A the rule was mainly valuable for its content and its importance is assessed to the degree it helps the A to prevent decubitus. As a justificatory tool, it gains content-independence. Its mere existence is presented as a sign that the hospital is well-run. It retains that content-independence in the eyes of the P, since it is for the P not a rule that is valuable for its content (the content is not directly linked to his aim, viz. assessing the quality of the institution).

But also the reverse can happen. Let us suppose the existence of a coordinative rule stipulating that visitors should be allowed from 16-20 hrs. The content of that rule was indifferent to the nurses (it could have been from 9-13 as far as they were concerned). However, in the annual report the rule is presented as a sign that the hospital takes seriously the interests of working family-members and is thereby directly linked to one of the aims of the hospital (to be customer-friendly). It loses content-independence. Finally, it depends on the aims of the P whether the rule succeeds in retaining that content-dependence or not. In case it is the P’s aim to foster customer-friendliness, the rule will remain content-dependent, otherwise it will lose that quality and its mere existence will suffice to do the job.

It is tempting to draw the conclusion that the rules that are developed in response to P’s orders are only marginally -or at best partly- effective in the context of daily work. And the rules that implicitly play an important role in everyday life can only marginally -or at best partly- be referred to in the official reports. Two normative realities seem to exist next to each other.

5 Self-regulation by outsiders

Self-regulation as outsourced legislation seems to produce a different kind of rules than the ‘spontaneous’self-regulation that took place in our fictitious group of nurses. And to the ex-
tent the same rules are presented, they are coloured and selected in view of the new and differ-
ent function they acquire.

In the previous section I assumed that the mere necessity of adjusting rules to ends implies an outsider’s perspective. Nurses who are confronted with goals are wondering: what is it we strive after? The activity of pondering about ends and ways to achieve these ends implies by itself the adoption of an external point of view. I think that this is one of the reasons (but only one of them!) that those who gradually take on such managerial tasks as developing targets and formulating performance-indicators almost imperceptibly -usually even unwill-
ingly- move to the fringes of the professional body. Those who contemplate an activity rather than carrying it out. The normative space that is created in the various committees and commissions that are established in order to meet the increasing burdens of rulemaking and reporting does the rest. The rules developed there only partly covers the reality of everyday life. And they only partly meet the needs of those they are meant to regulate. They meet the requirements of the P, perhaps, but not those of the regulating 'self', the A.

In the meanwhile, we have seen that the rulemaking and reporting bodies that have been established need to be able to compare standards as well as achievements to those of comparable others. In order to compare and to assess the extent to which hospital A performs better than hospital B, the stage-setting and heuristical rules that play such an important role in the context of P-A relationships, should be standardized. This further implies the need for all sorts of consultation with other comparable boards, committees and commissions. A new network is gradually established of people who from now on have acquired another profession: that of delegated lawmakers, bench-markers, reporters and auditors. Depending on the field at hand, these people are either professional managers recruited from without the profession or they are originally professionals who have taken on administrative tasks and gradually evolved into managers and administrators. In many instances, companies and institutions merged into greater units in order to cope with the administrative burdens imposed on them. And finally, a lot of this rule-drafting work is carried out by branche-organisations who act as representatives of the field and as sparring partners for the P. The A is therefore often a multi-
layered whole itself, consisting of professionals, representatives of professionals, profes-
sionals turned into representatives or fulltime administrators. The 'self' of the A only exists as a simple whole in the eyes of the P. In reality the A consist for a large part of people whose job it has become to adopt an outsider's point of view in drafting 'policies'. It should be noted that some of these new outsiders are at the same time helpful in formulating the goals of P. In both official and unofficial ways, as reliable experts, consultants, etc. they can be involved in formulating’s P’s policies. So neither the A nor the P are simple entities, but both are in reality composite and complex wholes.

Keeping in mind the fact that the new layers of intermediate rulemakers, administrators, and reporters live in a different reality and a different normative space than those who they profess to represent, it can be expected that they in turn will feel the need to coordinate their actions, to invent rules of the craft, to allocate among themselves funds and resources and to regulate competences and powers. In other words; as a new professional group, carrying out tasks of 'their own' so to speak, they will feel the need to spontaneous self-regulation,
in just the same way as our fictitious group of nurses did in their work. As such they will live in two realities: in their reality as administrators they adopt an external point of view. As professional rule-makers, however, they are forming a new 'in' group, developing rules of their own. Until, of course, these latter rules are in turn transformed into justificatory tools for representation to an outside P, for instance when more central bodies call for regulations regulating the regulators. It is a dazzling - but, I fear, not an unrealistic- thought.

6 Conclusion

In this article I have tried to show that the cry for 'self-regulation' as a means to relieve the burden of rulemaking from the shoulders of central legislators should not be understood as a mandate to norm-addresseses to regulate themselves. Rather, the relation between legislator and norm-addresssee can be analysed as one between a principal and an agent, in which P outsources the task of rule-making to A. The A should draft its rules and laws, not for its own sake, but in order to achieve the aims aspired to by the principal. In order to control whether A fulfills that job adequately, the A has to report on the rules it drafted and the progress it made towards the imposed aims.

In order to meet these requirements, the A has to analyse the imposed aims into workable units that can function as targets to be reached. For the rest, it can rely on a body of rules that already had been developed as a response to the needs of everyday life. However, the different kinds of rules that were already developed and followed acquire a different function here. They are now mainly presented as justificatory tools. This implies they have to be transformed. Most of them will be modeled as so-called stage-setting rules, that have a firm connection to the imposed goals.

In general, those rules that can be represented as directly linked to underlying goals are preferred above rules where such a link is less evident, and which are mainly useful in virtue of their being rules. The criteria that distinguish useful from useless rules are not whether they facilitate working and living together, but to which extent they are capable of justifying performances in the light of P's aims. This means that the burdens that are imposed by such rules on those whose activities are governed, are not compensated for by benefits. They constrain but do not liberate. The 'self' that is governed, is in fact governed by a groups of professionals who live in a different (normative) reality and have different criteria, since they are mainly accountable to the P who commissions them to make rules in order to achieve P's own aims.

This state of affairs threatens to undermine the very foundations of goal-regulation itself. I noted above that the leading assumption in a system in which rulemaking is outsourced, is that norm-addresseses can be trusted to devise their own means in order to achieve P's aims. But of course, that liberty is in reality quite modest. If a hospital claims to advance health by an intensive practice of spiritual healing, this implementation will not be welcomed warmly. Goal-regulation is only possible in a world in which a certain level of performance is already realized and in which some (professional) values and practices are widely shared. In a situation in which these values and practices need to be presented as justificatory proofs that P's aims are realized, they risk to lose these important functions.
CRIME AND CUSTOM IN THE DUTCH CONSTRUCTION INDUSTRY
A Socio-Legal Case Study of Self-Regulation

Marc Hertogh

1 Introduction: Fiddling with Millions

In 2001, the construction industry in the Netherlands was at the heart of many public and political debates. A television documentary (entitled ‘Fiddling with Millions’) suggested that all major construction companies were involved in an illegal clearing system that colluded in price offers for public works. After this TV program, the Dutch parliament decided to conduct a parliamentary enquiry which showed a widespread use of cartels and structural “bid rigging” within the Dutch construction industry (PEC 2002a). Although collusion in the construction industry is not extraordinary and is also well documented in other countries (McMillan 1991; Gupta 2001; Lee & Hahn 2002; Transparency International 2005), the Dutch collusion scheme is exceptional in its scale, durability and the way it is institutionalized (Doree 2004, 149). Despite the fact that the clearing system of the Dutch construction industry was prohibited by the European Commission in 1992 and by the 1998 Dutch Competition Act, Dutch builders continued their illegal activities as if nothing had changed. According to the Parliamentary Enquiry Committee (hereafter PEC):

‘This seems to indicate that the “culture” of the construction industry (...) has played a more important role than the rules of the Dutch and the European government.’ (PEC 2002b, 134)

This case raises several important questions. Why were these practices so widespread in the Dutch construction industry? Why did Dutch contractors continue these practices even after they were made illegal? And – in more general terms – what does this case tell us about the interplay between state-regulation and self-regulation? In addressing these issues, this chapter focuses on how contractors think about Dutch competition law and EU antitrust regulations. Most previous studies focus on the lack of compliance in the Dutch construction industry with antitrust law. This is often explained by the fact that these rules were not sufficiently enforced by the authorities. According to Van den Heuvel, ‘prosecution of cartel offenses

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1 Thanks to Friso Jansen for his help in collecting and reviewing the literature.
2 An earlier and less comprehensive version of this case study was previously published in Dutch, see Hertogh (2005).
3 Wikipedia defines ‘bid-rigging’ as: ‘a form of fraud in which a commercial contract is promised to one party even though for the sake of appearance several other parties also present a bid. (...) It is a form of price-fixing and market allocation, often practised where contracts are determined by a call for bids, for example in the case of government construction contracts.’
4 Unless indicated otherwise, all quotations in this chapter were translated from Dutch into English by the author.
had no priority in the Netherlands’ (Van den Heuvel 2005, 138). As a result, he has suggested to ‘introduce more serious sanctions’ and to ‘regulate contacts between the authorities and the business world more strictly’(Van den Heuvel 2005, 148) By contrast, this chapter uses a ‘constitutive’ approach. Our aim is to move ‘away from tracking the causal and instrumental relationship between law and society toward tracing the presence of law in society’(Ewick and Silbey 1998, 35; emph. added). Rather than focusing on legal compliance, I will use the theoretical framework of legal consciousness to focus on people’s understandings of law (cf. Fleury-Steiner and Nielsen 2006, 1). Thus, rather than asking how much does law matter, this paper asks: how does antitrust law matter in the Dutch construction industry? This case study is primarily based on the proceedings of the public hearings of the PEC with a large number of contractors and other representatives from the industry (see PEC 2002c).

In the early 1960s, Stewart Macaulay published a paper which would later become one of the most important studies of contemporary sociology of law. Inspired by Malinowski’s (1926) classic anthropological field-study of the Tobriand Islanders Crime and Custom in Savage Society, Macaulay (1963; 1995) studied business practices in Wisconsin and found that a significant amount of business exchanges was done on a noncontractual basis. First, business agreements were frequently made without knowledge of the relevant rules of contract law. Moreover, disputes were frequently settled without reference to the contract or potential legal sanctions and law suits for breach of contract were rare. Macaulay argued that the key in understanding this practice, is the long standing relationship between businessmen. In this chapter, Macaulay’s study will be used as our central frame of analysis. To what extent is Macaulay’s account of the practice of Wisconsin businessmen similar to the practice in the Dutch construction industry?

After a brief introduction of the Dutch construction industry and the relevant legal framework, I will discuss two types of legal consciousness studies. The first type asks: How do people experience law? And the second type asks: What do people experience as law? Both perspectives demonstrate how Dutch contractors relate to antitrust law. Moreover, they show that the construction industry has its own internal legal order, with its own rules and its own system of rule-enforcement. Based on the outcomes of our case study, it will be argued that normative concerns are an important determinant for legal compliance. In the final section, the analysis of the Dutch construction industry will be used to draw several general conclusions about the interplay between state-regulation and self-regulation.

2 The Case of the Dutch Construction Industry

2.1 Introduction

The construction industry is a major contributor to the Dutch economy. ‘The Dutch construction industry is characterized by many small firms and some large companies, by heterogeneity in the types of firm and by strong price competition in local markets.’(Bremer and Kok 2000, 99) In 2002 (at the time of the Parliamentary Enquiry) the industry had a yearly turnover of 15 billion Euros. With over 5 billion Euros in commissioned works, its most important client was the government. Moreover, 5% of all jobs in the Netherlands is provided by its construction industry. This chapter will focus on the roads and groundwork sector.
2.2 Self-Regulation in the Construction Industry

The TV-program ‘Fiddling with Millions’ showed that all major Dutch construction companies regularly met in secret just before an offer procedure in order to determine which company was cheapest and to increase its price offer. The winning company shared the increase in profitability by reserving compensation for the other companies. This practice goes back to the 1950s when the Dutch government stimulated an elaborated system of self-regulation in the construction industry (see Graafland 2004, 127).

In 1953, the so-called Wegenbouw Aannemers Combinatie (road construction building contractors combination, WAC) was founded. According to rules approved by the Dutch government, the WAC organized pre-consultations between the construction companies, in which companies communicated their prices. The cheapest company was elected and received the order and compensated the other companies for the calculation costs involved in their offers. In 1963 a similar organization was founded for the entire construction sector (the union of cooperating price-regulating organizations in the construction sector, SPO) covering 28 cartels and 4000 companies in the construction sector. The Dutch government also approved of this organization.

In the early 1990s, however, after several decades of (government monitored) self-regulation, this Dutch practice was no longer considered legally and politically acceptable. In 1992, the European Commission prohibited the practice of pre-consulting, arguing that it violated Article 85, Section 1 of the EU Treaty. Consequently, the EU ordered the SPO to dismantle the cartel and imposed on its member organizations fines totaling several million Euros. Instituted by the EC, the Dutch government eventually decided to forbid the practice of ex-ante consultations as well. In 1998, this was also reflected in the new Dutch Competition Act and the establishment of the National Anti Trust Authority (NMa). Finally, in 2004 three government departments together with representatives of the construction industry established the so called ‘Management Council’ (‘Regieraad Bouw’). This Council is aimed at promoting and monitoring a profound ‘process of change in culture’ in the construction industry, along the lines suggested by the Parliamentary Enquiry Commission.

2.3 Limited Impact of Anti Trust Laws

Although the Dutch system of pre-consultation has been prohibited since 1992 (and later again in 1998), the Parliamentary Enquiry and several other studies show that in practice these new legal rules were hardly complied with and most consultation meetings continued as they did before. The TV documentary contains a clear illustration of this. It shows a copy of the financial accounts of a large construction firm, in which all deals and agreements from pre-consultation rounds were carefully recorded. Until 1992, all entries were registered automatically by computer. After 1992 the list of entries is simply continued, only now in handwriting.

The PEC concludes that the illegal practice of pre-consultation was not limited to a handful of businesses, but covered the entire Dutch construction industry. Nearly every single company was involved. Or, in the words of a senior manager of a major road building company:
‘The system [of pre-consultation] simply continued after 1992 the same way as it did before.’ (public hearing 28, 537)

In a public hearing before the PEC, he explains this practice in the following terms:

‘This system has been passed on from father to son, from director to son, etc... I guess you could say: we will switch off the lights on December 1, 1992... But this system continued throughout the years. You don’t get out of it easily, it is a circuit, you don't just step out of it.’ (public hearing 28, 544)

Other contractors paint a similar picture. The former secretary of one of the price-regulating bodies in the construction industry gives the following account:

‘Everybody did it and everyone knew that it was no longer allowed. In 1992 there was a temporary pause, but soon afterwards we picked up our old habits again. Those former senior executives from large construction businesses, who now claim that these practices did not exist in their own companies, are simply not to be believed.’
(cited in Vulperhorst 2005, 27)

Finally, this picture is also confirmed by the following exchange between a member of the PEC and a contractor:

- ‘So, you knew this was not according to the rules?
- Sure.
- But you continued, nevertheless?
- We didn’t continue, it has always been like this and it has it stayed this way.’
(cited in PEC 2002a, 92)

After the publication of the final report by the PEC in 2002, many politicians and public officials were confident that from now on the Dutch construction industry would act in accordance with the law. The industry has, no doubt, adopted many changes in recent years. And it seems as if most major construction companies are no longer structurally involved in illegal practices. There are, however, several strong indications that the practice of pre-consultations has still not yet completely disappeared. For example in 2004, two years after the PEC report, the Dutch media revealed the existence of yet another set of ‘black accounts’ in the construction industry (see Van Bergeijk 2007, 118). Moreover, a recent survey among businessmen in the Dutch construction industry suggests that – in some places – the system of pre-consultation is still alive (Foekema and Nikkels 2008). More than half of the respondents thinks that not much has changed in the industry and several companies admit that they are still occasionally approached to participate in illegal bid-rigging. Similarly, in the Winter of 2009 the Dutch media reported that five construction companies were being prosecuted for illegal price-fixing and other cartel activities. Although all these companies were concentra-

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5 Throughout this chapter, these numbers indicate the order and the page numbers of the public hearings, as they were published in the official proceedings (see PEC 2002c).
ted in the south of the country, the Chair of the National Anti Trust Authority (NMa) suspects that there may still be many more similar cases like these:

‘We have received several signals that, although there have been drastic changes in the construction industry, these cartel practices continue to exist throughout the country. That is something that we are now looking into.’ (cited in Dohmen and Van der Steen 2009)

What does this tell us about the system of self-regulation in the industry? Unlike most previous studies, this cannot be fully explained by focusing on issues of legal compliance or by a lack of enforcement by the authorities, but we also need to look at the Dutch construction industry through the lens of ‘legal consciousness’.

3 From Legal Compliance to Legal Consciousness

3.1 Introduction

On a cold winter’s day, anyone who takes a walk outside immediately senses the impact of the wind-chill factor. This is the temperature that a person feels because of the wind. For example, a thermometer may only read minus 2 degrees Celsius outside. But when the wind is blowing at 45 kilometers per hour (km/hr), the wind-chill factor causes it to feel like it is minus 10 degrees Celsius. For a good understanding of the local weather conditions we should therefore take into account both objective and subjective elements. The same holds true for law. If we want to understand the social significance of law, we should not only focus on the law in the books, but also on the way that people experience law. This ‘legal wind-chill factor’ plays a central role in recent legal consciousness studies.

3.2 Legal Consciousness Studies

Using a popular definition, legal consciousness could simply refer to ‘all the ideas about the nature, function and operation of law held by anyone in society at a given time’ (Trubek 1984, 592). Yet, under this general heading various researchers have applied the term in many different ways. Legal consciousness can refer both to: aptitude, competence or awareness of the law; and to perceptions or images of law. Most empirical studies in the first category date back to the 1970s. In these studies levels and degrees of public knowledge and opinion about law are treated as social facts to be discovered and recorded. In this approach, which has come to be called the KOL (knowledge and opinion about law) literature, attitudes are seen as measurable data, which can be compared with the content or policy of legal provisions. Using large statistical surveys, many KOL studies point to low levels of legal knowledge and considerable variations in attitude to law and the legal system. More recent studies argue that, contrary to the central belief of much of the KOL research, legal systems are not simply ‘social facts acting upon society’ (law and society). Instead, law is the label given to a certain aspect of society (law in society). This has led researchers of legal consciousness in more recent years to focus more on ‘images of laws and legal institutions that people carry around

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6 This section has been adapted from Hertogh (2004).
in their heads and occasionally act upon’ (Engel 1998, 119). Unlike the early KOL studies, the fieldwork involved in these more recent examples is often detailed descriptive ethnography. As I have argued elsewhere, we can differentiate between an ‘American’ and a ‘European’ conception of legal consciousness (Hertogh 2004).

3.3 An ‘American’ Conception

Most of the contemporary literature on legal consciousness originated in the United States. Merry (1990), for example, studied litigation and mediation among working-class Americans in two New England towns. In her book she looks at the ways people, who bring personal problems to the courts, think and understand law and the ways people who work in the courts deal with their problems. Similarly, Nielsen (2000) examined the legal consciousness of ordinary citizens concerning offensive public speech. Drawing on observations in public spaces in three California communities and in-depth interviews with subjects recruited from these places, she analyzed variation across race and gender groups in attitudes about how offensive public speech should be dealt with by law. According to Nielsen, the legal consciousness of ordinary citizens is not a unitary phenomenon, but must be ‘situated’ in relation to particular types of laws and to race and gender. Finally, in their book, Ewick and Silbey (1998) develop an empirically based theory of legal consciousness. In over 400 in-depth interviews they asked New Jersey residents general questions about their lives and the problems they face in their schools, workplaces, and communities, allowing respondents to elaborate whether and how they thought of law’s role in these spheres. Based on their interviews, Ewick and Silbey identify three predominant types of legal consciousness. Subjects can be ‘Before the Law’, impressed by its majesty and convinced by its legitimacy; ‘With the Law’, utilizing it instrumentally and generally understanding law as a game, and ‘Against the Law’, cynical about its legitimacy and distrustful of its implementation.

These studies by Merry, Nielsen, as well as Ewick and Silbey are three representative examples of an ‘American’ conception of legal consciousness. The primary focus of this conception is: How do people experience (official) law? In these three studies ‘law’ is considered an independent variable. The definition of ‘law’ is provided by the researcher and is not part of the empirical enquiry itself.

3.4 A ‘European’ Conception

In his review of the current literature, Engel (1998, 139) has argued that ‘studies of legal consciousness have sometimes forgotten important lessons from the past’. A prominent example of this is that, although decades of law and society research have convincingly demonstrated that ‘[d]ifferent groups have different kinds of law’, most studies still focus almost exclusively on ‘official’ law. Yet, law is not necessarily an instrument of state power and its connection with the state is ‘a problem to be studied rather than a fact to be assumed’. Moreover, ‘[e]ven if one focuses on “official” law, one still finds a significant dependence on unofficial or customary rule structures to determine norms of reasonableness or fairness’. Engel therefore calls for a view on legal consciousness ‘from below’. The basis for such a view can be found in the European tradition of the sociology of law, most notably in the work of the Austrian legal theorist Eugen Ehrlich (see Hertogh 2009).
In 1912, Ehrlich presented a unique research project aimed at studying the ‘living law’ of the peoples of the Bukowina, where Armenians, Germans, Gipsies, Jews, Hungarians, Romanians, Russians, Ruthenians, and Slovaks lived side by side. To study the legal consciousness of these people, Ehrlich wanted his project to register those ideas and personal histories that were typical for their own ideas of law (Rechtsauffassung der Leute). To Ehrlich, the law is a notion (Gedankengebilde) that lives in people’s heads and which can be identified on the basis of people’s attitudes.

Legal consciousness in this sense essentially refers to people’s own ideas about law, regardless of any ‘official’ laws. Law is considered a dependent variable; the definition of law is not provided by the researcher, but is part of the empirical enquiry itself. I will refer to this as a ‘European’ conception of legal consciousness. This primary focus of this conception is: What do people experience as ‘law’?

Both approaches to legal consciousness will now be applied to study the way in which businessmen in the Dutch construction industry relate to law.

4 How Do Dutch Contractors Experience Law?

4.1 Introduction

Although Macaulay did not use the term ‘legal consciousness’ himself, this approach is very much at the heart of his study of how Wisconsin businessmen relate to contract law. Most of them are very critical about law. In their experience, law is often far too inflexible to apply in their every business dealings. Moreover, they consider law as a threat to the necessary level of mutual trust among businessmen.

4.2 Law is Inflexible

According to Macaulay, businessmen often consider law to be very inflexible. By putting everything down in writing, the much needed flexibility for doing business is lost. One of the respondents in Macaulay’s study, a lawyer with many industrial clients, explains this in the following terms:

‘Often businessmen do not feel they have “a contract”- rather they have “an order”. They speak of “cancelling the order” rather than “breaching our contract”. (...) There is a widespread attitude that one can back out of any deal within some very vague limits. Lawyers are often surprised by this attitude.’ (cited in Macaulay 1963, 57)

Similar views are also dominant in the Dutch construction industry. The chairman of a national organization of employers in the building industry puts it like this:

‘Lawyers are very respectable people. Yet building is first and foremost a technical job that has to take place on one particular site and where you cannot simply take the products from the shelve. You have to prevent a situation in which you have to record all conditions and all possible exceptions in a contract, while – as
soon as things slightly go wrong – you have to take the case to court...’ (public
hearing 55, 1072)

In the public hearings before the PEC, some builders also emphasize that preparing a bid is
often a very complicated job with many different calculations. As a result, it is easy to make
mistakes. By putting everything into legal terms, some feel their margin for error becomes
very small. According to one respondent, this is an important reason why he preferred the old
situation of pre-consultations:

‘If you had made a mistake, you had to the right to withdraw from a bid. It fre-
quently happened that we made a big mistake. At the time there were no compu-
ters yet.’ (public hearing 27, 511)

The idea that a large emphasis on formal legal rules makes doing business too inflexible and
too slow is also reflected in a more recent survey among members of the Dutch construction
industry (Foekema and Nikkels 2008). According to this survey, a large majority of builders
(93%) – in principle – supports the prohibition of cartels and the promotion of more compe-
tition. There is, however, considerable less support for the way in which this general idea has
been translated into law. Their major point of criticism is, that this has simply produced too
many unnecessary rules. Most respondents (87%) feel that, generally speaking, ‘there are too
many government rules that we have to comply with’ and nearly two thirds of the respondents
(62%) is ‘getting tired from all those government rules related to a procurement’.

4.3 Law Corrodes Trust

In Macaulay’s study, many businessmen also emphasize that you can only do business based
on mutual trust. In their view, this is why the use of official contracts is usually not necessary.
Moreover, they claim, contracts can have all sorts of negative side-effects. One businessman
expressed a common business attitude when he said:

‘If something comes up, you get the other man on the telephone and deal with the
problem. You don’t read legalistic contract clauses at each other if you ever want
to do business again.’ (cited in Macaulay 1963, 61)

Many people in the Dutch construction industry feel the same way. They, too, emphasize
the value of mutual trust and they feel that the use of law may corrode this trust. ‘Legalism
produces all sorts of bad mechanisms’, according to a former senior manager. And he con-
tinues:

‘If fear and overly legal thinking take over in a relationship between two par-
ties with a unique product, this will turn into a disaster… If lawyers would take
charge in business, there will be no more deals.’ (cited in Camps 2002)

The senior manager of another major Dutch construction industry supports this claim:
Imagine that three lawyers have to be present before we can sign a contract! There has to be some basic level of trust. We have to be sure about what we're involved in.’ (public hearing 21, 398)

4.4 Discussion

This perspective on legal consciousness provides an interesting account of how the Dutch construction industry relates to law. Using Ewick and Silbey’s (1998) typology, it is clear that very few contractors are ‘before the law’. Generally, they are not convinced by the legitimacy of antitrust law. Instead, they criticize the law because it is inflexible and it corrodes the level of trust among businessmen. As a result, the law is not being used instrumentally by most contractors and there are no clear examples of a ‘with the law’ legal consciousness either. Overall, the Dutch construction industry seems to be rather cynical about the legitimacy of law and distrustful of its implementation. This makes ‘against the law’ the most dominant type of legal consciousness.

It should be stressed, however, that this type of legal consciousness is typical for their attitude towards antitrust law, but is probably not representative for their attitude towards ‘the law’ in general. Thus far, there have been no signs that the Dutch construction industry frequently ignores or breaks other aspects of private or criminal law. This seems to suggest that, with regard to fields of law other then antitrust law, the legal consciousness of the construction industry can be more accurately described as ‘before the law’ or ‘with the law’. This is one of the reasons why a frequently made comparison between the Dutch construction industry and criminal organisations (like the mafia) (see Vulperhorst 2005, 200) does not hold.

After this analysis, some important questions are still left unanswered. It appears that the way in which contractors relate to antitrust law also depends on their own normative ideas about doing business, about competition, and about the way in which conflicts should be dealt with. But what exactly are these ideas? This requires us to shift our focus from the goals and ambitions of the legislator and law enforcement agencies (top-down) to the values, norms and internal rules of the construction companies themselves (bottom-up).

5 What Do Dutch Contractors Experience as Law?

5.1 Introduction

The final report of the PEC concludes that the system of pre-consultation played an important role in the Dutch construction industry. In this system, all the firms involved had an individual claim account. Adjustments to these claims were recorded through phantom book-keeping (Doree 2004, 149). When a project was open to offers, a special meeting would be arranged shortly before the contractors had to submit their bids. In this meeting, the contractors would resolve who would put in the lowest bid and how high this bid would be. The price to be tendered by the successful bidder was decided upon and the ‘unsuccessful’ companies would submit higher tenders. To compensate the ‘losing’ companies, the ‘winner’ would transfer an agreed amount from its claim account to those of the other contractors. For the running of this system, they applied their own set of rules and they relied on their own internal mechanisms
of rule enforcement. In this sense, the Dutch construction industry can be considered a ‘semi-autonomous social field’ with its own internal ‘legal order’ (Moore 1973).

5.2 Internal Norms and Rules

In his study of Wisconsin businessmen, Macaulay found that contract and contract law were often thought unnecessary, because there were many effective non-legal rules and sanctions (Macaulay 1963, 63). According to Macaulay, two internal norms were widely accepted: ‘1. Commitments are to be honored in almost all situations’; and ‘2. One ought to produce a good product and stand behind it.’

Similarly, the PEC found that the system of pre-consultation in the Dutch construction industry was based on ‘a detailed system of agreements, and mutual rights and obligations’ (PEC 2002a, 243). In some cases this internal system was highly institutionalized. While some contractors simply kept a small notebook or registered all their deals on their laptop, other firms used special registration forms with matching envelopes:

‘It was just a regular form. You could fill in the number of bidders, the total sum and sometimes separate amounts reserved for “clearing” money. All this information was collected in one central place... I believe I had to keep the blue form and that a yellow form was sent out.’ (public hearing 27, 519)

Underlying these systems of registration, was an elaborate system of internal norms and rules. Based on the public hearings before the PEC and other empirical material, it is likely that the following four rules were widely accepted in the Dutch construction industry:

a. ‘Each Claim Should Be Compensated’

In the construction industry each claim needs to be compensated. When it is agreed that one contractor is allowed to put in the lowest bid; this immediately creates an obligation towards the other contractors participating in the pre-consultation round. The next time, he will step aside and one of his colleagues will be allowed to put in a bid. This emphasis on reciprocity is also reflected in the fact that most contractors record all their deals and their claims carefully (elaborate system of phantom accounts). Also, it is a general feeling among most contractors that they have a right to be compensated for all expenses related to the calculation of their bid (even if their bid was rejected).

b. ‘All Bids Should Be Distributed Equally’

Within the closed circle of contractors participating in the system of pre-consultation, all parties have equal opportunities, provided that they act in accordance with the internal rules. As a result, small companies (who in a situation of open competition would probably not survive) are equally ‘protected’ as bigger companies. However, anyone who does not comply with the internal rules of the construction sector gets excluded. The ‘insiders’ will do anything possible to exclude ‘outsiders’ from ‘their’ business; and to prevent them from working as much as possible. It should be emphasized that this focus on equality is not related to the promotion of some abstract socialist ideal, but was primarily aimed at increasing the predictability of a highly unpredictable market (Van de Bunt 2008, 137).
c. ‘All Accounts Should Be Cleared Internally’
In the Dutch construction industry, contractors rarely exchanged real money (see Doree 2004, 14). A contractor’s claim account would accrue over time but then reduced whenever a project was ‘bought’. The individual contractors tried to keep their claim accounts balanced as much as possible. Occasionally, special meetings were arranged to smooth the accounts (referred to as ‘clearings’). According to one of the participants, this meant: ‘clearing ‘til the bitter end.’ Only in those rare cases in which this failed, real money would be exchanged.

d. ‘Don’t Talk to Strangers’
The fourth and final rule of the Dutch construction industry provides that the details of the internal system of pre-consultation should never be discussed openly. This rule not only applied to those contractors who participated in the system, but the rule was also followed by those contractors who were not involved in pre-consultations themselves. In a way, the importance of this rule is still reflected in a recent survey among Dutch contractors. In 2008, almost half of the respondents still admit they prefer not to talk about former price-fixing arrangements (Foeckema and Nikkels 2008, 10).

5.3 Internal Rule-Enforcement
The PEC report shows that in most cases these internal rules were fully complied with. Moreover, there are very few reports of deceit or internal conflicts in relation to these rules and there are no documented cases of violence in the Dutch construction industry (see Van de Bunt 2008, 140). To secure this high level of compliance, the industry relied on two highly effective internal instruments: reputation and exclusion. Both elements were also reported in Macaulay’s study. According to Macaulay, two businesses who are involved in a business deal do not only want to do business with each other again, they also want to deal with other companies in the future. The way one behaves in a particular transaction or a series of transactions, will color his general business reputation. Macaulay (1963, 64) points to the highly effective informal sanction of ‘blacklisting’. A similar mechanism is also at play in the Dutch construction industry (Van Erp 2008). Once it becomes known that one business does not comply with the internal rules (or tries to avoid the system of pre-consultation), it immediately becomes isolated by the other businesses. To sustain this system, contractors also tell each other stories about former colleagues. One contractor explains, for example:

‘At this one company, they’ve tried to get out of it for over year. You’re then immediately treated as an outcast. Those people never got any decent work again.’
(public hearing 21, 390)

This also explains why the illegal system of price-fixing could be sustained for so long. Most contractors felt that it was impossible to step out of it. If they did, they were simply excluded from the market. According to Doree (2004, 153), individuals could not break out of this system. Firms that tried to do so were cut off from new projects or resources and had to rejoin the system or face bankruptcy. One contractor describes this situation in the following terms:
‘People were collectively and structurally captured in a system from which one did not want to or could not escape. To some extent, you were a prisoner of the system.’ (cited in Van de Bunt 2008, 135)

Likewise, the director of a major construction company explains:

‘As soon as your company decides to step out of it, you immediately seal the end of your business.’ (public hearing 11, 193)

Finally, this highly effective internal system of enforcement also influences the way in which the construction industry thinks about the official enforcement agencies, like the National Anti Trust Authority (NMa). Consider, for instance, how the secretary of a board member of a major construction company talks about her work to the PEC:

- ‘How did people in the industry think about the NMa?
- I don’t know; their name was hardly ever mentioned.
- Their name was hardly ever mentioned?
- Yes.
- So, it was not as if the NMa was held in very high regard?
- No.’ (public hearing 8, 147)

6 Linking Legal Consciousness with Legal Compliance

Why do people obey the law? Tyler (2006, 3) differentiates between an ‘instrumental’ and a ‘normative’ perspective. The instrumental perspective underlies the deterrence literature: ‘people are viewed as shaping their behavior to respond to (…) incentives and penalties associated with following the law’ and to judgments about the personal gains and losses resulting from different kinds of behavior. The normative perspective, on the other hand, focuses on ‘people’s internalized norms of justice and obligation’. In this view, people obey the law ‘because one feels the law is just’ (Tyler 2006, 4).

Both perspectives are also helpful in analyzing the case of the Dutch construction industry. Why did the illegal price-fixing in the Dutch construction industry continue, despite the fact that - since 1992 - it was illegal? The answer of this contractor reflects both perspectives:

‘Why did this practice continue (…)? There are two explanations. First, the economic motive. (…) In the short run, the gains were bigger than the losses. Second, the ethical motive. The new legal norms were not supported by the common values of the industry.’ (cited in Vulperhorst 2005, 110)

Thus far, the ‘instrumental’ perspective has dominated the literature on price-fixing in the Dutch construction industry. Economists have pointed to important structural characteristics of the industry which make it vulnerable to the creation of cartels. Moreover, lawyers and criminologists have argued that the illegal system of price-fixing in the Dutch construction
industry can be explained by the fact that enforcement agencies were not as strict as they should be.

Tyler (2006, 64) has suggested that ‘normative concerns are an important determinant of law-abiding behavior, in contrast to the instrumental concerns that have dominated the recent literature on compliance.’ Our case-study suggests that this is also true for the Dutch construction industry. Seen through the lens of legal consciousness, this section discusses three reasons why Dutch contractors consider the new antitrust laws unjust.

a. ‘Price-Fixing Was Always Supported by the Dutch Government’
First of all, it is considered unjust that something which has long been tolerated is now considered illegal. According to one contractor:

‘All of a sudden, something that you’ve always done is suddenly considered fraud. I find this very strange.’ (cited in Vulperhorst 2005, 100).

Moreover, the Dutch government itself has actively participated in a system of price-fixing in the construction industry for many years. In the eyes of many contractors, this should also be taken into account:

‘You may argue, there is a double standard. People look at the events from the past with today’s sense of justice.’ (cited in Vulperhorst 2005, 70)

b. ‘Antitrust Law Is Not Really Law’
The second reason why many Dutch contractors feel that the strict antitrust policies are unjust, is that they do not accept the normative status of these laws. In addition, they feel that they can break the law, as long as this causes no serious harm to others. One manager explains this general attitude in the following terms:

‘We from the construction industry always felt that we were only breaking traffic laws. This was not a real felony, because we didn’t hurt anyone.’ (cited in Vulperhorst 2005, 115)

The director of a major construction company makes a similar point, which he also considers a general characteristic of Dutch legal culture:

‘Sometimes, the Dutch do something which is not allowed by law, but which doesn’t directly harm others. All right, those agreements were illegal, indeed there was a breach of competition law, but no one suffered from this. It was in the sphere which wasn’t really criminal. Builders did not live with the idea to go out and to commit an economic crime.’ (cited in Vulperhorst 2005, 101)

c. ‘Two Conflicting Sets of Values’
Finally, based on a great number of interviews, one researcher concludes that the Dutch government and the Dutch construction industry operated on the basis of two conflicting value-systems (Vulperhorst 2005, 98). Although both parties talked about the same events, their judgment of these events was completely different. There are, for example, important
differences in how both parties think about the role of government, the role of law, and what
should be the most appropriate remedy to prevent similar events from happening again.
Arguably the most fundamental difference between both parties is how they see the relation-
ship between individual contractors. The underlying idea of the EU directive and the new
Dutch antitrust laws is to promote as much competition as possible. By contrast, one of the
most important rules within the Dutch construction industry, is that all bids should be distrib-
uted equally among all participating businesses. This type of solidarity - which means that
large, well-run and healthy companies are equally protected as small, badly-run and suffering
businesses – clearly goes against the core of competition law.

These three arguments (previous support by the government; it is not really law; and con-
flicting sets of values) suggest that the normative support for antitrust law in the Dutch con-
struction industry was not very strong. As a result, compliance with their own internal rules
was considered far more important than compliance with the official rules. Or, in the words
of a Dutch contractor:

‘In the Netherlands, if we consider a law unjust, then we breach that law without
any remorse. Our conscience is stronger than the law.’(cited in Vulperhorst 2005,
101)

This supports Tyler’s central position, who argues that in addition to deterrence and self-in-
terest, legal compliance is primarily a matter of legal consciousness. A recent study suggests
that this mechanism is not limited to the Dutch construction industry (Couvret and Mulder
2008, 51). In a national survey among Dutch businesses, about half of them (48.5%) claims
they never make a cost-benefit analysis (instrumental approach), 43.5% has made such an
analysis only once and only 5% claims they frequently make a cost-benefit analysis. More-
over, when asked what or who motivates them the most to comply with the law, 73% answers
‘myself, my own set of values and norms’ (normative approach); and 43.5% says ‘my com-
pany’s reputation’. Only 13% of all businesses lists ‘the potential penalty’ as their principal
motivation for compliance and 5% refers to ‘my own personal gain’.

7 Conclusions

Why was the use of cartels and structural price-fixing so widespread in the Dutch construc-
tion industry? And why did these practices continue to the present day? In the late 1950s, and
based on the advice of his father in law (an experienced businessman), Stewart Macaulay set
out to interview Wisconsin businessmen on the role of contract law (see Macaulay 1995). He
discovered that most of them usually did not act in accordance with the rules of contract law.
Instead, they relied on their own informal rules and procedures. On at least three points, our
case study of the Dutch construction industry shows a remarkable resemblance with Macau-
lay’s findings.

First, and similar to most Wisconsin businessmen, Dutch contractors consider the rules of
antitrust law much too slow and too inflexible to apply in their everyday business dealings.
Moreover, they consider law as a threat to the necessary level of mutual trust among busi-
essmen. Second, and much like the situation in Wisconsin, the Dutch construction industry
has developed its own elaborate system of self-regulation. Their own internal ‘legal order’ includes both a set of internal norms and rules and their own system of enforcement, largely based on reputation and exclusion. Finally, and this point has remained largely implicit in Macaulay’s study, the normative support for contract law and antitrust law is not very strong among businessmen in Wisconsin and among members of the Dutch construction industry. As a result, they consider compliance with their own internal rules more important than compliance with the law.

This socio-legal case study highlights important elements of the interplay between state regulation and self-regulation. More similar studies are needed to establish if these mechanisms are equally important outside the specific context of the Dutch construction industry. In this chapter it was argued that these studies should include both objective and subjective elements. They should not only focus on whether people comply with law, but also on the variety of ways in which people experience law.
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SELF-REGULATION THROUGH QUALITY MANAGEMENT SYSTEMS

How Nurses in Dutch Elderly Homes Concretise the Goal of “Responsible Care”

Anne-Wietske Enequist

Abstract

This article describes the self-regulation of professionals in elderly homes based on the Dutch Act on the quality of health care institutions (Kwaliteitswet zorginstellingen). This goal oriented framework act demands that all care providers create a quality management system (QMS) to implement the goal of responsible care. Care providers are thereby forced to co-regulate: in the QMS they formulate the rules on how they intend to achieve this goal. Although many different organisations, in different compositions co-decide what responsible care encompasses, the QMS of a care provider is central to the implementation of the Quality act. Through the QMS the nurses regulate their own activities, although within the framework of the goal of responsible care.

1 In Dutch: verantwoorde zorg. ‘Responsible’ is used in a double meaning: as a description of the quality of health care (sound care), and as holding the care provider accountable for the quality of health care (accountable care).

1 Introduction

“I do not experience the protocols as an obstacle: it is an improvement that we have them!” Lucy, nurse and coordinator of the health care in an elderly home in the Netherlands, is very positive about the regulation she is implementing in her daily job. As a ‘health care coordinator’ she is responsible for the health care activity and the wellbeing of the residents in the elderly home. As the nurse highest in rank, Lucy is manager of the working place: she instructs the other care employees in their work, is responsible for a good working environment and takes part in drafting the policies of the elderly home. A large part of her activities are prescribed by rules, guidelines, protocols, and instructions, which is different from 30 years

1 Often, residents are also referred to as clients, to emphasise the contractual (“equal”) relationship between the care provider and the resident and to mark that the wishes and needs of the resident are central to the care that is provided. Different care providers choose different terminology, but can still provide care in the same way. Therefore I will only use the more neutral word resident.
ago when she started her career. However, she feels she has enough room for adaption of rules and manoeuvre within these rules: “There is always room for interpretation.”

Lucy’s view on the regulation she daily works with is quite surprising. Although the Dutch legislator in the last two decades has drafted legislation from a new point of view, which should grant professionals more freedom in deciding how to do their job, it has not been proved that these new acts have contributed to this goal. A spearhead of this new policy has been lowering the administrative burden of legislation for professionals. However, the Act on quality of health care institutions (Quality act) is concretised by a large amount of lower regulation, which demands a lot of administration at the working place. Therefore one would expect the nurses in elderly homes to be lost in the regulative chaos of lower (administrative) levels, instead of experiencing the new ‘administrative burdens’, such as the protocols, as an improvement.

This lower regulation is derived from the central article from the Quality act, which demands from care providers that they deliver responsible care. Which care can be described as responsible care is not specified. When the law was drafted in 1996, the purpose of the legislator was that care providers themselves would determine what responsible care is, thereby using the knowledge of the professionals, since they have better insight in what determines the quality of health care then the legislator will ever have.

However, different organisations besides care providers have issued reports and documents on what responsible care is: the Health inspectorate (IGZ) in its reports and publishing of performance indicators, the HKZ organisation with norms on quality management systems, and the insurance companies through the Care offices. At the same time the Steering committee for reliable care, in which several professional organisations take part, has issued the Quality framework for responsible care. From a traditional hierarchical perspective, it is not easy to describe how the goal of responsible care is concretised, since all these organisations contribute in a different way to the concretisation of the goal: any attempt to a description only depicts chaos. The amount of reports and regulation leads to the question: who regulates the main activities of professionals? What rules do the professionals in an institution have to implement and who has made these rules? Are they made by the professional organisations, as was the purpose of the Quality act, by the professionals themselves within the care provider, or by the administration through different organisations?

This article formulates an answer to these questions, explaining why Lucy can be so positive about the regulation, although based on the amount of organisations involved and the accompanying bureaucracy one would expect the opposite. The article focuses on the implementation of the goal of responsible care in elderly homes in the Netherlands. The professionals in elderly homes, the nurses, form a rather homogenous group, which means there are not opposite interests within these care providers, which makes answering the questions less complex.

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2 Interview with Lucie van Beek (nurse), 19-01-2009
3 Rapport algemene rekenkamer, Implementatie kwaliteitswet, p.8; Interview Heleen de Groot, lawyer who helped to draft the Quality act at the Ministry of Health, Welfare and Sports
4 In Dutch: zorgkantoor
5 There are two types of elderly homes in the Netherlands. When I refer to elderly homes in this article I refer to the nursing homes where people live who need care, but still are self-supporting in some respects (verzorgingstehuizen).
Several interviews which I conducted as orientation interviews for my PhD research, such as the interview with Lucy, have inspired me to approach the question upside down. If we take the perspective of the legislator, we see endless proliferation in a kind of tree-like model. Seen however from the perspective from nurses in elderly homes, the concretisation of responsible care is not that divided, but centred in the quality management system (QMS) of each home. In a QMS all procedures and processes of the working place are documented, in order to reach good quality management, which is seen as the best way to improve client satisfaction while keeping the costs low, according to the latest development in 'the quality movement'. I will argue that Lucy and many other professionals influence how the goal of responsible care is implemented: through the protocols in the QMS, but also through several organisations which shape such a system by influencing its content and its implementation. Since the QMS is mainly used to guide the work of the professionals, and not to justify their actions, the extra administrative work load of the QMS is experienced as a positive improvement.

2 Concretisation of responsible care

2.1 Act on quality of health care institutions

The Quality act was drafted in 1996 after long deliberations on how to reform the health system in the Netherlands: increasing technological possibilities combined with the ageing of the population led to higher pressure on the health budget. When more people need care, and more care is technically available, it becomes important how the resources can be used as efficiently as possible. This need for change caused the legislator to use a new type of legislation.

Under the influence of New Public Management, which was very influential in the 1990s, the legislative preference in the Netherlands had changed from detailed national regulation to regulation which only set the framework: only setting a goal and not elaborating how and by which means to reach it. This new type of legislation instead orders its norm-addressees to make the more detailed rules themselves. The Quality act is one of these framework acts, only containing so called goal prescriptions accompanied by a rule which asks the norm-addressees, in this case the care providers, to make more detailed rules on how to reach the goal.

The goal prescription of the law, article 2, says “Care providers [should] provide responsible care. Responsible care is care of a good quality that is at a minimum effective, efficient, patient oriented and tuned to the realistic needs of the patient.” As Mackor describes in her article on performance measurement, article 3 further instructs the care providers to organise the care “in such a manner that the result is, or at least reasonably must be, responsible care.” Article 4.1 specifies that the organisation of the care encompasses “systematic monitoring, controlling and improving the quality of the care.”

6 Osborne and Gaebler, see A.R. Mackor
7 See article P.C. Westerman in this book
8 Translated by A.R. Mackor, see article in this book
On purpose, the content of the term responsible care is not specified in the act. One of the main reasons to use this new type of legislation is efficiency: when health care has to become as efficient as possible, the latest information should be used to regulate it. Since the national legislator always will have difficulties acquiring all this knowledge, the field itself should make the rules on how to reach the goal of responsible care. At the same time, this new form of legislation seeks to solve a second problem; the perceived diminished room for manoeuvre for professionals. The new legislation such as the Quality act seems to provide more room of manoeuvre for professionals, by not specifying the content of the goal of responsible care. The purpose of the law was to use the knowledge available in the field in the best way possible, which means professionals should get enough freedom within the rules to act as they see fit under the specific circumstances of their working place. Do professionals have enough discretionary room within the Quality act and its accompanying lower regulation to fulfil their duties in accordance with their own knowledge?

3.2 Top-down perspective

In order to find out how much room for manoeuvre professionals have within the goal of responsible care I chose to focus on professionals in elderly homes: the nurses. An advantage of focussing on elderly homes, instead of for example on hospitals, is that the group of professionals within elderly homes can be easily defined and is more homogenous. In hospitals both medical specialists, general doctors and nurses need to cooperate, which would distract too much from my question.

I started to investigate how this goal of responsible care is concretised on lower levels, and in what form it finally reaches the working place of these nurses. What I encountered was a huge amount of reports and many different organisations, which all decide for a small part what responsible care encompasses:

The Ministry of health, public welfare and sports (Volksgezondheid, Welzijn en Sport) develops policy to motivate care providers to implement the Quality act. The minister of health, public welfare and sports is ultimately responsible for the quality of health care in the Netherlands. When in 2001 and 2005 evaluations of the Quality act showed that most care providers did not meet the requirements of the act, the ministry ordered the Health inspectorate to form a Steering group Responsible Care (see point 2). The ministry is also the initiator of the platform ‘Care for better’ (Zorg voor beter), where all professional organisations, sector organisations and care providers meet, to exchange best practices in striving for the goal of responsible care.

The Steering Committee Responsible Care (Stuurgroep Verantwoorde zorg) has drafted the Quality framework Responsible Care for care for elderly people (Kwaliteitskader Verantwoorde zorg). The steering committee consists of representatives of the clients’ organisation (residents) LOC, the professional organisations for nurses NVVA, V&VN, the professional organisation for care takers Sting, the organisation of care entrepreneurs ActiZ, the Health inspectorate (IGZ) - chair of the committee, the Dutch Care Insurers (ZN) and the Ministry of Health Welfare and Sports. The Quality framework contains the Standards for responsible care (Normen verantwoorde zorg). These standards are a type of performance indicators.
The Health inspectorate (IGZ) uses these performance indicators to monitor how the care providers perform: how many residents fall in the elderly home, how many residents unintentionally loose weight (which indicates they are undernourished), how many residents have decubitus, and 13 other indicators. The care providers need to report on these indicators to the inspectorate in their annual report. The data is then compared to the data of all the other providers, and then publishes on the website www.kiesbeter.nl (choose better). If a care provider performs well on these indicators compared to others, the inspectorate can assume a care provider provides responsible care.

The inspectorate can also supervise certain care providers, based on an indication in their annual report that some part of the health process does not function as is should. In that case, the inspectorate investigates more into detail how the care provider provides care, which results in an inspection report on the required improvements. The report therefore contains instructions for a specific provider on how to reach responsible care.

The care offices, each region has its own, are run by the joint health insurance companies. They are the actual health purchasers, who spend the national budget for elderly care. A care provider needs to sign a performance contract with a regional health office, which assures him of receiving funds for the amount of care he has contracted for. One of the entry requirements for these contracts is that care providers should have a certified quality management system, which guarantees that they provide responsible care.

A care office only pays for care provided to residents who were entitled to that type of care. The CIZ organisation approves the care-status residents need to receive care in the elderly homes. Under the new ZZP-system, which January 2010 officially replaces the old system, a resident can obtain ten different care-statuses, on a level from one to ten, based on the level of care he or she needs. The more a resident can do by himself, the lower the care-status will be. On behalf of a (new) resident, a care provider applies for a certain care-status, of which it thinks it can provide the right level of (responsible) care to this resident. The CIZ organisation then decides whether it agrees with the assessment of the care provider. Every care-status comes with its own tariff, which can be charged at the health office. The care provider will only pay for the care that a resident is entitled to based on his care-status, and not for any extra care provided by the care provider.

The HKZ organisation designs certification documents for quality management systems of care providers. Although there are other certification documents, the HKZ-certificate is at the moment the biggest certificate. Therefore I focus in this text on the HKZ-certificate. The certification plan tells care providers what documents their quality management system needs in order to become certified. It does not say what action a care provider needs to take, but it does say which fields are so important that the provider needs to plan his activities. This means the certificate specifies themes of importance within the goal of responsible care: it makes the care providers all focus on the same issues, which according to the HKZ organisations are most important to guarantee the organisation provides care of good quality.

9 Decubitus refers here to bedsores, which are caused by lying in one position too long.
10 In Dutch: indicatie van het CIZ
11 ZZP is zorgzwaarte pakket, which means 'care-weight package'
The Quality institute for health care CBO issues guidelines for quality in health care. The CBO is an independent institute, which helps professionals in health care to improve the quality of care. Three guidelines have been issued specifically for medical problems of elderly people: a guideline on dementia, one on Parkinson and a third on the prevention of fall incidents. These guidelines are derived from research done by other organisations and they contain no legal rules. However, the inspectorate does use the guidelines as field norms: care in accordance with the guidelines is assumed to be qualitative good care (part of responsible care). If necessary, a professional can deviate from the guideline when the situation of a patient so requires, but this deviation has to be documented and the professional will have to explain why he acted differently.\(^\text{12}\)

The professional organisation for nurses and caretakers V&VN has issued the National Professional Code of Nurses and Caretakers, in which guidelines for professional behaviour are established.\(^\text{13}\)

The care providers concretise the goal of responsible care in and through their quality management system, as ordered in article 4 of the Quality act.

Even when summarised as above, it is very difficult to understand the interaction between the organisations, let alone depict this in an organised way. It resembles to a large extent the dark picture which Westerman sketches in her articles on the risks of using goal regulation: a lot of different organisations trying to concretise the goal towards its implementation, which will all try to further their part of the goal, resulting in chaos for the person who is implementing the goals in the end, in this case the nurses in elderly homes.

This long list of different organisations, all concretising responsible care in their own way, suggests that the goal of responsible care is already fully concretised by all these organisations and that there is no room left for self-regulation by the professionals themselves. Moreover, it is difficult to understand how a small care provider with a limited amount of time would be able to live up to all the wishes of these organisations, which are not necessarily synchronised. This hierarchical perspective therefore gives the impression that goal regulation in a framework act leads to chaos in lower regulation, higher administrative burdens and therefore higher transaction costs. Since diminishing the transaction costs for norm-addressees is a major topic in current Dutch politics, this would be an alarming conclusion.

However, there are some uneasy parts in such a description from a top-down perspective. First of all, organising the points above in a hierarchical list is not that easy. At a closer look, several organisations turn out to be a fusion of other actors. The professional organisations are represented in the HKZ and the platform, the inspectorate asks these same professional organisations to take part in designing the performance indicators, and the inspectorate itself is chair of the platform. A care office in its turn is in a contractual, non-hierarchical, relation with the care provider, except that the contract is more important for the care provider than for the care office. The care provider needs the contract to be in business, whereas the care of-

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\(^{12}\) CBO richtlijn preventie van valincidenten bij ouderen, p. 12

\(^{13}\) V&VN, Nationale Beroepscode van Verpleegkundigen en Verzorgenden
face can also purchase its care from other providers. The fluent borders and non-hierarchical relations between the different actors make it impossible to describe these relations as a mere principal-agent relationship, as Westerman suggests.

A second problem for the hierarchical description was the reaction of my interviewees, whom I asked how they implemented the regulation of these higher levels. Where I expected to hear stories of bewildered managers, who could not manage to incorporate all these different demands in their organisation, managers unanimously reported to experience little problems with the regulation. And where I expected to find nurses who felt there was no time left to do their job properly, because of all the paperwork and organisation which comes with all the regulation and requirements of responsible care, I only found nurses who thought the current regulatory system was an improvement compared to earlier systems. How do these positive views of the nurses and managers of the working place match with the chaotic picture of different organisations all concretising a part of responsible care which should be implemented on that working place?

### 3.3 Working place central

In order to gain a better understanding of the actual work that is done in elderly homes, and to unravel the chaos I had run into, I decided to interview some managers and nurses in elderly homes. I wanted them to explain to me what their job is about and what kind of rules and regulation they work with in their day to day activities: what parts of this regulatory mess really reaches the professional in an elderly home? To my great surprise, the picture that I had described before as a hierarchy of organisations, rules and reports changed completely when I looked at it from the perspective of the managers and nurses I interviewed. From their perspective, one set of rules was clearly at the centre of all of the other documents: the quality management system.

Every care provider in the Netherlands has the obligation to have a quality management system. Article 4.1 of the Quality act states that care providers should systematically monitor, control and improve the quality of the care, which is interpreted as the obligation for care providers to draft and implement a quality management system.\(^\text{14}\) The ISO 9000 norms, which are international standards for quality management systems, are widely used to determine what components a quality management system needs. Initially, the ISO norms were drafted to help improve the quality of manufactured goods, but now the norms are also applicable to the production of services, for example in the field of health care.

A quality management system should facilitate the improvement of the quality of care. In a quality management system, all the obligations of the care provider are documented: the care protocols, the fire safety protocol, the working environment protocol, the food hygiene protocol, protocol for incidents, and so on. When a care provider manages several elderly homes, all of these homes have the same quality management system. When a care provider only runs one home, this home has to have its own quality management system. The nurses I interviewed were not confused or disoriented by the amount of rules and reports that origin from the Quality act. In their daily job, they were only confronted with rules ori-
originating from the quality management system, and not with any of the other documents made by the steering group, inspectorate or care office. As Lucy said, they expressed that writing down all the procedures in the QMS is an advantage, although they also expressed a concern about the risk that the QMS can become a ‘paper tiger’, with too much focus on the ‘paper world’ instead of the implementation in ‘the real world’.

Switching from a hierarchical perspective to a perspective where the working place is central, means that the QMS will be the starting point to describe how the goal of responsible care from the Quality act is concretised. I will show that within the QMS, the professionals regulate their own activities. The other organisations influence the QMS, which can affect the room for manoeuvre the professionals have. As I will argue, having a QMS has advantages and disadvantages, but still leaves the professionals enough freedom to do their job in accordance with their own knowledge.

4 Quality management system

4.1 The quality movement

At the moment, quality is a term which is used frequently in health care planning, of which the Quality act itself is the best example. All managers I interviewed talk about quality, plan according to quality and write about quality. However, this development is quite recent. Before the implementation of the Quality act, quality in health care was not a frequent topic in board meetings of care providers, their annual reports or their other documents. The origin of the quality movement lies in the industry of the 1900s, where the concept, language and methods developed.

Before the industrial revolution, the quality of a product was guaranteed by the craftsmen, who often were member of a guild. Delivering good products protected the reputation of the individual craftsmen (and of the guild), which assured them of customers. When the production of goods started to take place in factories, where no one was responsible for the complete process, quality issues arose. The lack of quality in certain products threatened the trust of customers in the produced goods. To guarantee the quality of a product, quality control of the finished products was introduced. However, disadvantages of quality control were that work had to be redone, and both time and materials were wasted, since only the selling of low quality goods is prevented, but not the manufacturing.

In the 1930s, the statistician William Edwards Deming did research in the United States on how to improve the quality of products in an earlier stage of the production process. Deming developed a theory on quality management, which today is widely known as the circle of Deming. His findings were put into practice in the Japanese industry in the 1950s and 60s, when the Japanese economy had to be rebuilt from scratch after the war. According to Deming, meeting the customer’s expectations was central in competition, and if this was thoroughly implemented in the processes, any average company could become a market leader within

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15 Interview with Jaqueline Poortvliet, 22-01-2009 (location manager and nurse); Interview with Hendrik Hemminga, 23-04-2009 (region manager at Oosterlengte of amongst others the elderly home ‘De Tjamme’ in Beerta)
five years. Only in the 1980s, US producers became interested in quality management, after Japanese producers had taken a market lead in many former US dominated markets.16

In recent years, the quality movement also reached the health care sector, broadening its scope from only concerning manufactured goods to covering the production of services as well. Step by step competition is introduced in health care, which makes quality a central concept. The main difference between the private sector and the health care sector is that, in the Netherlands, the quality movement for the health care sector is mandated by the state, where in the private sector choosing to ‘quality-manage’ a company is a free choice of the management.

The circle of Deming is still today used as the starting point for quality management in health care. It is also known as the circle of Plan – Do – Check – Act. In all elderly homes that I visited17, managers explained to me they were working along this circle of Deming. Often they started working with it because it was one of the requirements of the HKZ-certificate. This circle of Deming is meant to help a care provider continuously improve the quality of its services. First the care provider has to plan his activities, he then has to implement them, measure whether the results were as he had planned them to be and finally act upon the findings of the measurement, which leads to a new planning cycle. In the meantime, while continuously improving the quality of the care, the managers need to make sure that the quality level that is reached is guaranteed by the processes that are already in place. The quality management system fulfils a role in the improvement and guaranteeing of the quality.

Quality management can be summarised as “managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organisation while continuing to improve the process.” A quality management system is then “a formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management.”18 I will show that these quality management systems are central to the implementation of the Quality act, and the concretisation of the goal of responsible care.

4.2 Content of a quality management system

In this section I will use examples from the quality management system of elderly homes where I interviewed managers, nurses and ‘quality employees’. Every quality management system is unique, but section 4.3 will clarify why most quality management systems consist of comparable components.

I will explain what a quality management system is, by following the path of two of the major health concerns in elderly homes: the complexity of medication distribution and the prevention of falling incidents of residents. Falling is the most important cause of death by accident for the elderly. A World Health Organisation report concludes that injury caused by a fall is the third cause of health problems for elderly people. Fall injuries often lead to diminished self-support and many medical complications, such as decubitus and pneumonia.

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17 I conducted interviews in 6 elderly homes in the Netherlands, owned by 5 different care providers.
18 ms.pbru.ac.th/qit3/dl/QIT_Method_DrJareuk/Quality%20Information%20Technology%20Terminology.doc
Every year, 3,300 residents of Dutch elderly homes need treatment in the emergency room because of a fall injury. Therefore, it is very important to organise fall prevention within elderly homes, to ensure the goal of responsible care. Mistakes in the medication distribution are the most common incident caused by a mistake of an employee in elderly homes. For the patient safety, and therefore responsible care, it is very important that the amount of mistakes is minimised.

The basis for each quality management system is its planning in different documents. The quality management system is the start for each Plan-Do-Check-Act cycle. The documents form together the quality manual, which should guide all activity by the care provider. The documents (plan) need to be implemented (do), the results of the implementation will be monitored (check) and improvement if necessary will be made (act). For an elderly home, there is a planning on two different levels: the individual level, where the activities for the individual resident are laid down, and the institutional level, where all processes and procedures which take place in the organisation are planned, in mission and vision documents, and described in protocols.

The content of a QMS is different for each care provider: the type of documents that are used, what these documents describe or regulate and the content of the document itself. A care provider can choose to make procedures, protocols, internal guidelines, work instructions, forms, internal documents, external documents, or even other types of documents. If for instance a care provider wants to create a procedure on how to prevent residents from falling, he will have to decide: which measures the organisation should take to prevent falling; who is responsible for the implementation of the procedure and how the organisation will check whether the procedure really helps to prevent accidents.

Although care providers can name the documents in the QMS after their own wishes, based on the function of the document, every QMS is based on the following types of documents (every type is illustrated with the documentation on that level to prevent falling):

Abstract policy
The abstract policy, such as the mission and vision documents of the institution, state what the care provider wants to achieve.

Contracts
In the individual care plan, care provider and resident will decide together what care will be provided and how. When the resident has a risk of falling, because of a medical condition or a previous fall, the care plan will state how the individual situation is, and what measures will be taken to prevent falling. Under the section fall prevention it can for example say: “Madam walks with a walking aid, but is still scared of falling,” which shows that the topic of fall prevention is discussed with the resident, both external towards inspectorate, but also internal to other nurses. It describes what measures have been taken (the walking aid) and the current situation (she is still scared of falling, so it will be an item to follow up in the future). The contract can specify decisions into great detail, for example on what time the resident want to get up in the morning, which day activities the resident takes part in, and how the re-

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19 CBO richtlijn voor preventie vallen bij ouderen
sident wants to take a shower. If the nurse or care-taker feels that the decisions in the contract should be changed, they will need to discuss this with the resident. If the resident does not agree on changing the care plan, even though the nurse thinks continuing on the same basis does not meet the requirements of responsible care, the nurse has the responsibility to deviate from the contract, but she will have to explain and justify this deviation in the care plan.20

Rules (protocol)
All acts in the elderly home are described in protocols. Dependent on the formulation in the protocol, the nurses and care-takers have either discretion or no discretion in implementing the protocol. When the protocol leaves no possibility of acting differently, the protocol is a set of rules. An example of such a protocol containing rules is the medication distribution protocol of elderly home ‘De Tjamme’ in Beerta. All acts and responsibilities are described in detail and there is absolutely no discretion in these rules: the nurses and care-takers will have to follow the rules under all circumstances.21

Guidelines (protocol)
When a protocol describes a process which needs to be individually customised, the protocol takes the form of a guideline. The fall protocol in ‘De Tjamme’ in Beerta is not at all as detailed as the medication distribution protocol. It only contains aspects which should be checked upon with new residents or when a resident has developed a risk of falling. The nurse should for example check what medication the resident uses, what shoes the resident wears and whether the resident experiences difficulties with walking. The protocol explains how these factors can increase the risk of falling and suggests which measures can be taken to lower the risk of falling. The nurse will have a lot of discretion in deciding, together with the resident, what measures have to be taken to lower the risk of falling. The decision will then be documented in the care plan.

Forms to register observations or acts
Reports of incidents (both on residents and employees), autograph lists, and complaint forms are all examples of the forms which are used to register both observations and acts. The format of the forms is part of a protocol, which tells the employee when to fill in the form and what to do with it after it has been filled in. In the case of a fall of a resident the protocol could say that the employee who is the first to discover this, should file a ‘Report of incident – fall’ and submit it to the highest ranking nurse. In this report the circumstances of the fall, as far as they are known, will be described. When all of the reports of incidents are gathered, it is possible for the management to start looking for possibilities to decrease the risks of falling, by looking for larger patterns.

Concrete policy
The concrete policy documents are the improvement plans, in which the points that need change in the protocols or in the home itself are decided, based on the results of the implementation of the protocols in the home. For example, in an elderly home where the monitoring of falling incidents showed that most fall incidents occurred with residents who suffered from dementia, within their own home, they could make an improvement plan based on this
information. Research has shown that residents with dementia will fall more easily, since they cannot always distinguish between a white object and the white surroundings (white doorpost against white wall). Based on the information from their own monitoring and the available research, the care provider decided to paint the doorposts in red or blue and mount coloured toilet seats. This was written down in such an improvement plan, in order to show to the board and clients council that measures were taken to prevent falling in the future.

5 Self-regulation of nurses in elderly homes

5.1 Introduction

As I will discuss in this section, self-regulation of nurses takes place in two different ways: direct self-regulation through development of the quality management system in the care organisation, and indirect self-regulation through the professional organisations on higher levels. Other organisations do influence the concretisation of responsible care, but this has not such a large impact on the daily activities of the professionals (nurses), who are instead mainly confronted with the implementation of the rules which were ‘self-drafted’.

5.2 Direct self-regulation

Development of a quality management system

Just as every quality management system is unique, so is the way a quality management system is made. Every care provider can decide who is involved in drafting the contracts, rules and guidelines, and how they can be adapted. However, based on the interviews I conducted, care providers draft their quality management system through very similar procedures, especially concerning the involvement of nurses in the drafting process.

The nurses I interviewed all stated that they had been involved in the drafting of the rules and guidelines, mainly through staff meetings and working groups. For example the medication distribution protocol of ‘De Tjamme’ had been drafted by a small working group, in which one nurse took part, and then re-drafted by the pharmacist, the family doctors of the residents, the health care coordinator and the nurses with ultimate responsibility for the care of the residents. The care-takers lower in rank had the possibility to influence the content of the protocol through the monthly staff meetings. After the protocol had been used for half a year an evaluation was made, in which all care-takers and nurses could come up with alternative suggestions.

My interviewees all expressed that if they would disagree with a certain rule, it is always possible to bring this up, either in a staff meeting or through a special ‘staff initiative form’, which many care providers have. This does not necessarily mean the rule will be altered, but they felt that they had enough room to use their professional knowledge in their work.

Changes because of the quality management system

22 In Dutch: E/Ver (eerst verantwoordelijke verpleegsters)
In the interviews two main changes were mentioned as a positive result of the self-regulation through a quality management system. The first change is the amount of influence the nurses and care-takers have on the way the health care is provided, because of the formalisation process of the internal rules. By the change from unwritten procedures to written protocols, especially nurses and care-takers lower in rank have gained influence on the content of the rules and guidelines. One of the care-takers in an interview explained this, when asked what the biggest difference was between her work now and when she started working 30 years ago:

“When I started working in a hospital, many things were done because they had always been done that way. All patients’ temperatures were taken at 6 o’clock, while the light was on all the time. Why couldn’t we take their temperature at 7, when they got their breakfast? And why did we use the room light, which woke up everyone in the room, instead of the small bed-lights? I remember I was very surprised at the time, but it was impossible to do it differently, since the highest ranking nurse had decided that these were the procedures. There were many of these strange old habits, such as the bathroom rounds with fixed times to go to the bathroom. Luckily, a lot of this has changed now, and there is more attention for the wishes of the individual patient. It has become easier to come with suggestions of change for old rules.”

Because all the protocols are now in writing instead of remaining implicit, it is easier to talk about why the rules are as they are, change the content of the rules and to call colleagues to account for a deviation from the rules. This has increased the possibilities of self-regulation for care-takers and nurses in elderly homes. By making and adapting the documents of the quality management system, the staff of an elderly home are actively involved in the quality management.

The second change, which was mentioned in several interviews, is that residents now have a much larger say in how the health care is provided. Because of the focus on customer satisfaction, quality management also means adapting the protocols after the outcomes of customers’ inquiries and wishes. Several interviewees expressed that the most important change in health care in the past few years is that the health care is now organised after the requests of the resident, which are formalised in the care plan (contract), as a part of the quality management system.

“How the elderly people have a much bigger influence on the care they receive. The focus has changed from care to living: when I started working as a nurse the residents moved in on our working place, now we work in the units which are their homes. On the lowest level it is decided how things should be done, together with the residents themselves who then have had a say in their own care.”

5.3 Indirect self-regulation

However, the development of a quality management by the employees of a care provider does not happen in a vacuum. Where the previous section might suggest that a quality manage-
ment system is made by complete self-regulation of an individual care provider, this is only half of the story. Professional organisations define in several ways, which topics will at least be part of a quality management system.

If we continue to follow the path of the fall prevention protocol, we have to trace who decided that fall prevention is a major topic in elderly health care. I interviewed managers and nurses in 6 elderly homes in the Netherlands, and visited as many Swedish homes in the same year. Both in Sweden and the Netherlands, fall prevention was an important topic in all elderly homes. Apparently, this is not decided by individual care providers and neither by national organisations. Fall prevention is internationally recognised as a very important health care topic, in the international debate of professionals, in the WHO and through international contact of the professional organisations. I will call this indirect self-regulation of professionals: the professionals working in the elderly home ‘De Tjamme’ in Beerta had no direct influence on choosing fall prevention as one of their major topics, but it is instead self-regulation by professionals through professional organisations on a national and international level, of which group the professionals in ‘De Tjamme’ are a part as well, by education and membership of these professional organisations.

In the Netherlands, the topic of fall prevention is then incorporated in the concretisation of responsible care, by the Steering group Responsible care, in their Standards for responsible care. One of the indicators that care providers have to monitor is the indicator Fall incidents: “The percentage of clients that has been involved in a fall incident over the last 30 days”, which should be measured by dividing “the number of clients involved in falling incidents over the past 30 days” by “the number of clients with whom measurements were carried out on the day of measuring”.24

These standards for responsible care take a very central role in the quality management systems of care providers. This is an example of what the Health inspectorate calls a field norm. It is drafted by the professional organisations together with patient organisations and care purchasers and is regarded by the field as a standard which brings health care a step forward:

“Now we do not need to discuss anymore whether providing regular day activities is an important component of responsible care or not. Previously, we had to agree on such issues in the staff meetings, now we can spend our time instead on deciding which day activities we really want to offer.”25

This means that the daily decisions of managers, nurses and care-takers on what care should be prioritised to reach responsible care are made easier by the standards for responsible care. The standards for responsible care decide which topics within the care for elderly people are most important, and therefore are a necessary part of responsible care.

When the professional organisations have decided that fall prevention should be a major topic in health care, elderly homes need to decide how they will prevent falling. This will be done through the documentation process of the quality management, but in this process they use the knowledge from other organisations, such as the CBO which draft detailed guidelines on

24 Quality framework Responsible care, p. 41 (indicator 4.3), document is already translated
25 Interview with Hendrik Hemminga, 23-04-2009
for example prevention of falling incidents for elderly people. This guideline of 80 pages contains the conclusions of the available research on fall prevention in the Netherlands, and from these 80 pages elderly homes have to distill which measures work best in their organisation. The guidelines work according to ‘comply or explain’: it is possible to decide working differently from the way described in the guideline, but a care provider will then have to explain very thoroughly why he is deviating from the guideline.

The HKZ organisation is the third example of how professional organisations self-regulate. Within the HKZ organisation several professional organisations have contributed to draft the HKZ criteria for certification, based on the international ISO9000 standards, and applied to certain health care fields. The HKZ certificate is the largest certificate in elderly care in the Netherlands. In order for a system to become HKZ certified, its documents need to live up to the criteria in the HKZ scheme. This scheme, which is different for each health care field, describes which processes and procedures need to be part of the system. All providers need to have a formulated mission, vision and annual plan. The annual plan formulates the goals of the care provider, which should be reached in order to work along the mission and vision of the care provider. These goals should be SMART: specific, measurable, attainable, realistic and timely. For example, the HKZ scheme indicates that all elderly homes need to have an incident protocol (how to report incidents such as falling), but it leaves it up to the care provider how the reports are done.

5.4 Other organisations which influence the quality management system

Next to professional organisations, which influence the quality management system through indirect self-regulation, the Health inspectorate and the care offices influence the quality management system by concretising responsible care. However, they mainly try to make sure all care providers do what most care providers are already doing.

The Health inspectorate uses the different documents drafted by the professional organisations, such as the CBO guidelines, as field norms: most care providers do comply with these documents, which means that the inspectorate can ask from the care providers who do not comply to change their behaviour or explain why they think it is more responsible in their case to act differently. The indicators from quality framework are a field norm as well. The Health inspectorate, for example, obliges care providers to send data listing how many residents fall (within the measure-week) in their annual report. These data are compared to the data of all other homes, and then the comparison is published on the website www.kiesbeter.nl. A care provider receives then a score of one to five stars: five stars means that the elderly home belongs to the 10% best performing homes, one star means that the elderly home belongs to 10% worst performing homes. Publication of the benchmark data is supposed to push care providers to perform better next year, since future residents can look up what the quality of the health care in a certain home is. In reports on individual elderly homes, the inspectorate can directly state which changes a home has to make, to live up to the field norms and thereby provide responsible care.

26 HKZ manual for QMS, p.49
The only direct influence the care offices at the moment have on the concretisation of *responsible care* is their demand that care providers are certified. The Quality act itself does not mandate certification, but the care offices do. By forcing the care providers to start a certification process, they force them to live up to the specific demands on a quality management system of these certification organisations.

The Health inspectorate and care offices influence the concretisation of *responsible care* by obliging care providers to comply with field norms, by publishing benchmark data and thereby trying to force the care providers to perform better next year (and focus on the specific health care topics of which the data is published), by obliging them to receive a certificate, and thereby determining which documents should be part of the quality as management system. However, these activities only force all care providers to live up to what most care providers already do. The content of the field norms and the certificates is decided by professionals within professional organisations, and then by several professional organisations together. The Health inspectorate and care office try to make sure all care providers live up to these field norms, preventing that some care providers do not deliver *responsible care*, since there is no internal professional system which guarantees that all care providers comply with the standards on responsible care and other guidelines.

If the managers of an elderly home do their job, the nurses and care-takers are never confronted directly with the legal requirements of the Health inspectorate or the care office. The changes that are necessary should be made in the quality management system, which is the outline for all activity of the professionals in the elderly homes. Developing the quality management system takes a lot of time, but for the nurses and care-takers it means there is no chaos of regulation: the quality management system provides the possibility to coordinate all the demands and requirements in one set of documents.

### 5.5 Guiding and justifying behaviour

We now know that nurses in elderly homes have both direct and indirect influence on the content of the rules they need to implement, both through changing the rules or because the rules leave room for interpretation. This gives nurses the possibility to work in accordance with their own professional standards. However, this does not explain by itself why the nurses I interviewed were unanimously content with the rules they had to implement. Besides the possibility to influence the content of rules, an important factor for contentment with rules is what function these rules fulfil within the organisation.

Two main functions of the rules in a quality management system can be distinguished. As stated above, a quality management system “documents the structure, responsibilities and procedures required to achieve effective quality management”. This means that the rules and guidelines documented in the system should guide the professionals in elderly homes in how to reach the goal of *responsible care*. At the same time the quality management systems are used to prove to a certification organisation, the care office or the Health inspectorate that the minimum requirements for providing *responsible care* are met.

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27 ms.pbru.ac.th/qit3/dl/QIT_Method_DrJareuk/Quality%20Information%20Technology%20Terminology.doc
These two functions of the quality management system, guiding behaviour and justifying behaviour can support each other, but the justificatory function can also obstruct the guiding function. This can be explained by the ‘bureaucracy paradox’.\textsuperscript{28} One rule can have a double function, for example the rule on how to write down decisions on health care in the care plan of a resident. When a nurse has discussed the risk of falling with a resident, and they agree on that the resident from now on will use a walking aid, this should be clearly documented in the individual care plan. It serves both to inform her colleagues of the night shift that this resident will use a walking aid, which helps them to remind the resident of this. It also serves to show to the Health inspectorate and certification organisation that the topic was discussed. The two functions can co-exist without any problems, as long as the Health inspectorate and certification organisation do not require the nurse to write the care plan in a very time consuming way. A limited amount of bureaucracy supports the goal of responsible care, but too much bureaucracy will obstruct the care provider of reaching the goal, since the nurses will not be able to spend their time on other important topics in the care plan, such as decubitus or mental well-being.

At the moment many elderly homes are still developing their quality management system. The Health inspectorate is still inspecting elderly homes in the way they did before, by visiting the homes. In the new system, when all care providers have a functioning quality management system, the Health inspectorate will only visit a home when certain risk factors are found in the documentation: the annual report and the quality management system. This change from direct inspection to inspection at a distance, which focuses much more on the paperwork, could lead to a shift in the balance between the functions of the rules.

This shift is already visible in the focus on certification. Where the national legislator did not want to oblige a certificate for all care providers, the Care offices demand that care providers are certified. Certificates, such as the HKZ-certificate, demand a high level of documentation, which for the region manager of ‘De Tjamme’ focuses too much on the justification and not on the guiding aspect, which results in more paperwork than necessary for delivering responsible care.

If the justifying function gains a larger role, because of a larger focus on inspection through documentation, this could lead to more restrictive rules regarding the procedures of documenting acts and procedures in a quality management system. It is therefore of importance to follow the change from direct inspection to inspection at a distance, which could decrease the freedom of professionals to organise their work in accordance with their professional knowledge.

6 Conclusion

Nurses in Dutch elderly homes influence the rules and guidelines they need to implement through different forms of self-regulation. These guidelines and rules are part of the quality

management system of a care provider and ultimately stem from the Act on the quality of health care institutions. This Quality act prescribes that care providers should provide responsible care, by drafting a quality management system, which documents “the structure, responsibilities and procedures required to achieve effective quality management.”

Quality management is “managing a process to achieve maximum customer satisfaction at the lowest overall cost to the organisation while continuing to improve the process.”

Different organisations concretise the term responsible care, but from the perspective of the nurses on the working place it becomes clear that the implementation of the quality management system is central to the implementation of the Quality act. Through direct self-regulation they draft the rules and guidelines of the quality management system, which guide the actions in their daily work. Nurses have the possibility to influence the content of the rules and guidelines, when the quality system is drafted and they also have freedom of interpretation within the guidelines.

Through indirect self-regulation, nurses as a group of professionals influence the drafting of guidelines by their professional organisations. These professional organisations took part in the drafting of the Quality framework responsible care, which formulates the indicators for responsible care. Another example of indirect self-regulation is the drafting of guidelines on specific health topics by the Quality institute for health care CBO, such as the guideline on prevention of falling incidents for elderly people. These guidelines and frameworks, drafted by the national professional organisations, are also influenced by international organisations such as the WHO in which professionals are organised on an international level. This explains why the major health topics of quality management systems are similar in elderly homes in the Netherlands and Sweden, although all care providers individually draft these systems.

The Health inspectorate and care offices influence which parts of responsible care, as formulated in the Quality framework and in the certification schemes by the HKZ, need to receive more attention. Although these external organisations thereby decide which health topics should be prioritised by the care providers, they only strive to shift focus of the care providers from one topic to another, but they do not add new parts to the concretisation of responsible care, except for demands on the way a care provider should organise his administration process.

Based on the interviews that I have done so far, there seems to be a good balance between the guiding function of the rules and the justifying function of the rules. This explains why the professionals are so satisfied with the rules: they have a lot of possibilities to decide on the content of the rules, but receive also enough guidance from professional organisations and from the quality management system after it has been drafted. The Health inspectorate does not (yet) require the care providers to focus in their documentation on justifying their actions. This means that the quality management system to a large extent helps the professionals to organise their work, which makes that nurses do not experience the quality management system which is required by the Quality act as an “administrative burden”, but rather as an “administrative improvement”.

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29 ms.pbru.ac.th/qit3/dl/QIT_Method_DrJareuk/Quality%20Information%20Technology%20Terminology.doc
SMOKING BANS IN THE NETHERLANDS:
A Mix of Self-Regulation and Regulation by Government

Heleen Weyers

1 Introduction

Self-regulation is supposed to have many advantages. From a literature study, Baarsma and Mulder conclude that self-regulation is seen as cheaper than regulation by government because the sector concerned possesses more, and more specific knowledge than the government; self-regulation is considered to be more effective – because its rules are not imposed from above but are partly developed by the sector itself, the incentive and the readiness to comply are stronger; self-regulation is seen as more flexible – the rules can be established more quickly and the rules are more pliable; and lastly, self-regulation is seen as relieving the administrative bodies’ enforcement activities.

Such an enumeration of advantages overlooks the possibility that it may make a substantial difference who takes the initiative to self-regulation. At the one extreme, the initiative could come from the government, choosing to employ mechanisms of self-regulation as a means of regulation (top-down). At the other extreme, a sector could turn to self-regulation on its own initiative and authority (bottom-up). In the latter case, the advantages mentioned above seem much more likely to materialize than in the former. In this chapter, self-regulation processes regarding smoking policies are studied with this difference (bottom-up vs top-down) in mind.

The Dutch history with smoking bans is an example of the optimism felt for self-regulation. Self-regulation was attempted between 1990 and 1999 with respect to smoke-free workplaces in private enterprise and between 2002 and 2007 with respect to smoke-free areas in the hospitality industry. Both self-regulation processes were ended by the government because of their supposed lack of success. It was decided that legal bans were necessary.

This article describes the two self-regulation attempts and their results as they were reported to the authorities, with an emphasis on the self-regulation in the hospitality industry. The Government deemed these results unsatisfactory and decided to introduce legal bans. These

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1 Many thanks to Marieke van der Meij, who did a lot of necessary preparatory work for this article.
3 Stamhuis 2004: 8; 11.
bans proved to be more effective than the processes of self-regulation. I conclude with some reflections on these counterintuitive findings.

2 The first Tobacco Act: smoke-free public buildings and self-regulation by private enterprise

2.1 Introduction

The Dutch debate on the supposed dangers of tobacco smoke started in the 1950s. Doctor Meinsma, director of the Queen Wilhelmina Fund (KWF, an organization dedicated to combating cancer), called for attention to be paid to the negative aspects of smoking tobacco. An anti-smoking organization was founded in 1974, during his directorate, the Foundation Public Health and Smoking (Stivoro). Stivoro advocated smoke-free areas and workplaces on the grounds that they would contribute to changing attitudes to smoking.

From the 1980s, publications on ‘passive smoking’ resulted in anti-smoking campaigners winning the argument. ‘Passive smoking’ is seen as a danger to health and an infringement of bodily integrity. Societal pressure to free public places from tobacco smoke and to make them accessible for people with breathing problems increased.

Anti-smoking activities fell on fertile soil. The proportion of male smokers started to decline from about 95 percent in the late 1960s to a little above 40 percent in the early 1980s. The proportion of female smokers, which had always been lower (about 30 percent in the late 1960s), initially increased to above 40 percent in the 1970s and then started to decrease to its previous level in the 1980s.

2.2 Tobacco Act 1990

In late 1984 the Dutch government reacted to these developments with a bill that proposed ‘measures that limit the use of tobacco, aimed especially at the bodily integrity of the non-smoker’. The bill commenced by considering smoking, in particular cigarettes and rolling tobacco, a threat to health and sought to decrease the danger of smoking for public health. However, the government added, smoking policy could only be effective if the measures fit the changing societal attitudes towards smoking.

The Tobacco Act (entering into force in 1990) forced public bodies to impose on all institutions and services under their control the obligation to take measures to prevent the discomfort of tobacco smoke. Taking measures implied that they ‘set up and keep up a smoking ban’. This smoking ban was intended to protect both employees and users of public institutions and the services. The law did not provide for sanctions. The government considered sanctions to

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4 Stivoro emerged from a partnership between the KWF and two other health organizations: the Asthma Fund and the Dutch Heart Foundation.
5 See for example Hayes, 1984.
7 Second Chamber of Parliament 1984/85, 18749, 1-3. The Tobacco Act 1990 is not the first law that enacted smoking bans. Former regulation, however, did not aim to protect non-smokers; it was enacted for other reasons, such as preventing fire (for example in cinemas).
be too far-reaching because of their inflexibility. Imposing the same obligation on private enterprise was also viewed as too far-reaching. Private enterprise could voluntary follow the example of the government.

2.3 Self-regulation regarding smoke-free workplaces in the private sector

The Labour Foundation is the most important organization that considered developing smoking policies necessary. To initiate this policy the Foundation published a "Recommendation to employers and employees". This Recommendation advised enterprises to express the changing societal beliefs regarding smoking so that their acceptance by employees (smokers and non-smokers) would be as general as possible. The Foundation considered a smoking ban across all private enterprise too far-reaching and unnecessary. To support the introduction of smoke-free workplaces, the Foundation developed a step-by-step plan. With respect to smoking policies the Foundation referred to two "inextricable" elements: house rules to prevent the discomfort of tobacco smoke and initiatives to convince smokers to quit the habit.

Almost a decade later, the Foundation published a new recommendation regarding smoking policies. The Foundation expressed that tobacco smoke not only causes health problems but also influences employee performance negatively – smoking can cause absence, illness and diminished productivity. Furthermore, unresolved disputes with respect to the exposure to tobacco smoke may disturb relations in enterprises. In the Foundation's view smoking is a "matter of manners". In this second recommendation the Foundation placed more emphasis on the financial interests of enterprises in smoking policies.

2.4 Results of the smoking ban and self-regulation

At the end of the 1990s the findings of research into the effectiveness of the smoking ban became public. One such study concerned schools. It showed that a great deal had been accomplished in schools – smoking occurred in about eight percent of classrooms and cafeterias and in about ten percent of halls. The government, however, was not satisfied with these results and announced increased controls. It also announced the intention to propose that Parliament include a sanction for offences against the smoking ban into the Tobacco Act.

In 1997 and 2000 the self-regulation of smoking policies in private enterprise was also studied. These studies tried to establish how many businesses (of five or more employees) had a smoking policy. The research showed that in 2000, 53 percent of businesses had such a

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9 Second Chamber of Parliament 1986/87, 18 749, no. 9: 18. The Government also took the position that these institutions and services should of course comply with governmental regulations.
11 A foundation which provides a forum for employers and employees for the discussion of issues in the field of labour and industrial relations.
12 Stichting van de Arbeid, 1992.
13 GBW 1997. The GBW (Centre for the promotion of health on the shop floor) is an initiative of the Asthma Fund, the Dutch Heart Foundation and the KWF.
15 In 1996 the Foundation published its opinion that smoking near to a non-smoker could be considered undesirable behaviour (Stichting van de Arbeid, 1999: 6).
16 According to an expert from the GBW a smoker is absent from work considerably more often than a non-smoker (GBW, 1997).
policy (51% in 1997). However, only some of the businesses surveyed had taken measures to protect non-smokers: 74 percent of the 53 percent (that is 39% of all businesses). In 2000 all businesses showed an upward trend. A more detailed look at the findings shows that the business-to-business services sector towered above the rest (55% of these businesses had a smoking policy) and the hospitality sector was at the bottom (25% of these businesses had such a policy).

2.5 Public opinion on smoke-free workplaces

The desirability of smoking policies became clear from research carried out by Stivoro/NIPO: more than two-thirds of the employees questioned (67%) answered that they had been exposed to tobacco smoke at work and 43 percent of them considered this annoying. Of Dutch people over fifteen, 73 percent considered ‘passive smoking’ damaging and 82 percent took the position that you should be able do your job without being disturbed by tobacco smoke.\(^{19}\)

3 A legal smoking ban for workplaces

3.1 Introduction

In the late 1990s the government took the position that the results of self-regulation of smoke-free workplaces in private enterprises were too weak,\(^ {20}\) and on 10 April 1999 the government proposed changing the Tobacco Act 1990. One of the changes was the addition of Article 11a. This article obliges employers to take measures to permit employees to do their work without being disturbed by tobacco smoke.\(^ {21}\) Another important change in the Tobacco Act regarded the implementation of sanctions in cases of violation of the law. The administrator or the employer rather than the smoker were made liable for punishment as the parties under an obligation to take the measures required in the law.\(^ {22}\)

This decisive stance did not signify that government had decided to take the lead. In the explanatory notes to the Bill the Government suggests choosing a regulatory framework that matches societal changes in attitudes to smoking.\(^ {23}\)

The Tobacco Act 2002 (2002 is the year the law entered into force) creates the possibility of excluding areas within businesses and institutions and of exempting certain sectors from the prohibition.\(^ {24}\) The best known exception regarded the hospitality industry.\(^ {25}\) This industry had

\(^{19}\) StivoroVisie, May 2000.

\(^{20}\) Second Chamber of Parliament 1998/99, 26472, no. 3.

\(^{21}\) A reduction in the percentage of smokers in the Netherlands is the central goal of the proposal (Second Chamber of Parliament 1998/99, 26472, no. 3: 7). The importance of smoke-free workplaces is emphasized by the ruling of the District Court of Breda in 2000. The court recognized the right of an employee to a smoke-free workplace. (LJN: AA5611, Rechtbank Breda, 82307/KG ZA 00-150). The court refers, among other things, to Article 4.9 of the Law on Working Conditions, which obliges an employer to organize labour so that the health of the employee is not harmed. According the District Court this means that the employer is obliged to guarantee that a non-smoking employee can do his or her job and rest in areas which are free from tobacco smoke.

\(^{22}\) There are two types of sanctions: sanctions by administrative law and sanctions by criminal law. The Food and Consumer Safety Authority (VWA) is charged with the supervision of administrative law.


\(^{24}\) Such a provision already existed in the Tobacco Act 1990.

often been referred to in parliamentary debates as a sector that was not ready for a smoking ban. The sector itself, through its agency the Royal Dutch Hospitality Industry (KHN), never concealed its opinion that a smoking ban in the sector was impossible.\textsuperscript{26} Self-regulation was considered the means by which discomfort from tobacco smoke in this sector could be restricted.

### 3.2 Results of the Tobacco Act 2002

In May 2004 the Minister of Health, Hoogervorst, reported the first results of the new policy to Parliament. Research conducted by the trade union FNV showed progress with respect to the implementation of smoke-free workplaces. Four out of five businesses had adjusted their smoking policies and about 70 percent of non-smoking employees were protected against tobacco smoke. With respect to smoke-free public transport, Hoogervorst noted that its implementation was carried out without any problem.\textsuperscript{27}

In late 2004 the Food and Consumer Product Safety Authority (VWA) checked for the first time a considerable number of businesses with respect to smoking bans.\textsuperscript{28} The report shows that the law was not complied with in 32 percent of businesses. In sum, 30 reports and 1141 written warnings were issued, mostly in the industry (47\%) and construction (26\%) sectors. Checking workplaces, such as offices, production halls or shops, led to the conclusion that smoking took place in 21 percent of businesses. The construction and industry sectors were the worst offenders – smoking at the workplace was still common in around 33 percent of these businesses. Checking other areas, such as stairs, cafeterias and meeting rooms, showed that 17 percent were not smoke-free. To sum up, 76 percent of businesses met the requirements of the Tobacco Act 2002 – about 44 percent through a total ban on smoking and about 33 percent through a smoking ban complemented with special rooms in which smoking is allowed.\textsuperscript{29}

The VWA concluded that the construction and industry sectors needed special attention and checked them again (industry in 2005 and construction in 2006). This second round showed that both sectors had made progress – compliance rates had been increased to about 75 percent.\textsuperscript{30}

In late 2006, the VWA checked about 1400 businesses. Its conclusion was that workplaces and collective areas were smoke-free in about 86 percent of businesses. At the sector level the proportion of smoke-free businesses varied from 76 percent in industry to 100 percent in healthcare.\textsuperscript{31}

\begin{itemize}
\item \textsuperscript{26} KHN, 2003: 8.
\item \textsuperscript{27} Second Chamber of Parliament 2003/04, 29 200 XVI, no. 233.
\item \textsuperscript{28} The VWA checked ten different sectors: construction; culture, recreation and other services; financial enterprise, industry, agriculture; hunting, forestry and fishery; social security; public services; repair workshops for consumer commodities and trade; public transport, storage and communication; and rental and business-to-business services.
\item \textsuperscript{29} VWA, 2004.
\item \textsuperscript{30} VWA, 2005; VWA, 2006.
\item \textsuperscript{31} Intraval & VWA, 2006.
\end{itemize}
3.3 Public opinion on smoking

TNS/NIPO research confirmed the findings of the VWA. The percentage of non-smokers who stated they were disturbed by tobacco smoke regularly or very often had been decreased from 40 percent (in late 2003) to 28 percent (in mid 2005). Furthermore, it became clear that both smokers and non-smokers supported smoking policies in greater numbers. On average, 84 percent of Dutch people (smokers 72%, non-smokers 89%) took the position that employees should have the opportunity to do their jobs without being disturbed by tobacco smoke.

4 Self-regulation in the hospitality industry

4.1 Introduction

The Minister of Health exempted the hospitality industry from the obligation under Article 11a of the Tobacco Act in the ‘Exceptions to the smoke-free workplace Order’. This exception only applied to areas accessible to customers. Meeting rooms, changing rooms and the like for employees had to be smoke-free. From the outset, the Minister was clear that the exemption would only be temporary. The Government’s ultimate goal was a 100 percent smoke-free hospitality industry. In the interim a process of self-regulation, overseen by the KHN and another hospitality industry organization, was to be in effect.

4.2 The step-by-step plan

The KHN opted for a system in use in England. Under this system a notice is placed at the front of a bar, restaurant or hotel announcing the smoking policy of the establishment (smoke-free, partly smoke-free, etc.) This system is thought to stimulate market processes and to make manifest the societal support of smoking policies. Bars and restaurants in particular would benefit from such a system.

With respect to self-regulation, the opinions of the Minister and the KHN differed. The Minister thought of self-regulation as a short-term step towards legislation, the hospitality industry bringing the law into force in phases. The KHN considered self-regulation [a]n autonomous, voluntary action of an industry to realize concrete and societal goals to avoid (inflexible and hardly effective) regulation by government and to gain societal support for the goals concerned.

The KHN noted the usual advantages of self-regulation: the sector has the specific knowledge necessary to draw up a regulation, or can get this information more cheaply than the govern-

32 Koolhaas & Willemsen, 2005.
33 Staatsblad, 2003, nr. 561.
34 In the meantime (since 1 July, 2007) Great Britain has enacted a smoking ban in public places, including the hospitality industry.
35 In addition to this system, the KHN considered education about smoking policies and the possibilities of ventilation. However, on the basis of research reports from RIVM/TNO the Minister did not credit the reduction of tobacco smoke disturbance by ventilation: ‘with ventilation a complete reduction of the risks is not possible’ (Second Chamber of Parliament 2005/06, 30300 XVI, no. 144). Ever since, Dutch Ministers of Health have rejected ventilation as a solution.
36 KHN 2003: 10.
Self-regulation is better able to precipitate a cultural shift. Bluntly imposing a smoking ban in the hospitality industry would lead only to a lack of understanding and civil disobedience.

From the outset it was clear that the KHN and the Minister did not agree on the content of the policy. The KHN did not go along with the Minister in his opinion that the hospitality industry had to be 100 percent smoke-free in 2007. In its view the Minister asked too much of the sector because its percentage of smokers was higher than elsewhere. Furthermore, the KHN took the position that the one-man businesses are beyond the scope of self-regulation and asked for an exception for bars smaller than 100 square meters.

The version of the step-by-step plan that was accepted by the Minister stated the following goals: in 2007 all establishments should have a notice at their fronts, in 2008 75 percent of all bars and all restaurants should have smoke-free areas, furthermore 80 percent of fast-food establishments and 75 percent of discos should have such areas; 95 percent of hotels should offer a smoke-free breakfast option and all hotels should offer smoke-free rooms. In addition to all this, half of all the fast-food establishments and all ice-cream parlours should be free from tobacco smoke.

On the occasion of the presentation of the step-by-step plan to Parliament, Minister Hoogervorst took the position that its goal was to get employers, employees and visitors used to a smoking policy and thereby to ease the coming into effect of a smoke-free hospitality industry. He undertook to provide an overview of the results each year.

The results for 2005 were published in July 2006 (table 1).
Minister Hoogervorst was disappointed by these results. However, he granted the hospitality industry a second chance. If the targets were not met in 2006, he would consider withdrawing the exception. The table of results for 2006 shows that the sector caught up:

**Table 2: results 2006**

<table>
<thead>
<tr>
<th>Sector</th>
<th>2006 Target</th>
<th>2006 Results</th>
<th>Target Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice at front</td>
<td>85%</td>
<td>59%</td>
<td>No</td>
</tr>
<tr>
<td>Smoke-free areas</td>
<td>40%</td>
<td>47%</td>
<td>Yes</td>
</tr>
<tr>
<td>Restaurants</td>
<td>50%</td>
<td>58%</td>
<td>Yes</td>
</tr>
<tr>
<td>Discos</td>
<td>40%</td>
<td>21%</td>
<td>No</td>
</tr>
<tr>
<td>Hotels smoke-free rooms</td>
<td>75%</td>
<td>97%</td>
<td>Yes</td>
</tr>
<tr>
<td>Hotels smoke-free breakfast</td>
<td>40%</td>
<td>87%</td>
<td>Yes</td>
</tr>
<tr>
<td>Fast-food</td>
<td>50%</td>
<td>67%</td>
<td>Yes</td>
</tr>
<tr>
<td>Smoke-free Fast-food</td>
<td>30%</td>
<td>14%</td>
<td>No</td>
</tr>
<tr>
<td>Ice-cream parlours</td>
<td>70%</td>
<td>55%</td>
<td>No</td>
</tr>
</tbody>
</table>

The table shows that the hospitality industry achieved the required results. However, it was too late. A few months before the results were announced a new cabinet was formed. This new government, Balkenende IV, stated in its coalition agreement that it would ‘achieve a smoke-free hospitality industry in its term, in dialogue with the sector’.42

The new Minister of Health, Klink, immediately started talks with the KHN. The KHN took the position that the sector was ready for a new approach. It proposed making hotels, restaurants and fast-food establishments smoke-free from 1 January, 2008. Bars and discos would need more time: according to the KHN, they could be smoke-free from January 2011.

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42 Second Chamber of Parliament 2006/07, 30 800 XVI, no. 149: 3.
5 Smoking bans for the hospitality industry

5.1 Introduction

In 2008 TNS NIPO looked at the public support for smoking bans in the hospitality industry. They found that a majority of the industry’s customers supported such a ban (62%, a little less than in 2006 when 65% of the population supported it). The majority of those against were smokers (72%). More than half of those questioned wanted a smoking ban in the near future. With respect to restaurants this was 60 percent. A vast majority of the supporters of a smoking ban took the position that the government should be more decisive and force the hospitality industry to be smoke-free in 2011.43

The ‘Exceptions to the smoke-free workplace Order’ was withdrawn on 1 July, 2008. From that day on the hospitality industry44 was also subject to Article 11a of the Tobacco Law. A second order also came into force that day: ‘Smoke-free workplace, hospitality industry and other areas Implementation Order’. Provision 3 of this Order prescribes that the entire hospitality industry, and not only those businesses with personnel, should become smoke-free.45 Minister Klink argued that research in other countries showed that a strong decrease in turnover as a result of the smoking bans is not to be expected. In his opinion there were no arguments for distinguishing different parts of the hospitality industry with respect to the measures imposed. Such differences could lead to distortion of competition and thus to litigation.46

5.2 Compliance rates

As distinct from the introduction of earlier smoking bans, like the smoking ban in public transport and the smoke-free workplace, the VWA announced immediate compliance checking.

In late September 2008, the VWA published its first report on compliance rates:47 the smoking ban in most parts of the hospitality industry – hotels, restaurants and fast food establishments – was very successful from the point of view of the legislator. In these parts compliance was almost total: 94–99 percent. One part that lagged behind was the so-called ‘wet part’ (pubs, bars and the like). However even there the VWA found compliance rates of 79 percent.

From 1 July on, this ‘wet part’ expressed objections, a protest that grew during the first three months of the bans. Bar owners argued that their turnover had decreased to such an extent that they had no other choice than to put the ashtrays back on the tables. They did not agree with the distortion of competition argument and became more resolute in their protest against the smoking ban. Minister Klink reacted by threatenig that the VWA would check on these recalcitrant bar owners more often and that the VWA would apply administrative fines from

44 Defined as organizations run by entrepreneurs or companies required to register with the Hospitality and Catering Trading Association (Bedrijfschap Horeca en Catering).
45 Staatsblad, 2008, 122. This can be done on the basis of Article 10 the Tobacco Law.
46 Second Chamber of Parliament 2006/07, 30 800 XVI, no. 149: 3.
47 VWA, 2008.
that moment on. In November 2008 the Minister announced that those businesses violating the smoking ban systematically would be prosecuted under the Economic Offences Act.

In January 2009 the compliance rates for the first six months were published. Two sources were used. On the one hand are the findings of the VWA. Between 1 July 2008 and the beginning of January 2009, the VWA carried out more than 14,000 inspections. From October these inspections were especially concentrated on those businesses which did not comply with the bans. The results of these activities were that some 2,500 measures were imposed, 80 percent of them on bars. On the other hand, the research institute Intraval inquired into compliance in six cities. From this research it is evident that 90 percent of all 42,500 businesses in the hospitality industry comply with the bans. A large majority of the ‘wet part’ also complies – 77 percent. About 2,500 of the 11,000 bars, pubs and similar do not comply with the smoking ban. This number has not changed much since the first three months of the smoking bans.

6 Reflections

Compared to regulation by government, self-regulation is seen as cheaper, more effective, more flexible and as saving administrative costs. This article makes clear that many of the advantages attributed in the literature to self-regulation as a whole are also found with respect to self-regulation of smoking policies. Ministers pointed to the need to take existing norms into account, instead of imposing them, and to the flexibility and effectiveness of self-regulation. Societal organizations such as the Labour Foundation and the KHN are also convinced of the advantages of self-regulation – they took the position that it is better not to apply the most severe measure, a legal ban, immediately. They considered regulation by government as too rigid and therefore hardly effective, and thought that social support for smoking bans was more easily gained through self-regulation. The arguments regarding the accessibility of knowledge and of lower costs were also raised with respect to self-regulation of smoking policies.

However, the article also points out that the advantages attributed to self-regulation barely materialized in the case of smoking policies. Self-regulation of smoking policy is characterized neither by speed nor by flexibly drafted rules; it can only barely be associated with the formulation sector-specific norms and with incentives and a readiness to comply with the rules. Two reasons come to mind to explain these findings: the advantages do not occur in cases of top-down self-regulation and the self-regulation process was not given enough time.

48 Second Chamber of Parliament 2008/09, 22 894, no. 199.
49 http://www.minvws.nl/kamerstukken/pg/2008/handhaving-rookvrije-horeca.asp. In 2009 two bars were prosecuted on this ground. The cases have clarified that the legal grounding of the smoking bans in bars without employees is unsound (LJN: BH9853, District Court Breda; BI3572, Court of Appeals ’sHertogenbosch; BJ1286, Court of Appeals Leeuwarden (Van der Meij 2009).
50 Notably on small bars and pubs in city centres.
51 This number demonstrates that there is a considerable group of businesses which do not comply with the rule without being explicitly against. RKN (Save the Small Entrepreneurs in the hospitality industry – an organization that articulates its opposition to the smoking ban) has some 1,100 members. A small study conducted in Groningen shows the same results – only some of the bars that allow smoking, especially bars in the town centre, communicate this policy.
Self-regulation with respect to smoking policies is clearly an example of top-down self-regulation. The Government decided the norm to be implemented in advance – do not disturb others by smoking – a norm later complemented by a diminution in the proportion of smokers in society. Moreover, the Government also decided how the new norm should be established – by prohibiting smoking in certain places. Other methods of preventing discomfort such as ventilation, were rejected categorically – i.e. flexibility did not play a role at all. The only thing left to businesses and organizations to decide was how to palm off the norm onto their employees and customers. The case therefore suggests that the advantages attributed to self-regulation do not occur in top-down regulation.

Both in 1999 and in 2006, ministers decided that self-regulation yielded too few results. In the earlier case the Health Minister had not been explicit as to which results he expected and in the later case he changed expectations during the process. We do not know what would have occurred if the sectors had been given more time. This suggests that we cannot draw definite conclusions on the merits of self-regulation of smoking policies.

Fortunately, there is another way of looking at the process that provides a more satisfactory answer to the question of whether self-regulation is better than direct regulation by government – namely by looking at whether the legal bans imposed were less effective and more expensive than the smoking policies resulting from self-regulation.

The effectiveness of legal bans versus self-regulation can be assessed by comparing compliance rates. For example, after a year the rather soft demand of notices at the front of each establishment in the hospitality industry was complied with in only half of the cases, and smoke-free areas had only been implemented in large numbers in hotels. With respect to the legal bans: overnight (30 June 2008) 90 percent of the hospitality industry, and even 77 percent of the supposed most problematic sector – the ‘wet part’ – were smoke-free. There is only one conclusion possible: the legal ban achieved more (quantitatively and qualitatively) than self-regulation did.

Apparently these results were not caused by the enforcement activities of the administrative bodies. The lack of substantive enforcement is obvious with respect to the smoke-free workplace. Leaving aside the hospitality industry, the VWA conducted some 9,000 inspections between 2004 and 2007. This is very few considering the magnitude of the sectors: for example, in 2005 only one out of fourteen industry enterprises was visited by the VWA. With respect to the hospitality industry, enforcement activities are markedly more numerous. However, the hospitality industry differs from other industries, such as construction, with respect to compliance rates. Right from the first day, compliance rates were very high and therefore compliance in this sector cannot be explained by the enforcement activities of the VWA either.

Accordingly, not only did the supposed advantages of self-regulation not materialize, but it was also less effective than its counterpart, government regulation. How can this be explained?

A possible explanation of the results could be the moment the legal bans came into effect. Dutch governments were clear that they had delayed legal smoking bans until the moment they expected society had changed sufficiently to accept them. It is clear that at the time the
legal bans were imposed, the norm – do not disturb others with tobacco smoke – had considerable public support. With respect to the smoke-free workplace we know that smoking rates started to decrease before the law came into force and hardly at all thereafter. The legal ban gives the norm – do not disturb others with tobacco smoke – ‘moral force’ by clarifying its importance.

Another possible explanation could be the period of self-regulation attributed to the acceptance of smoking policies. In that period not only did non-smokers and smokers gain experience with smoking policies but entrepreneurs and managers did too. Regarding the latter two groups, this experience may have shown that the benefits exceeded the costs – for example fewer absentees, lower cleaning costs – and that employees and customers were positive about it.

Some proof for this explanation is to be found in the problems the ‘wet sector’ has. With respect to smoke-free areas, the KHN omitted this sector from the self-regulation rules. In their opinion smoking bans in this sector were premature because of a lack of support. Furthermore, the KHN never took into account that businesses without employees would also be subject to smoking policies. Therefore, if self-regulation served as a preparation for smoking bans, it is no wonder that the ‘wet sector’ was not ready for smoking bans. Furthermore, it is doubtful whether establishments in this sector, especially small bar owners, can afford even a small temporary fall in income. For them, probably, the outcome of the costs and benefits analysis is negative.

To conclude, the example of self-regulation with respect to smoking policies shows that the supposed advantages of self-regulation may not always materialize in cases of top-down self-regulation. Furthermore, the example puts the difference between regulation by government and self-regulation into perspective – despite the fact that the advantages of self-regulation did not appear, regulation by government did not show the supposed disadvantages. Furthermore, although self-regulation of smoking bans was not very successful, it apparently did a good job in preparing the various sectors for legal smoking bans. Regulation and self-regulation of smoking policies again showed that regulation processes are mixes of different forms of regulation, and the description provided of the example industry demonstrates, again, the complexity of such processes.

52 Nienhuis & Weyers 2005.
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DISTINGUISHING TRUE FROM OTHER HYBRIDS
A Case Study of the Merits and Pitfalls of Devolved Regulation in the UK

Nicolle Zeegers

Abstract
The model of ‘decentered regulation’ was claimed to offer the ideal instrument to cope with the specific challenges of technological innovation in a society characterized by diversity in moral beliefs. The central question of this article is whether the ‘model of decentered regulation’ indeed brought the solutions that were expected from it. This question will be answered by using the case study of the formulation of the rules concerning the creation of human animal hybrid embryos in the United Kingdom. The analysis of this issue will be used to reflect on four reasons that are brought forward in favor of the model of decentered regulation: 1) the inclusion of necessary scientific expertise; 2) a flexible and efficient mechanism of rule change; 3) coping with diversity in moral beliefs; 4) coping with the changeability of these beliefs in time.

Keywords: decentered regulation; biomedical technology; scientific experts; legal boundary conflicts; human-animal hybrid embryos

1 Introduction

The UK is one of the few countries in which the creation of human-animal hybrid embryos is allowed.\(^1\)\(^2\) As is the case with the regulation of biomedical technology more general the contribution of scientific experts to the formulation of the rules concerning the use of embryos

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1 A hybrid embryo is an embryo created by mixing the eggs and sperm of different species. A chimera embryo is a different form of human animal embryo: an animal or human embryo which contains cells from a different animal or human, in the case of an interspecies hybrid embryo these cells are from another species. Unlike a hybrid embryo, which is created by mixing the genes, a chimera contains cells which have different genetic information.

2 In countries as China, Japan and South Korea the creation of embryos by ‘somatic cell nuclear transfer’ is allowed and the creation of human-animal embryos not specifically prohibited.
in research has been indispensable because of the high technological character of this issue. However, unlike most issues of a high technological character, the creation of human-animal hybrid embryos provoked a fierce public and political debate. Therefore this issue lends itself very well to put the model of ‘decentered regulation’ to the test with respect to how it copes with diversity in and changeability of moral beliefs.3

The model of ‘decentered regulation’ anticipates the need of government for constant advice from technical specialists by giving scientific experts a structural position in the process of rule making. The case-to-case approach in this model at its turn is held to be capable to resolve the tension between the flexibility of legal rules, needed because of the dynamic development of technology and the changeability and diversity in moral beliefs, on the one hand, and, on the other hand, the precision required by legal certainty.

In this article the model of ‘decentered regulation’ will be put to the test by analyzing how it functioned in the regulation of the creation of human animal hybrid embryos in the UK. I will focus on the contribution of scientists to the formulation of rules concerning the creation of these forms of embryo because their role is a point of attack for the opponents of a model of decentered regulation.

The opponents of the implementation of a decentered model in the regulation of biotechnological issues consider both the privileged access that is given to scientists in the model as well as the case-to-case approach problematic in the light of democracy. Firstly, in a democracy citizens should have equal access to governmental decision making. In cases of devolution of (part of) the power of rule-making to a lower authority it is important to create conditions in which different opinions and interests are balanced against each other. In stead of this, the privileged access given to scientific experts would, according to the opponents, bring with it a disproportionate extent of influence for them over the formulation of the rules. The efforts of legislators to anticipate this effect and compensate the privileged access by also involving other stakeholders in the lower authorities would not present the right solution. The idea that including for example members that represent social and religious knowledge would compensate for the power given to scientists is based on the assumption that these members can represent a countervailing power to the scientific technocrats. However, as knowledge of the scientific details is the crucial source of influence of these technocrats the question is whether non-scientists are equipped to fulfill this role of countervailing power. Another reason that is given by legislators for including these members is the creation of conditions that could further support for technological innovation in broader society. The question is: which of these purposes are in fact brought nearer by including these members?

Secondly, the case-to-case approach is considered problematic because it would rather automatically push things forward to liberalization of policy. According to Levitt (2004) this is because with each new case a momentum is created that thanks to media involvement and commercial pressures leads to the allowance of yet another technique in spite of the strong resistance of some groups.4 A more democratic way of decision making would be to consider

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3 With the model of ‘decentered regulation’ I refer to the wide range of forms of regulation that nowadays exist and that are not centred on the state but decentered: Instead of the state, market parties associations and networks play a central role in this model of regulation.

alternative techniques and weigh these up against each other, also with respect to the moral values involved.

In the first part of the paper I will present the analysis of the regulation of the creation of human-animal hybrid embryos in the UK. In section 1, I will describe the UK regulatory framework for the use of embryos in research as existed at the time the creation of human-animal hybrid embryos became an issue. The 1990 Human Fertilization and Embryology Act and the HFE Authority, the statutory body that was set up with this act, are central to this regulatory framework. While the Act settled some issues concerning the moral boundaries of the use of human embryos in research, some questions about the moral status of the early human embryo were left unanswered. As will be elaborated on in this first section, the debate about these questions revived at the moment the creation of human-animal hybrid embryos became technically conceivable. The power to formulate rules concerning the creation of new forms of embryos to some extent is delegated to the HFE Authority and therefore two arenas have to be addressed in the analysis of the decision making concerning this issue. The first arena is the decision making about licensing specific research proposals by the HFE Authority. The second arena is the legislative process of amending the HFE Act that started in 2005 and ended with the 2008 HFE Act. I will reconstruct the decision making processes in these two arenas respectively in section 2 and section 3 by first describing the points of access scientific experts have to these processes and subsequently the strategic use of language that is made in the presentation of their knowledge in order to establish a specific version of situations and events in the face of competing versions. A striking insight that will be presented here is that a crucial part of the knowledge contributed by scientific experts in the arena of the decision making of the HFE was contested by the scientific experts participating in the arena of the legislative process. In section 4, I will answer the question whether or not the model of decentered regulation in this case has fulfilled the expectations of its advocates.

2 The 1990 HFE Act and its unstable moral boundaries

The particular model of ‘decentered regulation’ that has been chosen in the UK, as in some other countries, to control the practice and development of embryology and fertility treatment can be characterized as ‘devolved regulation’. The Human Fertilization and Embryology Act 2008 provides the legal framework for the use of embryos in research. Some of the rules in this Act are straightforward prohibitions, for example the prohibition on the development of an embryo in vitro beyond 14 days. However, the main part of this Act contains a more flexible, communicative, legislative approach that can be responsive to changing scientific, social or ethical understandings.

The HFE Authority, a statutory body with defined discretionary powers, is set up to administer the law within the boundaries of the Act. This Authority is responsible for licensing

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5 This is what political reasoning is about according to D Stone, Policy Paradox. The art of political decision making. (W.W. Norton & Company New York and London, 2002).

6 This choice was preceded by singling out reproductive medicine as an area of such particular social concern and significance that the state must have a stake in its development.

7 With the Human Reproductive Cloning Act 2001, the placement of a human embryo other than by fertilization in the womb of a woman became an offence.
the use of embryos in research, which in the UK case includes the creation of embryos for research. In order to get the approval of the **HFE Authority**, researchers who wish to use embryos in their research must submit a research protocol that makes clear that the research is ‘necessary or desirable’ for one or more of the purposes of the **HFE Act**. In addition to being convinced on the latter point the Authority cannot issue a license unless it is satisfied that the use of an embryos is necessary for the research.

As Dawson observed, the Authorities brief is a dual one as it combines the task of registration and inspection with the task of policy formulation. With respect to its task of inspection, the **HFE Authority** is required to ensure that licensed premises are inspected once in every calendar year unless a license committee considers that inspection is unnecessary. The **HFE Authority** has a policy formulation role through its decisions about individual research cases and its consultations of the public.

In the decisions of the Authority controversial ethical issues are touched upon as may be witnessed by the reasonable amount of occasions at which these decisions have been challenged in court. This is not surprising. At the one hand, the research proposals submitted to the Authority each time involve the most new techniques of creating embryos. Therefore, a recurrent question the **HFE Authority** has to deal with is whether the resulting form of embryo fits into the legal category of a human embryo and would fall under the remit of the Authority.

At the other hand, some questions concerning the moral status of the early embryo were left unanswered with the formulation of the **1990 HFE Act**. The law is grounded on the idea of intrinsic worth because of the potentiality of the embryo to grow into a human being. In addition the act incorporates the idea that protection should increase as the embryo develops, because of the growing probability that it will become a human being. So the moral worth of the embryo in law is considered to be dependent on its degree of progress through the stages of its development. The implantation phase, completed with ‘in vivo embryos’ after fourteen days, is deemed important in this respect and that is the reason why the law explicitly prohibits the development of embryos in vitro beyond this period of time. However, the exact relevance of the different stages of development is still contested. Until today, it is not possible to develop embryos in vitro longer than seven days, so the technological limit is more restricting than the legal limit. Therefore the legal limit of fourteen days of development in vitro has not been subject to debate. This is different for other issues such as what would determine the moral worth of the human embryo younger than fourteen days and where to draw the boundary of legal categories as ‘a full human genome’, ‘being alive’ and ‘where fertilization is complete’?

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8 Desirable is assessed in terms of the contribution to scientific knowledge or human health that can be expected from the research. Necessary means that creating such embryos (instead of using other sources of stem cells) is necessary for the research.

9 Human Fertilisation and Embryology Act 1990, sch. 2, para. 3 (2) and (6); R Lee and D Morgan, *Human Fertilisation and Embryology. Regulating the Reproductive Revolution* (London, Blackstone Press Limited, 2001), p. 120.


11 Lee and Morgan (n 9)116-17. In 1997 the Authority started with a three year licensing cycle, in which all clinics receive one broad-based general inspection once every three years with highly focused inspections in the intervening year.

12 Ibid 68-72
The answers to these questions are ambiguous. The Quintavalla case in 2003 is an example of how the HFE Authority as case-to-case decision maker is put at the forefront of ‘legal boundary conflicts’ of a high political character. The court case revolved around the legal category ‘where fertilization is complete’ and the question whether this part of the legal definition of a human embryo would exclude the human embryo that results from Cell Nuclear Replacement from falling under the HFE Act 1990. The appellant, representing the pressure group Pro Life Alliance, claimed that it did not because the HFE Act 1990 only referred to embryos that were created by fertilization. This challenge was successful in the High Court but was overturned by the Court of Appeal, whose judgment was approved by the House of Lords taking a purposive approach to the interpretation of Law. With their successful challenge in the High Court the Pro Life Alliance paradoxically created a situation in which human cloning was temporarily not regulated. As the Government subsequently rushed through legislation in order to repair this caveat this situation only lasted for a short while.

The question whether the creation of human-animal hybrid embryos should be allowed must be seen as the next ‘legal boundary conflict’ with respect to the 1990 HFE Act. This time the political struggle revolved around the categories of ‘having a full human genome’ and ‘being alive’. The definitions of these categories appeared to be contested even among scientific experts. The first part of the debate was fought out in the arena of the HFE Authority decision making whether or not to license research proposals involving the creation of human-animal hybrid embryos. I will analyze this debate in the following section.

3 The arena of decision making by the HFE Authority

Scientific experts have several points of access to the decision making process of the HFE Authority. A first point of access is the body that takes the license decisions. There are several provisions in the HFEA concerning the composition of the Authority: ‘The Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research.’ Most of these members, though not necessarily all, will qualify as scientific experts.

14 Cell nuclear replacement (CNR) is a technique in which researchers take a cell (such as a skin cell) from an adult and extract the genetic information (the nucleus) from the cell. They then transfer that genetic information into an egg from which the genetic information has been removed, activating the egg so that it starts to divide.
15 The appellant pointed out that in s. 1 of the Act an embryo regulated by the Act is defined as ‘a live human embryo where fertilization is complete’ and that CNR does not involve a process of fertilization.
16 The House of Lords rejected the argument of the appellant: ‘The crucial point … is that this was an Act passed for the protection of live human embryos created outside the human body. The essential thrust of section 3(1) (a) was directed to such embryos, not to the manner of their creation, which Parliament (entirely understandable on the then current state of scientific knowledge) took for granted.
17 According to commentators the reason why the Pro Life alliance did this was to unmask government as cheating the public in order to have the UK stay at the forefront of stem cell research. For this information I thank Joost Haarsen who as a student analyzed the debate about this Quintavalla Case.
19 There are several other provisions in the HFE Act 1990 concerning the composition of the Authority: The Secretary of State shall make appointments and has to ensure that the Authority must be informed by the views of both men and women. At least a third but not more than half of the membership has to consist of persons with a background as medical practitioner, human embryo research or the commissioning, funding of or decision making on this research. Persons belonging to these categories are disqualified from being appointed as chairman or deputy chairman in order to ensure that the overall direction of the authority is independent of the medical-scientific view. See Lee and Morgan (n9) 102-103.
A second point of access is the Scientific and Clinical Advances Group (SCAG) of the HFE Authority. This is a group of scientific experts that advises the Authority on questions concerning new scientific and clinical developments. A third point of access is the HFEA’s Horizontal Scanning Expert Panel (HHSEP), a worldwide panel of experts that includes experts in stem cell technology from universities in the UK, Australia and Japan, specialists in assisted reproductive technologies from the US and Belgium and leading academics in cloning techniques, developmental genetics and cryopreservation.

In the arena of the HFE Authority the debate concerning the issue of the creation of human-animal hybrid embryos started to develop from the moment the Scientific and Clinical Advances Group (SCAG) and the Ethics and Law Committee (ELC) of the HFE Authority were asked by the Department of Health whether this form of embryo according to them was covered by the HFE Act (1990) and would fall under the remit of the Authority. The department asked this question as part of the review of the HFE Act 1990 that was announced on 21 January 2005. The department wanted both, the group of scientists and clinicians as well as the ethics committee, to review the role that mitochondrial DNA plays in the development of the embryos and whether embryos containing human DNA and both human and animal mitochondrial DNA would be human. In spring 2006 the SCAG responded to the department that the proportion of human derived and animal derived proteins should be considered when deciding if these hybrid embryos should be classified as having a human genome. The SCAG and the ELC agreed that the hybrids should be regarded as an ‘embryo’ for the purposes of the Act 1990 and that the creation, keeping or use of such an embryo in principle could be regarded as necessary or desirable. From this the ELC concluded that the license committee of the HFE Authority ‘would have the discretion to authorize these activities in the case of application’.

However, in November 2006 the government proposed for a ban on the creation of the human-animal hybrids. At the moment scientists publicly had stated their wish to create human-animal hybrids by fusing human cells with rabbit cells, journalists reported about the planned research of the applicants using alarming headlines about ‘Frankenbunnies’, because cow or rabbit eggs would be used. For the government the public unease expressed in response to a public consultation was reason to make a statement about hybrid and chimera embryos in its White Paper: ‘The government will propose that the creation of hybrid and chimera embryos in vitro should not be allowed’. Apparently, the combination of human and animal material in the embryo was considered a bridge too far, although the Government in the same white paper proposed to include in the amended Act power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos in vitro may in future be allowed under license for research purposes only.

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20 The proposal to use animal eggs instead of human eggs originates from the shortage of human eggs that is the result from the fact that eggs donating is a physically demanding process for women that even can be harmful. The embryo that would result from this combination of human cells and animal eggs later in the debate was called ‘cytoplasmic hybrid embryo’.

21 The creation of ‘human-animal hybrids’ until the two cell stage had already been practiced in the ‘hamster test’, a well established and explicitly endorsed test in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm.

The \textit{HFE Authority} had received two applications from scientific teams to carry out research using human cells and animal eggs to produce stem cells in November 2006.\footnote{The scientists responsible for the applications wanted to produce stem cells using human cells and animal eggs. Because the mitochondria from the donor egg are still present, the resulting embryo contains nuclear DNA from the human cell and mitochondrial DNA from the animal egg. This means that the resulting embryo would contain a small amount of animal DNA from the mitochondria present in the animal egg (less than 1\%). The applicators for a license were Dr. Lyle Armstrong, Institute of Human Genetics, University of New Castle and Dr. Stephen Minger, Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Diseases, Kings College London.} The government proposal for a ban made the Authority less sure that an authorization of this research would survive legal scrutiny. Therefore it sought council's opinion about the question whether this research was covered by the legal meaning of embryos under the \textit{HFE Act 1990}. The Horizontal Scanning Expert Panel (HHSEP) was asked a number of questions to inform council's opinion. The respondents from this panel agreed that the hybrid embryo would contain a complete human genome. However, no consensus could be found on whether a hybrid embryo would be capable of implantation and therefore the question whether this embryo could be categorized as alive was not decided.

The council subsequently informed the \textit{Authority} that `if (...) it cannot be shown definitively that the embryo does not have the normal potential to develop, it is most likely that the court would find that this constitutes a live human embryo for the purposes of the Act'. In the reasoning of the council, the courts are likely to see the embryo in a way that ensures that this type of research falls under the scope of regulation rather than not. Here the council is referring to the purposive approach to statutory interpretation used by the House of Lords in the Quintavalle case in 2003 in order to interpret the 1990 Act.

On 11 January 2007 the Authority ruled that, under current regulation, the research would fall under their remit. However, it postponed the actual decision about the applications in order to first have a `full and proper public debate and consultation as to whether in principle, licenses for these sorts of research could be granted'.\footnote{See www.hfea.gov.uk.} Apparently, the Authority felt the urge to organize a public consultation itself, as `the public unease` for the government had been reason to proposing not to allow the creation of hybrid embryos.

\textbf{The strategic use of language in the consultation of the public}

In the public consultation, the \textit{HFE Authority} sought the views of the public, interest groups and the scientific community.\footnote{In fact the consultation was not only on human-animal hybrid embryos but also on human-animal chimeras. For reasons of clarity I will restrict the attention in this paper to the first category. The aim of the consultation was `to consider this kind of research in the broad context of embryonic stem cell research'. See HFE Authority, `Hybrids and Chimeras' (April 2007), 6..} In the consultation document three types of human-animal hybrid embryos were distinguished and two of these three were juxtaposed: the true hybrid and the `cytoplasmic hybrid'.\footnote{The third type that fell within the category of `hybrids' is the transgenic human embryo: forms of human embryo that have animal genes inserted into them during early development. The creation of these embryos has not been practiced yet, but the creation of transgenic animal embryos has.} These two types were presented as follows: The category of `hybrid embryo', also called `true hybrid' contains embryos which are created by mixing human sperm and animal eggs or human eggs and animal sperm. This is what people think of when they think of hybrids: `...they don't think of cytoplasmic hybrid embryos created in stem cell research, instead they imagine the half-human, half-animal monsters, like the minotaur that are associated with myths and legends'. However the only two species that are genetically similar enough to produce life are mules and hinneys. True hybrid embryos might possibly
be created in the laboratory but ‘any attempt to create a living hybrid from two closely related species would be extremely unlikely to even produce a viable pregnancy’. It is also stated that: ‘These embryos would be different from ‘cytoplasmic hybrid embryos’ in that they would have an equal amount of DNA from the two species from which the eggs and the sperm are obtained’. The ‘cytoplasmic hybrid embryo’ is created by combining a human nucleus with an enucleated animal egg and would contain less than 1% animal DNA.

In other words this document reassures the potential respondents to the consultation by juxtaposing the following picture of what people imagine when they think of human-animal hybrids to the schematic presentation of the cell nuclear replacement that will be applied in the submitted research proposals:

**Fig. 1:** This is what people are afraid of when imagining human-animal hybrids:

![Fig. 1](image1.png)

**Fig. 2:** But the research is more like the picture below:

![Fig. 2](image2.png)

*Source: HFE Authority, April, 2007, p. 8.*

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28 Ibid
In addition the Authority underscored the differences of ‘cytoplasmic hybrid embryos’ to ‘true hybrids’ by pointing at the amount of animal DNA. The description of ‘cytoplasmic hybrid embryos’ as containing 1% animal DNA at maximum was subsequently used in an opinion poll about the usage of embryos in research and 48% disagreed with the creation of such an embryo while over a third of the people agreed.29

On 5 September 2007, the HFE Authority published its statement on its decision regarding hybrid embryos. The following conclusion is drawn from the consultation of the wider public: ‘public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and it is likely to lead to scientific or medical advancements’. By calling public opinion ‘divided’ the Authority refers to the outcome of the opinion poll that 48% of the respondents was against the creation of ‘cytoplasmic hybrid embryos’. The claim that these respondents would withdraw their objection in case ‘the research would be tightly regulated’ is derived from the ‘public dialogue work’ that also has been part of the consultation.30 The Authority combined this conclusion and the contribution of scientists to the consultation with the former legal advice and concluded that ‘cytoplasmic hybrid embryos’ as specific form of hybrid and chimera research, could be permitted.31

So, at the point the HFE Authority took its decision the scientific experts that had been involved in the process of decision making had found common ground with lay persons, at least the ones consulted, in the combination of the acceptance of the creation of ‘cytoplasmic hybrid embryos’ with the rejection of ‘true hybrids’. The following quantitative criterion of scientists has proven to be successfull in convincing part of the opponents to human-animal hybrid embryos in this arena: acceptable were the forms of human-animal hybrids with less than 50% animal derived DNA were thought to be acceptable in contradiction to the forms with 50% or more animal derived DNA. With this distinction and the accompanying quantitative criterion the scientific experts participating in the arena of the decision making of the HFE Authority have shown to be responsive, at least to some extent, to the part of the public that thought of mixing human and animal gametes as repugnant.

However, from the responses the scientists of the Horizontal Scanning Expert Panel gave in the public consultation of the HFE’Authority one gets the idea that this quantitative criterion is based on a misleading picture of embryonic development. The criterion above is based on what kind of DNA is put together in the test tube in the beginning of the process of the creation of the entity. By characterizing the mix of human and animal material by focusing on the ingredients that initially are put together the point of what embryonic development contains seems to be missed. According to the scientists of the Horizontal Scanning Expert Panel the mixing of the material activates processes that produce new material that is not human or animal to the same extent as the initial mix. Their general view was that ‘at some stage after embryonic genome activation all proteins produced (with the exception of those coded by the

29 In July 2007 a sample of 2073 residents of the UK was interviewed.
30 This public dialogue work consisted in: meetings and workshops in which various public perceptions, motivations and attitudes to the creation of human-animal embryos were explored. HFE Authority (n)Section 4.
31 About other kinds of human hybrid and human chimera research the statement says that ‘not only did the scientific community not wish to perform such research at present but also (…) the prospect was so distant that they could not envisage what forms this research would take in future (HFE A statement, 5 September 2007).
animal mitochondrial genes) would be human’ (\textsuperscript{32} While until the four to eight cell stages the embryo is relying on proteins and genetic messages that were present in the oocyte from the animal, this changes with the genome activation taking place in the four to eight cell stage. After this genome activation the stem cells formed would be almost entirely human. So from the four to eight cell stages until the blastocyst stage, the point at which the stem cells are derived, it could considered human according to these international scientific experts consulted by the HFE Authority.\textsuperscript{33}

While the quantititave criterion above is based on where the genetic material is derived from, an animal or human, this information makes clear that the degree of either human or animal material in the early embryo changes with the stages of development the creature goes through.

4 The arena of the (pre) legislative process of amending the 1990 HFE Act

At the turn of the year 2006-2007, the prospect of the HFE Authority denying a license for creating human animal embryos incited a lobby of scientists and members of parliament. Their main activity consisted in sending a letter to the members of the Authority shortly before they would make a decision telling them it would be wise to support the research. The same day a summary of this letter was published in The Times.\textsuperscript{34}

This lobby is interesting with respect to the access of scientists to the legislative arena because it reveals the strong ties existing between scientists involved in stem cell research, such as Stephen Minger, Lyle Armstrong and Ian Wilmut and the members of the Select Committee Science and Technology.\textsuperscript{35,36} \textit{The Select Committee} is charged with monitoring the work and activities of the Office of Science and Innovation, which is part of the Department of Trade and Industry. The lobby was led by Liberal Democrat MP Evan Harris, member of the Select Committee and explicitly supported by a conservative member as well as a Labour ex-member of this committee who held the former chair.\textsuperscript{37}

Other points of access for scientific experts were provided by the inquiry the Select Committee Science and Technology made into the government proposals for the new legislation for the use of embryos for research and the inquiry of the Joint Committee on the Human Tissue and Embryos (Draft) Bill.\textsuperscript{38} The inquiry of the Select Committee Sci-

\textsuperscript{32} HFEA, ‘Hybrids and Chimeras’ (October 2007), Appendix II, section 6.
\textsuperscript{33} The blastocyst stage is preceded by the morula stage, a 16-32 cell stage.
\textsuperscript{34} The Times, 10 Jan, 2007.
\textsuperscript{35} Stephen Minger, Lyle Armstrong were the applicators for a license to create human animla hybrids, see n 24.
\textsuperscript{36} The Select Committee Science and Technology Committee is one of 18 departmental select committees in the House of Commons charged with monitoring the work and activities of a specific Government department. The Science and Technology Committee is unusual in that it monitors the Office of Science and Innovation, which is part of the Department of Trade and Industry, rather than a department in its own right. The Select Committee Science and Technology is made up of around 10 to 15 Members of the House of Commons.
\textsuperscript{37} The letter in the Times in addition to these persons was signed by other scientists, Nobel laureates amongst them, as well as social scientists, legal academics, medical ethicists and leaders of organizations of medical professional organizations and organizations of bio industry and bio science.
ence and Technology, among others, consisted in three oral evidence sessions during which it heard stem cell scientists as well as government officials, ethicists, a bishop and a leader of the organization Human Genetics Alert. The Joint Committee on the Human Tissue and Embryos (Draft) Bill was established by the two Houses of Parliament in order to consider the draft bill presented by government in May 2007. The Joint Committee was asked to report on it to both Houses by 25 July 2007. The report of the Joint Committee was informed by evidence coming from a few stem cell scientists, organizations involved in bioscience and government officials but also from organizations that are critical about the use of embryos in research, from religious as well as other backgrounds.

What strategic use is made of the language of the scientific experts participating in the (pre) legislative process? The Select Committee of Science and Technology held an inquiry because it conceived of the proposed ban on the creation of human-animal hybrid embryos as at odds with the recommendations of this committee in the last parliament. According to this committee there were scientific aims that would make the creation of human-animal chimera or hybrid embryos necessary: the pursuit of knowledge about the genetic basis of disease and the direction of stem cells into future cell-based therapy. Furthermore, the stem cells produced would be medically useful in drug discovery and toxicity testing.

In their inquiry the committee started with considering what name should be chosen ‘for what would result from the proposals to create embryos through somatic cell nuclear transfer of human genetic material into animal ova from which the main source of genetic material has been previously removed’. Various names given by scientists were considered: Professor Shaw of King’s college called them ‘pseudo-hybrids’, Dr Lyle Armstrong of Newcastle University ‘interspecies embryos’ and Professor Austin Smith of the University of Cambridge thought they would be better termed as ‘cybrids’. Professor Sir David King argued that the entities that the scientists wanted to create ‘should not be described as either chimeras or hybrids’. He proposed to call them ‘cytoplasmic hybrid embryos’, which seems to be a bit contradictory to not wanting them to be called hybrid. The Science and Technology Committee decided to use Sir David King’s description in the remainder of the report, without giving reasons for this choice.

The government followed the recommendation of the Select Committee and in its draft bill proposed to include the creation of ‘cytoplasmic hybrids’ in the categories of embryo that

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39 Ibid 7
40 Its membership consisted of 9 members of the House of Commons and 9 members of the House of Lords. Five of the MPs were members of the Science and Society Committee or had been a member of the former Science and Society Committee.
42 The committee also conducted an online consultation on four questions via its website, two questions related to interspecies research.
44 Report Select Committee Science and Technology (n 39) 61.
45 Ibid 6
46 Sir David King was the UK Government’s Chief Scientific Adviser and Head of the Government Office for Science from October 2000 to 31 December 2007.
may be authorized by a research license by the HFE Authority. The ‘types of embryos created by combining together human and animal gametes or human embryos altered using animal DNA of animal cells’ were named “interspecies embryos”.

Congruent with the line of reasoning of the HFE Authority, government in the draft Bill proposed to forbid the creation of ‘true hybrids’ In the introduction to the draft bill Secretary of State for Health states about the list of forms of embryo that would be conditionally allowed ‘This list (…) does not include ‘true’ hybrids created from mixing human and animal gametes. In a the secretary adds “Other than as currently permitted for the purpose of testing the fertility or normality of human sperm’. In contradiction to this exclusion of the category of ‘true’ hybrids in the draft bill, the Joint Committee on the Human Tissue and Embryos (Draft) Bill recommended the inclusion of this form of embryo in the categories that would conditionally be allowed. The reason was there was no ‘sound point of principle’ on which the distinction between true hybrids and the other categories would rest. The Joint Committee at this point explicitly referred to ethicist Holm, who as a witness before the committee had claimed that both categories of hybrid embryos were ‘equally objectionable on ethical grounds’. Once researchers have crossed the species barrier, no valid distinction is to be made between an entity that is 99% human and an entity that is 50% human According to the Joint Committee this view was supported by many others and it referred to the contributions of the All Party Parliamentary Pro-Life Group, Christian Action Research and Education and the Christian Medical Fellowship. In addition it was mentioned that Vivienne Nathanson, Director of Professional Activities of the British Medical Association saw no sense in the distinction

These organizations indeed were against the creation of all subcategories of interspecies embryos and, like ethicist Holm, objected to allowing this creation. However, the Joint Committee by giving a twist to Holm’s argument could use it to the advantage of their own purpose, which was to include the ‘true’ hybrid in the categories that would be legal. It would not make a difference to these organizations anyway, the Joint Committee stated.

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47 In this draft bill, the interspecies embryos were to be explicitly excluded from the definition of an “embryo”. Instead these forms of embryo were to be regulated under a new section 4A with the title Prohibitions in connection with genetic material not of human origin. The ‘cytoplasmic hybrids’ fall under the description given in (b) of the following forms of interspecies embryo that were distinguished in this draft bill:

(a) an embryo created by using human gametes and the gametes of an animal,
(b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell,
(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal,
(d) a human embryo that has been altered by the introduction of one or more animal cells, or
(e) any other embryo that contains both–
(i) any haploid set of human chromosomes, and
(ii) any haploid set of animal chromosomes of any other sequence of nuclear or mitochondrial DNA of an animal.

48 A way out of this ban was built into the proposal by stating that permission could be made possible by regulations made by the Secretary of State, see Human Tissue and Embryos (Draft) Bill, May 2007, p. X.
49 The Hamster test as well as the creation of (other) true hybrids would fall under the form of embryo as described in footnote 47 under (a) but is banned from being conditionally allowed by the statement of the Secretary of State. See Human Tissue and Embryos (Draft) Bill, May 2007, p.ix-x.
50 Joint Committee, Vol I (n 41) 46.
51 Ibid. The reason was that bringing the true hybrid also under the remit of the HFE Authority would make the rules more flexible and make it easier to allow the creation of true hybrids at the moment that this would become essential. See Joint Committee, Vol. II (n 41) 49.
The Minister opposed their arguments with the pragmatic argument that currently there was no call for research using ‘true’ hybrids and as public opinion was a concern she wanted to postpone the discussion on this point. The Joint Committee stated not to be persuaded by this argument and added to this evidence that ‘true’ hybrids already were created in the so-called ‘hamster-test’. This is a well established and explicitly endorsed test in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm. Government officials sought to explain the difference between the ‘true’ hybrid resulting from this test and any other sort of ‘true’ hybrid but again their explanation appeared not to persuade the Joint Committee. In its report the committee persisted that no distinction should be made.

The reader could easily get the impression at this point that ethicists have had the last word concerning the inclusion of true human-animal hybrids in section 4 of the 2008 HFE Act: While scientists brought forward a criterion for distinguishing ‘true hybrids’ from the other types of interspecies or human admixed embryos - the first being entities with a degree of 50% or more of an animal genetic constitution - ethicists declared this criterion to be ethically non valid. However, a closer look at the information brought forward by a scientists witnessing before the Joint Committee makes clear that the underlying scientific facts were contested. Witness Professor Richard Gardner is asked what he thinks about the idea that a human genetic constitution of 50 per cent or more is a significant factor in determining whether an interspecies embryo should be defined as human. He answers that it depends on what you are talking about when using the concept ‘genetic constitution of the interspecies embryo’: the amount of genes in the mitochondria of the animal cell or the amount of DNA that the mitochondria contribute to the (new) cell. He also declared that we cannot be certain about what will happen when you combine cells from two origins: ‘…one contributed can out-compete the other’. One can conclude from this that the degree of humanness of the resulting entity can not really be established by looking at the amount of human and animal DNA you put into it at the beginning of the process. Maybe, it could even be the case that the animal DNA out-competes the human DNA. This option was not accounted for in the reasoning about embryonic development that informed the quantitative criterion that was formulated by the scientists in the HFE Authority.

On 13 November 2008 the 2008 HFE Bill became an Act of Parliament. The name interspecies embryos that had been given to the human animal forms of embryo in the Bill, was changed by an amendment in the House of Lords into ‘human admixed embryo’. The ‘human admixed embryo’ refers to types of embryo which contain both human and animal DNA and five subcategories of these types are distinguished in section 4A(6). From the Explanatory Notes it becomes clear that the cytoplasmic hybrid embryo (section 4A(6)a ) as well as the

52 Joint Committee, Vol. I (n 41) 46.
53 Gardner continues his argument ‘the amount of genes in the mitochondria is about 13 genes compared to 30,000 in the human nucleus genome whereas the total mass of mitochondria and the amount of DNA that they contribute to a cell could be extremely substantial’ (Joint Committee, Vol. II (n 41) 207.
54 Human Fertilisation and Embryology Act 2008 (C22).
hybrid embryo (section 4A(6)b) is included in the subcategories of human animal forms of embryo that are conditionally allowed to be created.55

5 Conclusion on the contribution of scientific experts

What does this analysis tell us about the contribution of scientific experts to the legislative rules concerning the use of embryos for research? The knowledge brought forward by the scientific experts in the arena of the HFE Authority was contested by scientific experts that were consulted in the arena of the legislative process. The knowledge about the constitution of the embryo that will result from mixing cells and/or gametes of different species is contested, as the exact constitution remains to be seen from future research. Notwithstanding this contested character of the knowledge about the future constitution of the embryo the Authority formulated a criterion concerning the proportion of animal and human derived DNA in the forms of embryo that are proposed to be created to underscore the contrast between ‘cytoplasmic hybrid embryos’ and ‘true hybrid embryos’. This distinction was put central in their public consultation. The effort of Authority to make this distinction relevant in law was meant to reassure the part of the public that expressed repugnance toward the idea of combining human and animal material. However, this effort failed. In the legislative arena the distinction between the two forms of embryo in terms of animal and human DNA turned out to make no difference to the opponents of the creation of human-animal forms of embryo. At that point it was also made clear that the criterion of more than 50 % human DNA was scientifically contested.

The contribution of scientific experts is indispensable for formulating new categories of human embryo for the law as they are unique in having at least some idea about the new entities that would be created with the planned research. However, the constitution of the entity to be created cannot really be predicted in detail and the knowledge scientific experts brought forward in different arenas of decision making in the UK is not equivocal. While in the first arena scientific criteria were molded in a shape that took the repugnance of opponents into account by making a distinction between different forms of human animal hybrids, this apparently was not longer considered necessary in the legislative arena. After all, the conclusion that a near majority would agree with the creation of cytoplasmic hybrid embryos had already been drawn in the report of the public consultation on hybrids and chimeras of the HFE Authority. This agreement subsequently functioned as a stepping stone for the proponents of the creation of all forms of human animal hybrids. At this point the reasoning of the Joint Committee was as follows: if the public agrees with creating ‘cytoplasmic hybrid embryos’ it must

55 Different from the (Draft) Bill the cytoplasmic hybrid in the Act is described under (a) while the true hybrid falls under the description given under (b).
See Human Fertilisation and Embryology Act 2008 Section 4A(6)
(a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with-
(i) two human pronuclei or
(ii) one nucleus of a human gamete or of any other human cell, or
(iii) one human gamete or other human cell
(b) any other human embryo created by using
(i) human gametes and animal gametes, or
(ii) one human pronucleus or one animal pronucleus.
also agree with the creation of ‘true hybrids’ because the distinction is not ethically relevant and as we were made aware of recently also not scientifically sound.

This kind of providing false certainties will have a devastating effect on the trust of the people in scientific experts and in the regulation of technology in the long run. Therefore, it would be better for these experts to be more modest and give more room to moral and other considerations in the decision making about the rules.

6 The merits and pitfalls of this case of decentered regulation

In this last section I will turn to the central question of the article and elaborate on what this case study teaches us about the merits and pitfalls of the model of decentered regulation. I will start by describing the background of this model of regulation and contextualize the decision of legislators to bring this model into effect.

In the eighties of the last century, models of ‘decentered regulation’ were advocated in order to cope with the specific challenges technological innovation brings with it. In the literature on governance these challenges are characterized with three keywords: complexity, dynamics and diversity.56 The words complexity and dynamics in this context refer to the technological innovations: specialized expertise is required to understand them and the pace in which they develop and offer new possibilities implies that the legislator has to reconsider and adapt its policy on a constant base. The third keyword that characterizes the challenges of technological innovation in modern society is diversity. This refers to the diversity in the morals of people that nowadays exists: people express a variety of beliefs and opinions about the ethical boundaries of technological innovation and most of the time these are rather vague and leaving room for different options.

The idea that the model of decentered regulation can cope with complexity, dynamics and diversity echoed in the reasons given by legislators to choose for this model in the case of biomedical technology. In discussing the merits and pitfalls of the implementation of this model as revealed in the analysis above, I will reflect respectively on four of these reasons. First, specialized expertise is required to grasp all the relevant aspects involved in technological developments. By creating a body of scientific and other experts -in the case of the HFE Authority- a subordinated body- that on a case-to-case basis decides whether the use of embryos in the research will be allowed by government makes sure that policy decisions are informed by the relevant specialized knowledge. In this case the legislator has tried to anticipate the risk of giving scientific experts disproportionate power over the rules by stipulating that in addition to medical and scientific experts also members ‘representing social, legal and religious knowledge and experience’ should be chosen as member of the HFE Authority.57 However, this has not really solved the problem of the disproportionate power that in the model is given to scientific experts. Although the constitution of the new forms of human embryo to be created cannot be predicted in detail and the knowledge is contested it is given much weight

57 Lee and Morgan (n 9) 102-3.
because in a manner of speaking ‘it is all we have’. On top of that this knowledge is of such specialized character that the other participants in the decision making process cannot check it. Take for example the pivoting point in the analysis above: even the average well educated social scientist or ethicist will have difficulties to check claims about the degree of animal and human material in an embryo that will be created by replacing the nucleus of an animal egg cell with human cells.

A second reason to choose for a devolved model of regulation is the high pace at which biomedical technology is developing and constantly opening up new possibilities. Deciding on a case-to-case basis whether an innovation is within the boundaries formulated in an Act is thought to provide the mechanism that strikes the right balance between flexibility and precision as requirements for regulation. The case-to-case approach in the example turned out to offer indeed some flexibility to cope with new possibilities, such as new ways of creating embryos (Cell Nuclear Replacement) and new forms of embryo (human-animal hybrids). However, the claim of the proponents of the model of decentered regulation is the case-to-case approach would be more efficient in coping with such new possibilities than centralized legislation. The case study shows that devolution does not replace litigation and the need to change the law. The question whether Cell Nuclear Replacement fell within the 1990 HFE Act was challenged by the pro-Life alliance in the Quintavalla case in 2003. In the High Court Justice Crane had accepted the claim of the Pro-Life alliance that CNR did not fall under the legal definition of an embryo in the 1990 HFE Act. In the chaos after this decision, the Government rushed through legislation explicitly banning reproductive cloning.58 The case of human-animal hybrids, analyzed above, motivated the legislative process of amending the 1990 HFE Act. Although the legislative process of changing law may have been suspended by the case-to-case decision making and the public consultations of the Authority, the need for law change was obviously not avoided.59 From this it becomes clear that the model of decentered regulation does not necessarily exclude litigation and law change and that it remains to be seen whether it is more efficient than centralized legislation.

A third reason legislators give in defense of a model of ‘decentered regulation’ is that there is no widespread agreement on the fundamental ethical issues involved. The diversity problem clearly is an issue with regard to the use of embryos in research. No general agreement exists on the fundamental ethical issues involved. This is evidenced by the equivocal conceptual basis for the status of the human embryo.60 How does the model of decentered regulation succeed in coping with this diversity problem? The HFE Authority provides space and time for reflection in the consideration of new developments in the use of embryos in research. The idea of the legislator was that this space would be used for paying attention to and acknowledging the view of a significant religious section of the population, represented by the

58 See n 7.
59 In order to establish and compare the efficiency of the devolved model and of the hierarchical model of regulation, information would be needed about the ‘normal’ length of the different kinds of decision making processes.
60 The law is grounded on the idea of intrinsic worth because of the potentiality of the embryo to grow into a human being and the idea that protection should increase as the embryo develops, because of the growing probability that it will become a human being. In legislation, fourteen days after conception is considered a significant moment. Although based on biological facts of the development of the embryo in the womb, the decision of legislators to make this moment rather than other moments in the development moral relevant is not uncontested. Lee and Morgan (n 9) 68-72.
Pro-Life Alliance and also for ‘allaying general fears about the possible abuse of science’. For the Pro-Life Alliance the early embryo from the moment of conception is a person with full moral standing and any use of the embryo in research contravenes its rights. So the acknowledgement of their view in the consideration of new developments in this use would be hard if not impossible. This is different for the group of people expressing their fear of and repugnance of a specific kind of embryo research. The case-study shows in what manner the Authority made an effort to be responsive to their worries: it suggested the creation of true hybrids should not be conditionally allowed in contrast to the creation of ‘cytoplasmic hybrid embryos’. But in the legislative arena a coalition of MP members of the Select Committee and scientists succeeded in pushing the boundaries further and including also the ‘true hybrids’ in the category of ‘human-admixed-embryos’ that would be conditionally allowed. So with hindsight the strategic use of language the Authority made by describing ‘cytoplasmic hybrid embryos’ as not being true hybrids can be seen as ‘the camel nose under the tent’, once the first form of human-animal-embryos was proposed to be legalized the other forms followed rather automatically. Instead of acknowledging dissenting views on the issue the function of the Authority seems to have been to make the majority of the public ripe for accepting the creation of one form of human-animal hybrid embryo. The model of decentered regulation has served as a two-stage rocket in securing the compliance of firstly a dissenting part of the public and subsequently parliament. The model facilitates this by providing in an extra arena for the powerful proponents to convince other actors that their specification and interpretation of the rules is the right interpretation.

This brings us to the fourth reason for legislators to apply a model of decentered regulation: there is interaction between the pace of scientific, technological, development and the way the political community ‘chooses’ to interpret moral principles and ideas. Changes in technological possibilities provoke changes in the underpinning social acceptance. This also is the case with the political community in considering new techniques involving the creation of embryos: the interpretation of moral principles such as respect for human life and human dignity, changes in time. To be more precise, these choices change with the promises concerning the cure of diseases that are attached to these new techniques. A feature of the HFE Act that can be traced back to the Warnock report is that it gives a central role in policy making to ‘what the people think’. As Dawson (2004) suggests the readiness to base policy on the opinion of the public could very well stem from the idea that this provides a democratic justification for the policy. The case study shows that with the public consultations public opinion is not only scrutinized but also steered into a particular direction. In the case-study the HFE Authority with its public consultation tries to foster the acceptance of the creation of ‘cytoplasmic hybrid embryos’ by pointing to the promises it entails for improving human health and by underscoring that it is much less frightening than the creation of ‘true hybrids’.

In the introduction I referred to the conclusion of Levitt that the case-to-case approach of the HFE Authority each time creates a momentum pushing things forward to liberalization of policy. This conclusion actually concerned the decision making of the Authority concerning Assisted Reproduction but seems to be true also for the policy concerning the use of human

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63 Dawson (n 10)
64 Levitt (n 4)
embryos in research: After the UK legislator in 2001 conditionally allowed therapeutic cloning, in 2008 also the creation of embryos by combining human and animal material became conditionally permitted. The explanation Levitt gives for this phenomenon of liberalization is also applicable to this policy: Firstly, the public in consultations is asked each time to say yes or no to a specific technique, it is not asked about what should be the research and development priorities. It would for example be a wise thing to weigh up the expected effects of the new technique for human health against the effects of alternative techniques that would not involve the use of human embryos. Secondly, thanks to media involvement scientists and commercial pressures each time grasp their chance to portray the innovation as promising as possible with respect to human health. This brings in the commercial interests that are involved in the development of embryo and stem cell research. The pharmaceutical industry has a direct stake in the continuation of the innovation in this research, because of the medicines and therapies that are thought to result from it. This industry is also powerful in the sense of having resources, such as money, information and relations, which make it possible to exert much influence on the way innovations in the use of human embryos and the health results expected are portrayed in the media. Looked at from this perspective an interesting question would be whether the case-to-case approach empowers the pharmaceutical industry in influencing the rules rather than stimulating public debate. However, this question will not be addressed here as the role of the pharmaceutical industry was not part of the case study.

To conclude this article I will summarize the merits and pitfalls of the model of decentered regulation as conveyed in the analysis. The model guarantees the input of relevant scientific expertise. The case-to-case approach by a discretionary power serves to make the public ripe for accepting innovations in the use of embryos in research. The model facilitates the securing of compliance of the public because it makes sure that each new technique is considered at its own and because it provides in two stages of consideration of the technique. A clear disadvantage in the light of democracy is that it does give the scientific experts involved a considerable extent of power over the formulation of the legal rules. As the most important source of this power is their knowledge of the scientific details this cannot be checked by non-scientists participating in the decision making committee to which (part of) the power of rule making is delegated. The question whether the model is more efficient than the classical model of rule making, is left unanswered yet.
PERFORMANCE MEASUREMENT
Its Legitimacy and Its Efficacy

Anne Ruth Mackor

Abstract
In this paper it is argued that performance measurement deserves attention, not just of economists and scholars in business administration, but also of legal scholars. Section one explicates the notion of performance norms and explains how they relate to so-called ‘duty of care’ norms. Section 2 focuses on the history of performance measurement. It explains why the government, from the 1980-ies on, has begun to apply performance measurement to its own and other semi-public organisations. Section 3 deals with the question whether government enforced performance measurement is a legitimate way to regulate the behaviour of people and organisations. Section 4 discusses some doubts about the efficacy of performance measurement. Section 5 concludes that both the legitimacy and the efficacy of performance measurement deserve further study.

Keywords: performance measurement, legitimacy, efficacy

1 Introduction
At first sight, there cannot be any misunderstanding about the question what performance measurement is. Performance measurement is, quite simply, the measuring of performances. Performance norms enable us to do so. More specifically, they tell us what performance should be accomplished and the also contain indicators that enable us to measure whether the performance has been realised.

1.1 ‘Duty of care’ norms and performance norms
The role of performance norms has become increasingly important in governmental regulation of human behaviour. This is a consequence of the fact that the legislator nowadays often makes use of so-called duty of care norms. Duty of care norms differ in several important respects from classical legal rules. Classical legal rules are norms that forbid or prescribe

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2 Unless stated otherwise, I refer to the Dutch government and the Dutch legislator.
certain types of *behaviour*, such as norms that forbid to drive a car when under the influence of alcohol, and that oblige driver and passengers to wear a safety belt.

A duty of care norm on the other hand, does not prescribe or forbid any specific kind of behaviour. Instead such a norm tells the addressee to realise some, more or less specified and more or less concrete, *goal*. The norm does not tell the addressee, however, through which behaviour the goal is to be accomplished. It is, in principle, up to the discretion of the addressee to choose his own means to fulfil his duty. For example, had the legislator promulgated a duty of care norm for car drivers instead of a behavioural rule, the rule would not forbid driving cars after drinking alcohol. Rather, the rule would consist of a duty to take care of the traffic safety, for that is the main goal behind the behavioural rules concerning alcohol and safety belts.

Duty of care norms seem to have one obvious advantage over behavioural norms, viz. that the addressee himself can choose the most effective and efficient means to realise the goal (provided of course that the means are legitimate). The legislator has been aware, however, that a duty of care norm, on its own, does not give enough direction to the addressee. Therefore complementary norms are needed. What is of interest here, is the fact that it is not the legislator who promulgates these complementary norms. Instead, the legislator instructs the norm addressees to make and apply these complementary norms more or less ‘on their own’.

Part of these complementary norms are performance norms. Performance norms are therefore important means, not only for the addressees, but also for the government, to determine whether addressees have fulfilled their duty of care.

This may sound rather abstract so let me introduce an example. Article 2 of the Dutch Act on the Quality of Health Care Institutions (Kwaliteitswet Zorginstellingen) is a duty of care norm which instructs the provider of care to offer *sound care* (‘verantwoorde zorg’). Article 2 explicates sound care as ‘care of a good quality that is at a minimum effective, efficient, patient oriented and tuned to the realistic needs of the patient’. This is all the Act tells the addressees about the goal they have to achieve. Nevertheless, the legislator does not leave it completely to the discretion of the health care institutions to determine the way in which they choose to fulfil their duty of care. Article 3 and especially 4 and 5 give further instructions. Article 3 tells the care provider to *organise* the care in such a manner that the result is, or at least reasonably must be, sound care. Article 4 explicates *how* care should be organised in order to result in ‘sound care’. Article 4 therefore is, at least for the purpose of this paper, the crucial article of the Quality Act.

Without mentioning the terms ‘performance measurement’, ‘performance norms’ or ‘performance indicators’, the article nevertheless obliges care providers to measure their own performances.

Article 4 instructs care providers:
- ‘to systematically *collect and register* facts about the quality of care’
- ‘to systematically *check* whether the organisation of care as meant in article 3 does in *fact* result in sound care’,
- ‘if necessary, *to change* the organisation of care.’
Article 5, finally, demands of the care providers to give account of the quality of the care that they have been offering by publishing a *yearly public report*. As article 4 and 5 make clear, performance measurement serves more than one goal. The primary aim is to systematically *register* the quality of care that has been offered. The aim of registration is to enable others (the government, but also e.g. patients and consumer organisations) to *assess* whether sound care has been offered. A further aim is the *improvement* of the quality of care. Finally, performance measurement enables care providers to *give account* of the quality of care they have offered.

Moreover, performance measurement has several other goals that are not mentioned in the Quality Act. Performance measurement is also, among others, the foundation of subsidisation, audit and certification. Further, performance measurement also plays an important role in benchmarking. The relation between performance measurement and benchmarking is more complex than the relation between performance measurement and subsidisation, audit and certification.

There is only one way traffic from performance measurement to subsidy and certification in that the latter depend on the outcome of the measurement. Between performance measurement and benchmarking, however, there is two way traffic. On the one hand performance measurement is the foundation of benchmarking, since care providers are compared by means of the outcomes of performance measurement. Benchmarking, on the other hand, is also foundational to performance measurement since requirements, i.e. the contents of the performance norms, are established by comparing the actual results of the care providers. Only when the actual (average) performances of care providers are determined, it is possible to establish a norm. Obviously, the thought behind benchmarking is that these actual (average) performances are the ones one can reasonably demand from all (comparable) care providers.

1.2 **How do we get from duty of care norms to performance norms?**

We have just seen that the legislator instructs the addressees of duty of care norms to both make and apply their own performance norms. The question that will be addressed in this section is exactly how the duty of care norms can be fleshed out in performance norms. Again we will give an example. We will investigate how article 2 of the Quality Act can be made concrete with respect to the field of homecare, more specifically for maternity care.³

As a first step a provider of maternity care can formulate the following goal norms in her mission statement. These norms offer a first specification of the general goal of ‘sound care’:

‘The maternity care is delivered timely.’
‘The maternity care is given by a professional.’
‘The maternity care offered results in a high level of client satisfaction.’

Although these goal norms offer some specification of article 2 of the Quality Act, they are still not concrete enough to enable the care provider or others, such as inspection and patients,

to determine whether the care provider has in fact fulfilled his duty of care, viz. to offer ‘sound care’. Thus, these norms too have to be specified. This can be done, for example, by means of the following norms:

‘In 95% of all maternity care, the professional is present within 1 hour after the call of the client.’

‘50% of all professionals has followed course X.’

‘90% of all clients rates the treatment of the professional with an 8 or higher.’

The latter three rules are examples of performance norms that refer to concrete verifiable facts and make use of numbers. Only by means of such concrete facts it is truly possible to measure the quality of care.

Following Donabedian, most authors distinguish three types of performance norms, viz. norms that contain a process-indicator, norms that contain a structure-indicator, and norms that contain a performance- or outcome-indicator.4 Although it might seem attractive to focus on outcome-indicators (since these measure the quality of care most directly), it has been argued that performance measurements that make use of all three types of indicators, offer the best quality measurement.5 In other words, it is better not only to look at the end result, but also at the (alleged or real!) means by which that result has been achieved.

The three examples of performance norms just mentioned contain different types of indicator. The first norm contains a process-indicator: it refers to the process of care (attending the patient within one hour after the call). The second norm contains a structure-indicator that reveals a fact about the way care is organised (courses being followed by professionals). The third norm, finally, contains an indicator that tells us something about the outcome of the process (client satisfaction).

The example of performance norms in the field of maternity care is not unique. In all care sectors, as in many other public and semi-public sectors, performance indicators are being developed and applied in order to give ‘hand and feet’ to duty of care norms that the legislator has promulgated.

2 From performance measurement in business to performance measurement (by order) of the government

2.1 Why should lawyers and legal scholars think about performance measurement?

We have seen that the government not only promulgates duty of care norms, but also tells the norm addressees to make and apply their own performance norms. This is an instance of conditioned self-regulation. The term ‘self-regulation’ refers to the fact that norms are not promulgated by the government, but by citizens (that is to say, not individual citizens but larger societal organisations). The claim that the self-regulation is conditioned points to the fact that these organisations do not promulgate norms from their own free will, but only because the

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government obliges them to do so. In fact, in the case of the Quality Act quite some pressure and coercion were necessary before care providers took seriously their obligations to make and use quality systems and performance norms.\(^6\)

The example of the Quality Act shows how the use of performance norms hangs together with, or rather, logically follows from the use of duty of care norms. The example does not, however, answer the question why the government has, quite recently, begun to make use of duty of care norms in combination with performance norms instead of classical legal rules that forbid and prescribe behaviour.

Performance measurement is a management technique that has been developed, at the beginning of the 20th century, in the world of business and industry. Only since the 1980-ies it has also been applied to and by the government. Since the end of the 1980-ies performance measurement is applied to (semi-) public organisations such as municipality, police and the judicial system. This paper, however, focuses on the fact that performance measurement is nowadays applied by order of the government via conditioned self-regulation. Performance measurement is especially demanded from organisations that serve a public interest, such as providers of care and education.

The government, in other words, is doubly involved in performance measurement (governmental organisations are measured and government obliges others to measure themselves). Because of this, performance measurement becomes relevant to legal scholars and scholars of public administration. More specifically, these scholars will have to investigate into the question whether the use of performance norms is legitimate as well as effective. Obviously, when there are doubts about the legitimacy and/or efficacy, it is questionable whether the government should go on with obliging non-governmental organisations to develop and apply these norms. In sections 3 and 4 we will see that there are some serious doubts, in particular about the efficacy of performance measurement. If these doubts hold, it might imply that duty of care norms, or at least the instruction to specify them by means of performance norms, does not fulfil the condition of good legislation.

### 2.2 Performance measurement in business

Before we discuss the efficacy and legitimacy of performance measurement, however, we will investigate how performance measurement entered the public sector. As was stated above, performance measurement finds its origin in business and industry. The period between 1870 and 1910 has been called the Second Industrial Revolution. It is characterised by an ongoing mechanisation of the production, more specifically by the introduction of assembly lines. Another characteristic of this period is the fact that firms begin to invest in (scientific) research to establish more efficient methods of production. Henry Ford (1863-1947) and especially Frederick Winslow Taylor (1856-1915) are generally considered to be ‘the’ pioneers of the rationalisation of production processes. Taylor’s aim was to establish objective production norms and improve, via these norms, the production processes. Henry Ford was the first to bring these insights into practice.

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At this time, there was not only approval, but also severe critique of the proposals to automate and rationalise production processes. As a consequence even today many speak mainly in negative terms about Taylor and ‘taylorism’. According to these critical view, taylorism is a worldview that contributes to the alienation of human being from his work. Taylorism, or so the critique goes, reduces man to a cog in the machine. The perhaps most vivid and touching representation of this critique is probably Modern Times (1936) a movie in which Charlie Chaplin goes (literally and metaphorically) of the wheels as an assembly line worker.

Despite its rhetorical power, the question remains whether the critique is completely fair. For one thing, Ford and Taylor did not only have the interests of the employer in mind, but also – at least on paper – those of the employees. For example, the first sentence of the first chapter of Taylor’s The Principles of Scientific Management states: “The principal object of management should be to secure the maximum prosperity for the employer, coupled with the maximum prosperity for each employé.”

Whatever one might think of the critique of taylorism, it should not come as an surprise that similar critique is offered from the 1990-ies onward when performance measurement was first introduced in the public sector. According to contemporary critics, the rationalisation of public services undermines the autonomy of the professional and perverts the professional-client relation.

2.3 Performance measurement of and by the government

Before we go into the question whether this fundamental critique of performance measurement is correct, we will first have to understand the origin of performance measurement in the public sector. We have just seen that the introduction of performance measurement in the industry can be explained from the ongoing mechanisation of production processes that lend themselves more easily to rationalisation than earlier more traditional production processes. The introduction of performance measurement in the public sector also is a consequence of an ongoing mechanisation, in particular the computerization and the scientific study of public services. It is also connected, however, to the emergence of new ideas about government. These new ideas, called New Public Management (NPM), were introduced in the beginning of the 1980-ies in America and came across the Atlantic at the end of the 1980-ies.

NPM can best be explained by reference to Reinventing Government of David Osborne and Ted Gaebler. This book, also called the Bible of NPM, consists of ten propositions that are explicated each in one chapter. The central thesis of the book holds that the government has, especially after WWII, interfered too much in the execution of public tasks. This, or so it is argued, has resulted in a cumbersome inefficient and bureaucratic governmental apparatus which blocks innovation and private initiatives. NPM aims to offer an alternative view of government. More particularly, it answers the question how government should operate if not by interfering in the execution of public tasks..

Below, I discuss the ten propositions of Osborne and Gaebler and illustrate them by examples taken from the field of health care in the Netherlands.

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According to Osborne en Gaebler the government should:

1. **Not row but steer**
The government should formulate policies in general terms, but leave the details to the specific sectors such as care and education. In the first section of this paper, we have seen that this is exactly what the Dutch government has done in health care. Article 2 of the Quality Act only formulates a general duty of care (i.e., the government steers) and instructs in articles 3, 4, and 5 care providers to both fill in and fulfil this duty of care (i.e. obliges the organisations to row).

2. **Not serve but empower**
By offering the care providers (and other organisations such as inspection and client organisations) the opportunity to deal with their own business, the government not only gets rid of a lot of work that caused so much bureaucracy, but it also empowers these organisations by offering both the opportunity as well as the responsibility to deal with these tasks in ways they think most efficient and efficacious. This too was illustrated by the example of the Quality Act. The performance norms are not one-sidedly enforced by the government, but are the result of a decision-making process that takes place between inspection and care providers. In other words, the advantage of duty of care norms is that they offer service providers the opportunity and the responsibility to arrange their ‘own’ business.

3. **Introduce competition**
According to NPM, care providers and other organisations should not only get more room to deal with their own ‘business’, they should also make use of the ‘elbow room’ that the government thereby offers them. Among others, care providers should compete with each other, because, or so it is thought, it will lower costs and, at the same time, improve the quality of the services. In other words: competition creates a win-win situation. This idea too has been realised in Dutch health care sector. Both insurance companies and care providers have to compete with each other. Also discussion has recently started over the question whether the Netherlands should introduce the American P4P (‘pay for performance’) system. The P4P system is based on the thought that insurance companies giving extra money to the best hospitals, will be an incentive to deliver even better care.⁹

4. **Formulate a mission and goals, not rules**
The next claim of NPM is that the tasks of the service providers are extremely complex and that an optimal execution of their tasks is too unpredictable and too changeable to be put into detailed (legal) rules. Therefore, governments should only formulate a mission and general goal norms, and not prescribe precise behavioural norms.
Again, the Quality Law is an illustration of this credo. Its central article is a duty of care norm and it does not consist of specific behavioural norms.

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5. Choose a result-oriented approach: no input- but output-financing
So NPM claims that governments should, just like companies, not focus on rules, but rather on results. However, governments should be aware of the risk that mission statements and goals without additional measures, run the risk of remaining empty slogans. One way to prevent this from happening is to assess organisations less in terms of their plans (input), and much more in terms of their results (output), for example via the P4P system. Hence, we see that the emphasis on result-oriented working and assessing cf. article 3 and 4 of the Quality Act makes performance measurement into an inseparable part of NPM.

6. Introduce a consumer- instead of bureaucracy-oriented approach
By analogy with business world, the citizen (in the care sector: the patient) should be perceived as a consumer and customer. Since customer is always right, care providers should no longer operate in a supply-, but in a demand-oriented and demand-driven manner and compete for the favours of the consumer.

7. Not be spending money, but earning it
Until the 1970-ies, government did not pay much attention to the budget, but from the 1980-ies onward the budget of the government has gained more attention. NPM argues that, just like companies, government should have a balanced budget. However, this is especially difficult for the health care sector to achieve.

8. Anticipate: not be curing, but preventing
A good businessman is not overtaken by the events, but anticipates on new developments. In the same manner, the government should anticipate on, for example, the rise in the ageing population and technological developments and the explosive rise of costs in the health care sector that can be expected to go with these developments.

9. Decentralise and delegate
The central government should delegate more to lower governmental organisations. The central role that has recently been attributed to municipalities in the implementation of the Social Support Act (‘Wet Maatschappelijke Ondersteuning’) is an example of this.

10. Introduce a free market system
Osborne and Gaebler’s last claim is that a free market system will result in both better quality and more efficiency.
From the 1980-ies on, a free market system has been a serious topic in the debate about the reorganisation of the health care sector in the Netherlands. In a free market system, improvements in health care are not initiated by the government, but rather by care providers, insurance companies and clients. Care providers will improve the efficacy and efficiency of care, since they have to bid for the favour of insurance companies (compare the P4P system mentioned earlier). The insurance companies in their turn bid for the favour of clients. Clients, finally, can choose care providers and insurance companies by making use of top-100 lists resulting from performance measurement. Again, there is a quite straightforward relation between a free market system and performance measurement. A free market system demands transparency, and therefore hard figures, and thus performance measurement.
In this section we have expounded, in a nutshell, the tenets of NPM and the role this view has played in the Netherlands. What should have become clear by now is that NPM has been, not only in America, but also in the Netherlands, the driving force behind the introduction of duty of care norms and performance norms. From the 1980-ies on, the government has defended the view that governmental interference with public tasks should be pushed back. For NPM, in particular the slogans ‘not rowing but steering’ and ‘no rules, but missions and goals’, to be successful, classical ways of legislation, viz. behavioural norms, should be abandoned or at least be supplemented by goal norms and duty of care norms. Moreover, the slogan ‘do not serve, but empower’ implies that care providers themselves should fill in these duty of care norms. Finally, both for a free market system as well as for adequate supervision ‘hard’ figures are needed. Therefore the goal norms and duty of care norms should be fleshed out by means of performance norms.

3 Legitimacy of performance norms

3.1 Introduction

In the foregoing we have both seen what performance measurement consists in and what the historical and ideological roots of performance measurement are. In this and the next section we discuss the question under what conditions performance measurement can be a legitimate way of regulating behaviour. We discuss three kinds of critique of performance measurement of public services. The first, most fundamental, but also most global point of critique states that public services are principally not suited for performance measurement and that performance measurement has a perverting influence on the public sector. The second argument holds that performance norms are not legitimate insofar as they can conflict with the rule of law. The last point of critique holds that the legitimacy of performance norms is at stake insofar as the efficacy of performance norms can be seriously doubted. In this section we will discuss the first and second point of critique. In section 4 we investigate the efficacy of performance norms and the implications of a possible lack of efficacy for their legitimacy.

3.2 Service providers are unlike factories

According to the first type of critique, performance measurement misunderstands and even distorts the value laden character of public services. The critique holds that service providing organisations do not deliver ‘products’, but rather value laden services and that for this reason quality assessment cannot take the shape of performance measurement. It is not a coincidence that this critique looks much like the critique that was brought to the fore when performance measurement was introduced in the industrial world. The classical critique of rationalisation of production processes held that rationalisation alienates the workman from his labour and that it reduces him to a cog in the system. In its contemporary shape, the critique says that performance measurement changes the character of service providing organisations as well as of professionals and clients. Government and (semi-)public service providers are wrongly considered to be ‘normal’, i.e. profit seeking, companies; professionals loose their autonomy; clients become consumers; only efficacy and efficiency matter; and the normative debate
about the values of health, autonomy, solidarity etc. disappears and is replaced by a purely technocratic debate.

The problem about these quite polemic critiques is that there are often worded in very general terms and often are of an ideological and conservative nature. They are ideological in so far as they consider the free market, performance measurement and bureaucracy by definition to be contradictory and thus harmful to public services. They are conservative to the extent that they seem to start from a romantic view of the relation between professional and client as one of trust and mutual respect.

A positive exception to these diatribes is De Bruijn’s *Managing Performance in the Public Sector*.

He offers a nuanced view of the (dis)advantages of performance measurement of (semi-)public organisations. Part of his objection to performance measurement is practical, part of it is more principled. One of the practical, but nevertheless quite fundamental, objections is the claim that the causal relations between input and output of a service provider are unknown or at least contested. The health care sector is supposed to be ‘evidence based’, but nevertheless a lot (still) is unknown about the relation between effort and result. The question is, in other words, whether it is fair, and even whether it is possible to judge care providers on their results. This objection can partly be met by taking not only outcome-indicators, but also process- and structure-indicators into account.

Another objection to performance measurement relates to the fact that (semi)public organisations do not deliver their services autonomously, but rather in cooperation with other organisations as well as with their clients. The results of a hospital treatment, for example, depends also on the general practitioner, home care providers and also on patients themselves. This problem too can partly be overcome by not only relying on outcome-, but also on process- and structure-indicators.

As a result of this, it has been observed that performance measurement increases the chance that care providers will try to pass on ‘hard cases’ to other care providers, or even that they will bluntly refuse them. In the next section we will discuss the risk that care providers will even try to manipulate the figures in order to comply with the performance norms.

We have just argued that care providers do not deal with products but with value-bound services. What does this imply? It is argued that the requirements with respect to products like cookies and lemonade are fairly univocal: they have to be safe, not too unhealthy, tasty, etc. What, however, are the goals of service providing organisations like care providers? Guar-

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11 Note, however, that Tonkens is also in favour of inter- and supervision and more qualitative forms of inspection.

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ding and advancing health care and wellbeing is one important goal, but not the only one. The autonomy of the patient is a central value too and fair distribution of care (implying that ‘hard cases’ should not be refused) is again another aim. Also, care providers have to comply with requirements that have to do with the environment and working conditions for example. Now, the question is: how can we measure, given these very different and possibly conflicting demands, whether ‘good care’ has been offered? What if the patient is cured, but his autonomy was not fully respected? What if the quality of care was good, but the distribution was unfair? What if working conditions were not met, etc.? The assessment, in other words, is not so much a matter of facts, but of values.

The question here is not only how the assessment should be made, the question is, first and foremost, who should determine what aspects should be measured and who should determine how these different aspects should be weighed. The most fundamental question is whether such a fundamental assessment can be made via performance norms that are not made by a democratically chosen legislator, but by organisations from the health care sector.

There is yet another problem connected to the fact that performance norms are not promulgated by the legislator. The main justification for the legislator to use goal norms, duty of care norms and other so-called open norms is that society is complex and changing constantly. Therefore a legal system that only consists of clearly specified behavioural norms will always lag behind the facts. However, the performance norms that the care providers are supposed to make and apply, suffer from the same deficit as traditional behavioural norms. These norms too need a fairly stable environment in order to function well. In other words, by shifting the obligation to make more precise (performance) norms from the government to societal organisations, the legislator also puts the burden on them to constantly update these norms in order to keep step with changes that take place.

3.3 Performance norms and legal principles

The objection to the fact that performance norms are created and enforced via conditioned self-regulation brings us to a second objection to performance norms. The question to be discussed is: does this type of conditioned self-regulation conflict with the rule of law?

It should first be noted that performance norms do not satisfy the demand of legality. One can respond to this objection that this is not a serious objection in the Dutch democratic system which is characterised by its emphasis on consultation and consensus for thereby at least the demands of inclusiveness and representation will nevertheless be met. In health care, for example, performance norms are not determined by the care providers themselves, but by a coordinating organisation which consists of delegates of the Inspection and several kinds of organisations from the health care sector. Of course, one can have doubts about the extent to which these delegates truly know about the work being done on the ‘shop floor’, i.e. to what extent they truly represent professionals and patients. However, the demands of inclusiveness and representation are met at least to some extent.

A more important question is to what extent the demands of legal certainty and equality are fulfilled. At first sight, one might think that performance norms truly serve the aims of certainty and equality. They serve certainty since they make more precise what the rather vague duty of care norm of the Quality Act consists in. However, performance norms turn out to be
less univocal and stable than one might think since there is a tendency to constantly re-adjust performance norms.

Performance norms seem to fulfil the demand of equality. On the one hand they formulate clear and univocal demands that make possible not only to treat like care providers alike, but also to treat unlike care providers unalike. For example, performance norms for hospitals differ from norms for nursing homes or rehabilitation centres. As long as the differentiations are approved of by all stakeholders, it seems that the principle of equality is served by the introduction of performance norms.

However, and now we come to the most critical point, for performance norms to truly fulfil the demands of equality and certainty, it is crucial that performance norms are sound. This implies, firstly, that performance norms should measure what we want them to measure and not something else. Secondly and at least as important is the demand that it is possible to apply the norms properly and that is impossible or at least not too easy, to apply them wrongly. This, in turn, implies that addressees should not have (too many) opportunities to manipulate the outcomes of the measurement.

In the next section we will learn that there some serious questions can be posed with respect to both demands. It turns out to be difficult to make good performance norms and it turns out to be possible and (obviously) attractive to manipulate the figures.

4 Efficacy and legitimacy of performance norms

4.1 Goals and audiences of performance measurement

In section 1 we have seen that performance measurement can be used for different purposes. The primary goal is to make transparent how service providers have performed. The services that have been delivered can then be compared to the services as intended. If there is a discrepancy between the delivered and the intended services, two things can be done. The purpose can be that addressees learn from their failure and try to improve their performances. Another purpose can be that addressees give account of their performances and that they, if necessary, get fines or rewards for their insufficient or excellent results. The thought behind the second aim is, obviously, that punishment and reward are an indirect but effective route to improvement. In other words, transparency, learning and improving, accountability and fines and rewards, are the keywords of performance measurement.

A second distinction is the one between internal and external audiences. It should be noted that the distinction is relative. The board of a hospital for instance, is external in relation to a specific department of the hospital, but it is internal in relation to the inspection. The distinction is used to distinguish between groups of persons with and without detailed information about the organisation. Members of the internal forum know, so to speak, the world behind the numbers and figures, whereas members of the external forum don’t.

Members of the external forum only ‘see’ the hard figures (what percentage of maternal caretakers arrived within one hour after the call, how many followed a course, etc.). The
external audience cannot, at least not without further explanation and clarification by the care providers, interpret and, if necessary, nuance the outcomes. A good example of such an external audience is the class of potential patients/consumers who can acquire information about hospitals via different top-100’s that yearly are published. A significant detail about these top 100’s is that in 2006 there was no concurrence whatsoever between the three most prominent rankings.13

A serious risk of performance measurement is that it is often introduced to serve an internal audience with the primary aim of quality improvement, but that at some point external audiences also get the disposal of this information which is then used for the purpose of accountability, benchmarking, and even for ‘naming en shaming’. Shifts of purposes and audiences is risky for several reasons. In the first place, external audiences cannot properly read, i.e. interpret and nuance the outcomes. External audiences are more inclined to treat the outcomes as ‘hard figures’ than as the indicators they were intended to be. Since services providers are aware of the risk that internal figures might be used externally, they will not be fully open and they will be inclined to give a rosy picture of how things are in the organisation. Investigations on this point show that both risks are real.14

We have seen that NPM favours competition between service providers, but it has been show that the more competitive (public) service providers have to be, the less willing they are to share their ‘formula for success’. Schools and hospitals for example, are inclined to show that they are successful, but not how they achieve the success. This is especially so when they are rewarded (P4P) for excellent results. Another effect of competition based performance measurement is that public service providers are less inclined to be inventive. When the evaluation is good, it is safer to keep what you have than to try new but risky routes. Also, organisations sometimes only improve those parts that are measured and do so at a cost of parts that are not measured.15

The conclusion of this section is that if performance measurement is used externally for the purpose of benchmarking and competition and sometimes even for naming and shaming, the risks of improper use and of withholding and even manipulation of facts increases.

4.2 Is it possible to make good performance norms?

Before we discuss an example of manipulation of performance measurement, we first have to find out whether it is possible in principle to make sound performance norms. For performance norms to be sound, they should be valid, reliable, responsive and useful. This section briefly discusses these requirements. We will use the example of hospital mortality to illustrate them.16

15 See De Bruijn 2001.
16 I take this example from P.P.M. Harteloh en A.F.Casparie, Kwaliteit van zorg. Van een zorginhoudelijke naar een bedrijfskundige aanpak (Quality of care. From an approach to the content of care to the management of care), Maarsen, Elsevier/De Tijdstroom, 1998 (4e druk).
1 Validity
The first requirement is that indicators are valid. Valid implies that indicators measure what we want them to measure. So in our example the question is: is hospital mortality a valid indicator for the quality of care? In order to answer that question we have to make a distinction between sensitivity and specificity.

1a Sensitivity
Harteloh en Casparie argue that only 11% of the cases of low quality of care can be signalled by means of the indicator hospital mortality. The indicator has a low sensitivity because it does not allow us to detect low quality that is caused by other facts, such as e.g. infection en re-operation. In other words: low sensitivity implies in this example that the indicator does not detect 89% of the cases of low quality. This implies that we need other indicators if we want to properly measure the quality of care.

1b Specificity
Hospital mortality turns out to be a highly specific indicator. In 96% of the hospitals where the quality is good, the mortality is low. High specificity implies, in other words, that only few hospitals are wrongly accused of offering low quality. One might say that mortality is a ‘fair’ indicator. As the example shows, the final judgement about the validity of an indicator is not a hard and objective fact. It is rather the outcome of a normative weighing and balancing of specificity and sensitivity. Depending on the decision that it is more important to find ‘bad’ hospitals or rather not to falsely accuse ‘good’ hospitals of delivering bad care, the verdict about the validity of mortality will be negative or positive.

2 Reliability
An indicator should not only be valid, but also reliable. Reliability means that all institutions should register their facts in the same manner. Again when we look at our example, we see that it is very reliable. There is hardly ever debate about whether someone is dead or not, it is not hard to register 100% of the cases and (not completely unimportant) it is hard to manipulate the mortality figures since all deaths have to be reported anyhow.17

3 Responsiveness
Not only should the indicator be valid and reliable, it should also be responsive. This implies that an indicator should also serve the purpose of reflecting or even initiating quality improvement. Hospital mortality has turned out not to be suitable for this purpose. In the USA no changes in mortality figures have been found despite drastic changes in health care.

4 Usefulness
The usefulness of an indicator depends among others on the accessibility of the information needed, the costs to collect and process the information and the acceptance of the indicator by all stakeholders.

17 However, even here there is an escape: according to the definition of hospital mortality all patients who die within 30 days after having left the hospital should also be taken into account.
4a Accessibility of information
The accessibility is not an issue in the case of mortality figures. In other cases, however, this can be a more serious issue.

4b Costs
The costs of collecting and processing are not a trivial issue. Many organisations complain about administrative work load and the number of hours not spend on their core task, offering cure and care. So many openly doubt whether the costs of performance measurement are outweighed by the benefits.

4c Acceptance
The acceptance of the indicator by addressees is important. In the USA for example, there has been a discussion about the soundness of the indicator hospital mortality. Partly because of this discussion, publication of hospital mortality numbers has been stopped in the USA in 1995.

The purpose of this brief discussion of the requirements for good indicators was merely to show that one (i.e., the legislator) should not think to lightly about the construction of good indicators. It is often referred to as ‘merely’ a practical problem, but it turns out to be problem that presupposes normative appraisals and takes a lot of time and money.

4.3 Perversion
The example of mortality in hospitals shows that the construction of indicators that satisfy all methodological criteria is not a simple matter. In this section we will discuss the fact that even if it is possible to make good indicators, there still is a discrepancy between what they actually measure and what they intend to measure. This discrepancy need not be problematic as long as indicators are taken for what they are, viz. literally ‘indicators’ of the quality of the service being offered. Now as we have seen, one of the risks of the use of performance norms is that they are not taken to be indicators of, but as hard evidence for, the quality of care.

If an indicator only has a signal function, then a (good or bad) outcome can be a reason to investigate possible causes of the outcome. In such cases the outcome will be discussed in a dialogue between investigator and the investigated organisation. For example: does high mortality indicate bad quality, or is it to be explained from a flue epidemic, a heat wave, or from the fact that the hospital’s clients are atypical as compared to other hospitals?

However, as soon as indicators are treated as a hard figures (‘dials’) that can not be debated and negotiated, the figures will start to lead a life of their own and it will be hard to correct wrong interpretations. Obviously, this is a serious problem both from the perspective of supplying objective information to the audiences, as well as from the point of view of justice to the organisations under investigation. The problem, however, is that there is an ineradicable tendency to treat numbers as hard facts, even if they were originally intended to serve a signalling function only.
This brings us to the problem mentioned earlier: the risk that organisations will manipulate the outcomes of performance measurement.

Bevan en Hood investigated several health care institutions in the English National Health System. According to Bevan and Hood the English system is more directed at punishment and reward and ‘naming and shaming’ than other British countries (and also than the Netherlands it seems). Bevan and Hood claim that, as a consequence, English institutions deliberately distort and embellish their performances.

One of the (almost hilarious) examples they discuss deals with the performance norms for the waiting period at the Accident en Emergency Department. One of the norms is that a patient should be treated within 4 hours after arrival at the department. According to Bevan and Hood this specific performance norm causes four different kinds of ‘output-distorting gaming’. First, a study of waiting time distribution revealed a frequency peak around 4 hours, whereas earlier there was no such peak. Second, departments drafted in extra personnel and third they cancelled operations in the period over which performance was measured. Fourthly, patients had to wait in queues of ambulances outside the A&E Department until the department was confident that the patient could be seen within four hours. Bevan and Hood claim that this last practice may have caused (possibly fatal) delays to other patients when ambulances (that were in fact available) were waiting outside the hospital to offload their patients.

Since Bevan and Hood studied the effects of performance measurement in English health care facilities where accountability and even ‘naming and shaming’ play a vital role, we cannot draw any straightforward conclusions when it comes to evaluating the efficacy and legitimacy of performance measurement of health care in the Netherlands. However, even if only a fraction of the consequences they discuss also occur in the Netherlands, that would have implications both for the efficacy and the legitimacy of performance measurement.

5 Conclusion

Must the conclusion be that performance measurement is a very dangerous instrument that we should abandon and abolish as soon as possible? Although Bevan and Hood are critical about performance measurement, they nevertheless do not draw this radical conclusion. Their prime concern is to disconnect performance measurement from naming and shaming. Another warning is to be careful about changes in goals and audiences of performance measurement. Changes (from internal to external audience and from learning to accountability) are possible, but hey should be discussed openly with all stakeholders. Moreover, if necessary indicators should be adapted to the new goals and audiences. Also, one should be careful not to focus one-sidedly on outcome-indicators at the cost of structure- and process-indicators. A final warning is not to introduce performance measurement too light heartedly, for it is more easy to introduce than to abandon it.19

The main conclusion is that in the next few years, the effects of performance measurement should be studied very carefully. Does it result, as critics claim, in a more unevenly distributed and scantier care? Or does it result, as proponents hold, in an increase of both quality and efficiency? To answer this question, we need something other than the ideological pleas of critics and adherents. Instead, empirical research is needed. A meta-analysis of the Dutch Health Care Council shows that there is hardly any research into the effects of performance measurement. Therefore we should not only measure the quality of (semi-)public services, but we should also start to empirically investigate the quality and the side-effects of performance measurement.

As long as empirical evidence is lacking, legislators should not think too light heartedly of regulation via a combination of legal duty of care norms and self regulated performance norms.

THE EMERGENCE AND USE OF SELF-REGULATION IN THE EUROPEAN DECISION-MAKING PROCESS:

Does It Make a Difference?\(^1\)

Theo van den Hoogen & Tobias Nowak

1 Introduction

Private policy stakeholders have always had a relatively open access to official officeholders in EU legislative processes, especially economic actors in sectors relevant to the working of the internal market. Their actions at the European level aim at achieving outcomes in public rule making that reflect their preferences and interests (Hix 2005, p. 12). The encouragement of self-regulation as an alternative to the classical legislative instruments intends to enhance further this role of private actors in European integration. It fits into a broader trend in Europe towards a more participatory style of governance which on its turn has been affected by the neoliberal ideological shift in public policy-making from government towards the market. In a pure sense, self-regulation concerns private actors who make rules for and by themselves on a voluntary basis to address common problems or interests.

This private rule-making takes place outside the legislative process, with no or only a marginal role for public authorities. Since the mid 90’s the European Commission has started to advocate self-regulation by private economic and social actors as an important new steering mechanism to improve the achievement of the objectives of the Treaties, in particular with regard to internal market policies (European Commission 2001).

In this paper we want to shed some light on self-regulation as a new mode of governance in the EU and the way it has developed in practice. Why did the Institutions of the EU pay increased attention to the concept of self-regulation in the 1990s? What advantages and disadvantages compared to normal legislation do the political actors expect from self-regulation? What regulatory framework for self-regulation did the institutions create? Has the introduction of self-regulation in the EU gained prominence as an alternative to traditional legislation? Does self-regulation offer an attractive new institutional opportunity for economic and social actors to influence European decision-making?

\(^1\) The authors thank Charis van den Berg for her support.
The first section deals with the emergence and institutionalization of self-regulation. After looking at the reasons of the Commission and other EU institutions to promote self-regulation as a new mode of EU governance (1.1), we present an overview of advantages and disadvantages of self-regulation as discussed in the academic literature and by a number of political actors who take part in the EU policy-making process (1.2). Then we continue with the way self-regulation is defined in the context of EU governance and the criteria and modalities that have been adopted for the use of this mechanism to fit it into the broader legal and institutional system (1.3). We finish this section with a quantitative overview of the actual use of self-regulation in the EU. (1.4)

In the second section we turn to the experience of self-regulation as it has been applied in practice by studying three different cases of self-regulation. Approaching self-regulation as part of a more participatory trend of EU governance, our focus is on the relationship between public authorities and private actors in rule making processes. The selected cases are the lawyers’ case (2.1), the social dialogue case (2.2), and the advertisement case (2.3). These cases represent three different policy-making models, from hierarchical top-down processes towards bottom-up voluntary private agreements: a classical law making model (a Council and European Parliament directive), a model of delegated rule-making (co-regulation), and a voluntary model (self-regulation).

The third and final section summarizes the main findings and presents some conclusions on the use and attractiveness of self-regulation as an alternative mechanism of EU governance.

### 2 The emergence and institutionalization of private self-regulation as an alternative mechanism of EU governance

#### 2.1 Historical background

With the acceleration of the European integration process since the mid 1980’s, a number of problems with the traditional “Community method” of regulation based on EU legislative procedures has surfaced, of which several remain unsolved until this day. Senden summarizes four of these problems, which are partially inherent to the EU law-making process and partially to policy choices of the European institutions (Senden 2008, pp. 127-130).

First of all, European policy competences have expanded tremendously during the past few decades, not only by virtue of new Treaties, but also because of extensive interpretation by the European Court of Justice (for example, the theory of implied powers). Parallel to this trend runs the decrease of national powers, or national sovereignty, as well as an ongoing discussion about the democratic legitimacy of the European decision-making process.

Second, the complexity and lack of efficiency in the traditional European law-making process is widely considered as essentially problematic. The Institutions do not always effectively use their law-making competence, which often results in stagnation of the law-making process. This is not only due to the strongly enhanced role and influence of the European Parliament as a co-legislator, but also because of the cases in which the Council takes decisions by una-
nimity. Additionally, the tendency of the Institutions which are involved in the law-making process to rule on details is an important factor in this.

Third, problems with quantity and quality have emerged: too much regulation, leading to unnecessary administrative burdens for economic actors and at the same time a lack of quality of European legislation. It often lacks consistency, clarity, accessibility and comprehensibility, due to the complexity of the law-making process.

Fourth, the absence of a hierarchy of norms is seen as a problem. Often, it is not clear for the member states what the character of a regulation is, whether it is a legislative or an executive document.

All aforementioned problems with traditional legislative regulation refer to more fundamental problems of the European law-making process: lack of efficiency and lack of legitimacy (Senden 2008, p. 130).

The legitimacy crisis, which broke out during the ratification period of the Maastricht Treaty, constituted a catalyst for the European Commission to start reflections on its legislative task and the use of classical law-based methods (regulations, directives, decisions) as the main instruments to attain EU policy goals. To address the identified shortcomings the Commission started its ‘better governance programme’ which included a proposal for ‘a new legislative policy’. This new policy consisted of two pillars which can be captured under the headings of “do less in order to do better” and “diversification of modes of governance” (Senden 2005, pp. 5-9). In practice, these pillars are rooted in, and represented by concepts such as flexibility, decentralization, differentiation, subsidiarity, reduction of administrative burden, and private actor involvement. Better governance should contribute to both democratic legitimacy and the performance of the EU policy-making system.²

With regard to new modes of governance the Commission emphasized the importance of the use of self-regulation as an alternative to top-down command and control legislation. Systems of self-regulation based on voluntary agreements of social and economic actors became to be viewed as a policy mechanism which could contribute greatly to enhance the efficiency, legitimacy and competitiveness of the European internal market.³ The Commission’s proposal to make more use of self-regulation as an instrument of European policy-making was endorsed by the member states in a protocol attached to the Treaty of Amsterdam (1997), and later on it became part of the Lisbon strategy for growth and jobs adopted by the European Council in 2000.⁴

² The “do less in order to do better” pillar is based on the notions “simplification” and “deregulation”. Simplification has been defined as the need to ensure that regulation imposes the least constraint on competitiveness and employment whilst maximizing the effects of direct government intervention. Deregulation has been regarded as an unavoidable extension of simplification and entails the reduction or removal of government regulations, when these are no longer necessary or when their objectives can easily be achieved through alternative mechanisms (COM(95) 288 final). The “diversification of modes of governance” pillar focuses on modes of governance or alternative means of regulation besides legislation. In this article, the first pillar will be left out of consideration.

³ A systematic overview of the perceived pros and cons of self-regulation, including the Commission’s view is presented under section 1.2.

⁴ Protocol on Subsidiarity, Treaty of Amsterdam 1997; Lisbon extraordinary European Council, 23-24 March 2000. This European Council also launched the open method of coordination as a new instrument to increase the convergence of macro-economic and social policies of the member states. The open method of coordination is a pure intergovernmental cooperation mechanism of governance which is separated from the community regulatory method. It is based on non-binding agreements on policy targets, benchmarking, best practices, mutual learning and publication and discussion of results. The open method shares the aspect of voluntariness with self-regulation. The main difference is that national public authorities are the principal participants in the open method of coordination, whereas forms of self-regulation are set up and managed by private social and economic actors.
To understand the rise and the encouragement, in particular by the Commission, of this new mode of EU governance, we have to look at some general and some more specific contextual conditions which surrounded its introduction in the mid-1990s.

First of all, the concept of alternative regulation was not an entirely new phenomenon. In the White Paper for the Internal Market of 1985 the Commission had already introduced a new method of product standardization, by which the task of the legislator (EP and Council) was limited to the establishment of the essential requirements of harmonization, mostly in terms of safety, health and environmental goals to be attained, whereas the filling in of the corresponding technical details was referred to private European standardization and certification bodies of the industries concerned. Products meeting the standards adopted by these bodies are covered by the so-called presumption of conformity, implying that all legal requirements for trading in the European market are considered to be satisfied. This form of co-regulation, which divides regulatory responsibilities between the EU legislative authorities and civil society actors, has worked well on the whole. It is generally considered as a crucial institutional innovation for the successful completion of the internal market (Egan 2007; Hix 2005, p.240; Majone 1996, pp 24-25).

Another example of delegating regulatory tasks to private actors can be found in the European social dialogue. The European social dialogue resulted from an effort in the mid 1980’s of then Commission President Jacques Delors to add a social dimension to the internal market project. European employer organizations and trade unions were invited to start a labour market dialogue as ‘social partners’. The Maastricht Treaty (1992) formally institutionalized this dialogue, providing the social partners with the right to be consulted on social policy issues (art. 138 TEC), and even to propose EC labour market laws themselves (art. 139 TEC). This empowering of private organizations with Treaty based regulatory capacity was an institutional novelty and expectations were high at the time that the social partners were going to negotiate many social policy agreements (Hix 2005, p.255-260; Falkner 1998). Both examples illustrate that the Commission had already gained experience with regulatory methods which deviated from the classical legislative procedure when it announced its new legislative policy in the mid-1990s. The demonstrated effectiveness of the new approach to product standardization and the expected potential impact of the European social dialogue may have strengthened the motivation of the Commission to promote forms of self-regulation and co-regulation as alternative instruments of European integration.

Second, ideas such as self-regulation and co-regulation or management by objectives fitted seamlessly in the then dominating theory of New Public Management. With the underlying goals of enhancing the efficiency and reducing the costs of public policies, this theory emphasized the need of decentralization of policy-making and public bureaucracies and to include private stakeholders in the formulation and implementation of policies. Reforms in the public sector in the 1980’s and 1990’s have made public policy-making more market-oriented (Peters and Wright 1996).

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5 For more detailed information on the social dialogue process and its (rather poor) practical significance as alternative mode of governance, see the case study on this subject in section 2.
Third, in the neo-liberal ideology of market liberalization, which became the dominant political approach to European economic integration in the 1990’s, self-regulation and to a certain extent also co-regulation are viewed as advisable alternatives to counter over-regulation by public authorities. Policy-makers should avoid resorting to legislative intervention when other options (including no regulation at all) could be more effective to achieve the objectives. Generally, European associations representing the interests of companies in industrial and service sectors strongly supported the use of private voluntary agreements. (Alliance for a Competitive European Industry, position paper)

Fourth, to prevent an incremental and unintended process of power centralization in Brussels (integration by stealth), the principle of subsidiarity was included in the Maastricht Treaty as a safeguard against undermining the sovereignty of member states. Concepts of self-regulation fit into this political strategy of decentralized policy-processes.

Fifth: alternative instruments as co-and self-regulation create opportunities for the Commission to enhance its institutional position in the European political system. Under the traditional Community method the role of the Commission is part of an institutional balance which is closely monitored by all the other Institutions. Arrangements of self-regulation largely diminish the activities of the Council and the European Parliament in the policy-making process, whereas the Commission as the only remaining EU interlocutor builds a strong relationship with private regulators concerned. A stronger weight for self-regulation and co-regulation in the EU policy system may serve the institutional interests of the Commission (Wincott 2001; Eberlein and Kerwer 2002).

Conclusion
The debate on non-legislative modes of policy-making was initiated after a number of problems with the traditional law-making system were identified as an obstacle for the democratic legitimacy and the performance of EU policies. The legitimacy crisis in the wake of the Maastricht Treaty put additional pressure on the Commission to reassess the existing repertoire of policy instruments. An ideological and scientific climate favouring decentralized and market-friendly approaches, previous positive experience with forms of co-regulation as harmonization method and institutional self-interest of the Commission were all factors which favoured the introduction of self-regulation as a panacea for perceived weaknesses in European decision making.

2.2 The pros and cons of self-regulation

This paragraph first presents the advantages and disadvantages self-regulation might have compared to normal regulation in general. It then describes the positions and arguments of a number of political actors who play a part in EU decision-making.

The advantages and disadvantages in theory
From the theoretical literature a list of advantages that self-regulation allegedly has compared to the standard legislative process can be derived.
First, the voluntary commitment of private actors to a certain measure is assumed to reduce political decision making costs because these actors will mobilize less political resistance.
Second, the decision-making process of private actors is thought to be faster, especially when the alternative is decision-making in a system of multi-level governance involving many levels of governance of different states. Third, the compliance rate of the private actors with measures they have formulated themselves is expected to be higher than in cases of hierarchical decision making. They are expected to mobilize resources, such as obliging members to comply, expertise, money, sanctions in cases of non-compliance, and thus make implementation easier. Fourth, private accords are seen as more flexible and they can therefore be adjusted to new developments more easily (Heritier 2001, p. 11, 16; Majone 1996, pp 23-25). However, the disadvantages found in the literature (and in the documents of the institutions) seem to be informed by empirical experience with self-regulation instead of by theoretical considerations.

First, most self-regulatory action is not initiated by the private parties but by the European Commission and is often flanked by threats of hierarchical decision-making. Therefore, the voluntary character of self-regulation and with it the assumed advantages of voluntariness cannot be taken for granted. Prosser correctly points out that “the effectiveness of enforcement is an empirical matter, not one to be determined a priori by the choice of regulatory regime” (Prosser 2008, p. 104). Second, the participation in the formulation process of private accords is selective and non-representative. This is especially problematic in cases in which private accords lead to binding regulations for actors who were not involved in the formulation (for example the exclusion of UEAPME in the parental leave and part-time work negotiations, see case study on social dialogue). Third, private accords do not satisfyingly guarantee legal certainty. Fourth, private accords lack accountability (Heritier 2001, p. 14-15; Majone 1996, p. 26)).

Arguments of the Commission
The Commission produced a number of documents in which it praises the advantages of self-regulation. As noted, for the Commission self- and co-regulation are part of its project on better governance. One goal of this project is ‘participation’ which the Commission considers will contribute to the effectiveness of EU governance.6 The Commission counters the fear that the principle of participation will lead to a lengthy consultation process by arguing that such a consultation process will later lead to faster adoption and easier application and enforcement.7 The Commission also argues that co-regulation makes good use of the practical expertise private actors have in their field and that compliance, even with non-binding rules, will be higher. However, the Commission stresses that “with more involvement comes greater responsibility”.8

Arguments of the European Parliament
Not surprisingly the EP is rather sceptical towards self-regulation (including the social dialogue) because decision making in such cases usually circumvents the EP. Actually, not many statements of the EP concerning self-regulation exist. Only two reports seem to address the

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7 Ibid, p. 16.
8 Ibid, p. 12. In a later report the Commission “proposes to make greater use of alternatives to traditional legislation without undermining the provision of the Treaty or the prerogatives of the legislator” Commission 2003 Report from the Commission on European Governance, Office for Official Publications of the European Communities, p. 21, emphasis in the original. The latter part of this sentence can be seen as a forerunner of the Interinstitutional Agreement of December 2003 which contains all legal and institutional requirements for the use of co- and self-regulation, see section 1.3.
issue. The first one concentrates more generally on soft law but the arguments brought forward by the EP against soft law instruments can easily be transferred to the realm of self-regulation and they sound indeed similar to what the EP later said on self- and co-regulation. On soft law the EP is of the opinion that soft law is legitimate as long as it is not used as surrogate for legislation in fields where the Community has legislative power. It stresses that especially in cases in which no procedure exists which would give consultative rights to the EP, soft law cannot be a substitute for legislative acts. In its report on better law making the EP doubts “the appropriateness of encouraging self- and co-regulation” It fears that the use of self- and co-regulation will lead to “legislative abstinence” and that only lobby groups and powerful economic actors will benefit from it. For the sake of legal security the EP concludes that law-based regulations are the best way to achieve the objectives of the Community.

Arguments of civil society

The arguments of the civil society can be found in the many hearings held by the European Economic and Social Committee (ESC) concerning self- and co-regulation. Civil society is far from united in its view of self- and co-regulation. Here it is important to make a distinction between profit-organisations (business) and non-profit organisations (public interest organisations). As seen before, business in general supports self-regulation. However, it becomes clear that non-profit NGOs are much less enthusiastic than one would expect looking at the list of advantages presented in the theoretical literature or by the Commission. Many of the arguments advanced in the hearings either in favour or against co- and self-regulation are familiar. Eva Belabed, president of the study group on co- and self-regulation, for example, stresses that although problems could be resolved more flexibly by co- and self-regulation because of the skills of the involved actors, acts of co- and self-regulation could appear exclusive and therefore not legitimate. She also questions the value of voluntary agreements as she considers compliance rates to be low. Besides the usual positive points found in the theoretical literature most contributors to the debate emphasise that voluntary rules need mechanisms that ensure their application. A similar reserved tenor can be found in the conclusions of a workshop of the ESC on co-responsibility of organised civil society players held a few years earlier: “Responsibility for drawing up legislation (and regulation) must remain with the official institutions [...]” and in order to reconcile individual interests of civil society organisations with the general interest it is necessary that “the legislative authority always has the last word.” A recent hearing of the ESC on self- and co-regulation pointed to the problem of free riders, stressing the importance of enforcement of voluntary agreements (ESC 2008 p. 3). Thus, support of self-regulation in general is accompanied by critical undertones.

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12 § 14 of motion contained in EP report on better law making.
13 § 14 of motion contained in EP report on better law making.
14 ESC 2004: Summary of the hearing on the current state of co-regulation and self-regulation in the single market, p. 1
15 See for example the contributions of Verver, p. 3, Portalier, p. 7, Giovannini, p. 8 in ESC 2004.
16 ESC 2001 Conference on “The role of civil society in European governance” Workshop 1 Co-responsibility of organised civil society players, p. 2.
from a large part of civil society. One could say that civil society holds a yes-but-position on co- and self-regulation.

Table 1: Pros and Cons of self- and co-regulatory acts as compared to hierarchical rulemaking

<table>
<thead>
<tr>
<th>Argument</th>
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<tbody>
<tr>
<td><strong>Pros</strong></td>
</tr>
<tr>
<td>Reduce decision making costs</td>
</tr>
<tr>
<td>Make decision-making faster</td>
</tr>
<tr>
<td>Compliance is higher</td>
</tr>
<tr>
<td>Easier implementation</td>
</tr>
<tr>
<td>Can be adjusted more easily</td>
</tr>
<tr>
<td>Better participation</td>
</tr>
<tr>
<td>Better regulation because experience of affected actors s used</td>
</tr>
<tr>
<td><strong>Cons</strong></td>
</tr>
<tr>
<td>Lack of legitimacy (lack of representativeness, opaqueness)</td>
</tr>
<tr>
<td>Lack of legal certainty</td>
</tr>
<tr>
<td>Benefits only powerful private actors</td>
</tr>
<tr>
<td>Compliance is lower (free rider problem)</td>
</tr>
</tbody>
</table>

**Conclusions**

This overview makes clear what kind of advantages and disadvantages the actors expect of self- and co-regulation. The positions of the three actors can be summarized as follows: the Commission acts as driving-force, proponent and policy entrepreneur; the European Parliament is rather sceptical; and civil society welcomes the possibility of co- and self-regulation, especially the profit sector. Doubts are expressed by non-profit NGOs which represent public interests (consumer groups; environmental movement etc). They stress the need for a strong institutional framework especially in the monitoring phase. The advantages of co- and self-regulation are mostly seen in terms of efficiency gains; while the disadvantages mostly point to the issue of democratic legitimacy of the rule making process. In addition, some of the theoretical arguments seem to be rather weak: Is decision making by private actors really faster? This is rather doubtful considering the composition of some of the civil society actors at the European level (members from many states with different interests are combined in the European umbrella organisations). Is the compliance rate with voluntary agreements really higher than in cases of top-down regulation? We do not know of any empirical research which addresses this point. Are private actors really more flexible? As with faster decision making the civil society with its many conflicting interests might be even more inflexible than the normal legislators. Not mentioned anywhere is the possible lack of transparency and legitimacy created by processes in which the actors are different for each field and point in time and are often unknown to the public (who has ever heard of the UEAPME before?). In the three case studies in the second part of this paper we will look into several of these questions.

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18 This classification of advantages and disadvantages of self-regulation in terms of efficiency and democratic process corresponds with Scharpf’s distinction between input democracy and output democracy as the two sources of legitimate authority in the European Union (Scharpf 1998).
The regulation of self-regulation: the 2003 Interinstitutional Agreement on better law-making

Although self-regulation and co-regulation were proposed as new modes of governance which could improve the EU’s regulatory system, it was clear from the beginning that these alternative instruments could not be developed and used completely separate from the existing legal and institutional system. General principles such as legal consistency, legal certainty and democratic legitimacy are fundamental to the effective and democratic working of the system of European integration.

The demand for legal and institutional compatibility created a need for a legal framework which specified the conditions and modalities of the use of the new instruments. This framework was provided for in the Interinstitutional Agreement on better law-making adopted by the European Parliament, the Council and the Commission on 16 December 2003.

Conditioning and defining co-and self-regulation: the legal framework

To some extent, the IIA on better law-making reflects the experiences already gained with European co- and self-regulation and elaborates upon these. The provisions of the IIA are divided into ten paragraphs, which show the variety of aspects of the better-lawmaking policy as initiated by the Commission in the mid 1990’s.

Of specific relevance to co-regulation and self-regulation is the fifth paragraph, ‘Use of alternative methods of regulation’. In the first article of this paragraph, article 16, the three institutions reiterate their observance to the principles of subsidiarity and proportionality, which entails “the need to use, in suitable cases or where the Treaty does not specifically require the use of a legal instrument, alternative regulation mechanisms”. Most important is article 17 which spells out the basic requirements for the practical use of co- and self-regulation at EU level. It provides some basic duties of the Commission in this respect. The Commission has to ensure not only consistency of any use of alternative regulation (co-regulation or self-regulation) with Community law, but also transparency, representativeness of the parties involved, and demonstration of added value for the general interest. The article concludes with an enumeration of the circumstances in which co- and self-regulation are not an option. When fundamental rights or important political options are at stake or in situations where the rules must be applied in a uniform fashion in all Member States use of co- and self-regulation is not permitted. They are also not permitted when they affect the principles of competition or the unity of the internal market.

Following these general conditions on the use of co-and self-regulation, the concepts are defined in article 18 respectively in article 22.

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21 Simplifying and reducing the volume of legislation, improving the quality of legislation, utmost transparency of the legislative process, and adherence to general principles such as democratic legitimacy, subsidiarity, proportionality and legal certainty might be regarded as some of the ultimate goals that are pursued by the IIA, European Parliament, Council, Commission, “Interinstitutional Agreement on better law-making”, Official Journal of the European Union C 321/1, 31 December 2003, art. 1.

22 However, we find self-regulation in the media sector (and self-regulation in the advertisement industry is even used as a good example of self-regulation at the EU level by the Commission in several documents) which seems to contradict the rule that self-regulation is not an option when fundamental rights are concerned since one could argue that the fundamental right of freedom of speech is being regulated in these cases.
“Co-regulation means the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations).”

The advantages of the use of this mechanism are enumerated. They correspond with some of the advantages discussed in the previous paragraph. According to the IIA co-regulation enables “the legislation to be adapted to the problems and sectors concerned, to reduce the legislative burden by concentrating on essential aspects and to draw on the experience of the parties concerned”.23

The contribution of private actors under co-regulation clearly exceeds mere consultation. However, agreements between the concerned private actors on measures to attain the objectives in a legislative text have an inter partes (between signatory parties only) and not an erga omnes (general application) character.24

The procedural conditions for the use of this instrument, such as the duties of the Commission, are stipulated in the three subsequent articles.

A definition of the concept of self-regulation can be found in article 22:

“Self-regulation is defined as the possibility for economic operators, the social partners, non-governmental organisations or associations to adopt amongst themselves and for themselves common guidelines at European level (particularly codes of practice or sectoral agreements).”

The continuation of this article stresses that self-regulation must be regarded as a voluntary initiative that does not necessarily imply any involvement or standing of (one of) the Institutions, especially in cases in which no Community legislation on that subject exists, or when the subject is not dealt with by the Treaties. Thus, when social and economic actors are faced with specific situations on the ground not covered by a Community law solution, they can regulate themselves. As in the case of co-regulatory contracts, the solution commits only the signatory actors. Nevertheless, these agreements may form the basis for a Commission proposal to other institutions “to confer general application upon these agreements within the EU through a vote on the proposal”25. The Commission, however, is placed under a duty to verify practices of self-regulation on points mentioned in article 17.

Although certain manifestations of co-regulation and self-regulation within the European Union had already been apparent in the years preceding the IIA of 2003, the conceptualization and institutionalization of these alternative methods had not been developed accordingly.26 The IIA for the first time addressed the concepts of co- and self-regulation and provided a general legal framework for the practical use of these instruments within the single market.

25 Ibid.
26 See L. Senden 2008, p. 133.
In addition, it transformed these practices into a set of legal rules and requirements to enable coexistence, compatibility and complementarity of both notions with the general principles of Community law. Finally, the Interinstitutional Agreement also provided for monitoring and follow-up mechanisms.

In addition to this legal compatibility motive for the institutionalization of alternative methods of regulation a more political argument can be put forward. As has already been noted, the use of co- and self-regulation may distort the balance between the Institutions in the decision-making process. In particular the European Parliament repeatedly warned against being sidelined by new methods of governance which take place entirely or to a large extent outside the legislative framework. The adoption of the IIA might be viewed as an answer to address these worries and to gain broad institutional support for alternative regulation. One might argue that the Institutions have exerted their power and influence to secure their role as decision-making bodies. Another view is taken by the European Economic and Social Committee: the situation that gave rise to action related to the institutionalization of self-regulatory instruments was characterized by the lack of a legal framework governing its position, which caused considerable disparities between the national situations. Primarily English-speaking states were generally inclined to acknowledge and support European self-regulation, to which they referred as “soft law”, whereas other countries saw them as a potential threat to public authority. Self-regulation in the EU formed a “grey area of Community law”, inherently controversial and ambiguous. Institutionalization could throw light on the legal status of alternative regulation.

The IIA can be criticised for its rather narrow view of the two forms of regulation defined. The IIA definition of co-regulation only applies to scenarios in which the legislator formulates aims which then are to be realised by the concerned sector through self-regulation. However, many more co-regulatory scenarios are imaginable. Goals, for example, could be formulated by private actors and goal attainment monitored by public authorities. And indeed, the social dialogue is generally considered to be a co-regulatory instrument but here the goals are formulated by the social partners and not by the legislator. In certain cases these goals are then adopted as law. In addition, the definition of self-regulation contained in the IIA can be criticised for the fact that it is too restrictive to cover forms of rule making that are actually referred to as self-regulation by the actors. All so-called self-regulatory acts take place in a highly regulated environment. Self-regulatory regimes are often the reaction to pressure from the Commission and they are being scrutinized by the Commission for their compatibility with EU legal principles.

28 Ibid.
30 Ibid.
32 See also DG Health and Consumer 2006: Self-regulation in the EU advertising sector: a report of some discussion among interested parties which criticises that the definitions leave “a grey area of self-regulation that is not quite as purely autonomous as this wording implies and yet has none of the characteristics required for a system to qualify as CoRegulation” <http://ec.europa.eu/dgs/health_consumer/self_regulation/docs/report_advertising_en.pdf>, p. 9>.
Conclusions
The ‘better governance policy’ of the EU made non-legislative alternative regulation one of the key points of that policy. In order to prevent the undermining of legal certainty and democratic legitimacy in the internal market by the extensive use of alternative regulatory instruments, co- and self-regulation themselves became subject to formal regulation. Political pressures from the European Parliament and the Member-States also contributed to this institutionalisation.

Legal rules were laid down in 2003 IIA to delineate the scope of alternative regulation and bind its use to procedural and substantive requirements. In case of policy failure of voluntary agreements the legislator retains the right to intervene with binding law instruments. On the one hand the IIA addressed some of the concerns on self-regulation as expressed by a number of political actors, on the other hand it had the effect to bind self-regulatory methods firmly to the constraints of the hierarchical command-and control order. The freedom of private actors to rule for and by themselves in specific policy areas at the EU level became to be strongly restricted in practice. In the European policy-making system the law-maker never disappeared out of sight.

2.4 The practical use of co-regulation and self-regulation in the EU: some empirical information

The ‘new regulatory policy’ advocated by the Commission and other EU institutions emphasized the need to make more frequent use of co- and self-regulation. Especially in policy-making areas related to the internal market, these alternative instruments became a focus of attention as promising alternative options to the classical legal instruments. However, both co- and self-regulation rely on the willingness and possibilities of civil society actors to make use of this option by committing to voluntary agreements on policy issues at the EU level.

According to modern theory of politics, private economic stakeholders are assumed to be rational actors which behave strategically in the policy-making system to achieve outcomes that reflect organizational interests (Hix, 2005, p. 12). They are expected to make use of new institutional opportunities when these serve their interests in the policy-process in more effective way.

European industry has expressed repeatedly its support for the use of self-regulation (Alliance for a Competitive European Industry 2004, p.2). Compared with traditional top-down legal regulation the new methods are seen as more flexible and effective ways to attune European measures to the specific circumstances and interests of the companies concerned.

Most of the individual economic operators in the European market are affiliated with and represented in the European policy process by European umbrella organizations, the so-called recognized parties in the field. These European associations are key actors in taking initiatives to draft self-regulation proposals on behalf of their members. To what extent has the Commission’s call in the mid 1990’s to introduce more diversification in the modes of governance been taken up by these associations? The rest of this paragraph summarizes some empirical information on the actual use of co- and self—regulation at the European level.
The total number of all registered cases of European co- and self regulation in the period 1990-2008 adds up to 105, with a strong concentration (nearly 75 per cent) in the years 2000-2005. (Table 1, Annex 1) Although some non-legislative regulation already existed in the beginning of the 1990’s, a sharp rise in co- and self-regulation cases started just in the last years of the 1990’s, coinciding with the Commission’s promotion campaign. In this period the average number of new initiatives per year approached 13. However, this upward trend did not last long. It ended abruptly after 2005 when new initiatives dropped back to the same low level as in the first half of the 1990’s. In the practice of EU policy-making, co- and self-regulation remains of minor importance. This empirical marginality in EU policy-making also shows up in comparison with the classical legislative output in the EU, such as directives and regulations. The statistics lead to the conclusion that the introduction and promotion of self-regulation as an alternative policy instrument has not decreased the dominant position of the law-making process, at least not in quantitative terms.

About one-third of the registered cases can be classified as co-regulation and two-third as self-regulation. As regards the spread over policy sectors most voluntary initiatives originate in industrial and service sectors operating in the European market. Environmental issues and social affairs take a prominent place as subjects of European self-regulation. The dominance of social affairs in co-regulation agreements is not surprising when considering that this policy field is covered by the Social Dialogue with its Treaty based provisions for co-regulation. Besides environment and social affairs there is a broad variety of subjects covered by self- and co-regulation, from European professional standards to consumer protection issues. (Tables 2a and b, Annex 1)

It is interesting to have a more detailed look at some features of co-regulation and self-regulation. The co-regulation cases can be subdivided according to the initiating type of legal act, which can be a legislative act (of the Council, the Council and the European Parliament, or the Commission), or a non-legislative legal act, for example a recommendation of the Commission or the Council (soft law). It turns out that co-regulation is mostly related to legislative acts, in particular to Council/EP or Council directives. It is remarkable that more than half of the cases in which a legislative act creates a framework for co-regulation is not followed up by private initiatives. At least this raises doubt about the qualification of these legal frameworks as co-regulation (Table 3, Annex 1)

33 This information is calculated from a database on self-regulation and co-regulation set up in 2006 by the European Economic and Social Committee in cooperation with the Commission. The database aims to take stock of all European initiatives (involving more than one member-state) of self-regulation and co-regulation, and to update them regularly. So far, it is the most comprehensive source of empirical information on this subject in the EU. In classifying cases as co-regulation or self-regulations the data-bank applies the EU definitions of the Interinstitutional Agreement 2003. <http://eesc.europa.eu/self-and-coregulation/index.asp>, last accessed: 10 March 2009. It is quite possible that besides these ‘official’ registered cases of self-regulation several ‘unofficial’ non-registered voluntary agreements exist at the European level. More research is needed to identify ‘unofficial’ self-regulation at the European level and to assess its empirical significance and relevance for the European integration process.

34 Actually, the total number of cases in use declines to 89 after deduction of cases which have become obsolete or have been replaced by updated versions in the meantime.


36 These directives sometimes encourage the member states to transpose its provisions in the form of self/co-regulation at the national level. National voluntary agreements are then linked to goal attainment at the EU level.
**Self-regulation** cases often start with a private initiative at the beginning (for example guidelines or code of behaviour). A substantial part of these initiatives is motivated by the wish to prevent a threatening law-making proposal of the Commission. The Commission can endorse the private agreement in a recommendation (non-binding legal act). On the other hand, when self-regulation does fail to achieve the expected results, the Commission can nullify the self-regulation by proposing a legislative act. The process of private rule-making is always linked to actual or potential legislation.

There is great variety in the methods which are applied in the collective actions of private actors to regulate themselves. Codes of conduct are the most popular. Codes of conduct and other forms of self-regulation differ enormously in terms of goal commitment, monitoring, compliance mechanisms and provisions for conflict resolution. Without more information on these internal provisions of voluntary agreements and the way these are applied in practice it is difficult to assess whether self-regulation agreements actually enhance the efficiency, effectiveness or democratic legitimacy of EU governance ([Table 4](Annex 1))

**Conclusions**

For private stakeholders, especially business, the introduction of self-regulation at the EU level created a new institutional channel to influence policy measures which affected their interests. However, the repeatedly declared support for this part of the Commission’s better governance policy has not led to a significant change in the way EU policies are made in practice. In empirical terms, self-regulation remains a rather marginal phenomenon, in absolute numbers as well as relative to the classical legislative process. Furthermore, many cases of self-regulation are non-committal codes of conduct or guidelines with unknown effects on the behaviour of its signatories. Prevention of formal legal intervention in their sector of interest is an important motivating factor for private actors to develop voluntary initiatives. The ‘shadow of law’ also extends to the implementation phase of self-regulation. The Inter-institutional Agreement 2003 has empowered the Commission to propose legislation when self-regulation contracts fail to meet the expectations of the EU law-makers. In practice, the attractiveness of self-regulation seems to be considerable less than in theory. First, initiatives of self-regulation have been reigned in by the legal and institutional conditions of the IIA 2003. Second, the drafting of a voluntary agreement is not an easy enterprise. European associations represent private actors from many countries which have shared interests but who are also competitors in the European market. Conflicts of interests are part of the negotiations on voluntary agreements and problems of free-riding, monitoring and enforcement have to be addressed. The question arises whether the assumed contribution of self-regulation to better governance and better interest intermediation in EU policy-making holds out in practice. Is self-regulation indeed a better institutional option for private economic stakeholders to attain their interests than the traditional law-making process? This is one of the questions addressed in the case-studies in the next section.
3 Self-regulation in practice: three case-studies

3.1 Introduction

In order to get a better understanding of how different forms of co- and self-regulation work in practice and to highlight some of the difficulties one encounters when studying regulation with these concepts in mind three short case studies are presented below. They show that co-regulation in the EU is a general phenomenon that comes in different forms. These case studies also highlight some of the elements identified above, such as the problem of representativeness or the alleged higher efficiency of self-regulation. Although all three cases under investigation contain elements of self-regulation, they differ among other things along the lines of legal status (of civil society’s involvement as well as of the produced agreements) and degree of institutionalisation.

The first case study takes a look at the making of the lawyer’s establishment directive. Although this directive was passed according to the standard law making procedures of the EU, the special role given to the lawyer’s interest group in the formulation phase of the directive brings it close to self-regulation. The second case concerns the much spoken of treaty based social dialogue between management and employees. The social dialogue makes it possible for the social partners to negotiated agreements amongst themselves which will then be adopted by the Council and receive the status of directives. The third case deals with the advertisement industry, an example often used by the Commission for a pure form of self-regulation. In this field national self-regulatory organisations established a European umbrella organisation which reports regularly to the Commission on advertising standards.

3.2 Self-regulation as part of the legislative process: The making of the Lawyer’s Establishment Directive

The biggest interest group of lawyer’s in Europe, the Council of Bars and Law Societies of the European Union (CCBE), was deeply involved in the making of the European rules governing the provision of legal services. According to the Commission’s definitions of self-regulation (private actors voluntarily adopt amongst themselves and for themselves common guidelines at the European level) and co-regulation (the legislators define objectives that they then leave to private actors to attain), this involvement would not classify as self- nor as co-regulation. However, the decision-making process that led to the passing of the Lawyer’s Establishment Directive37 shows characteristics usually attributed to self-regulation: non-governmental actors formulate rules that apply to them. Thus, a short description of the political process surrounding the Lawyer’s Establishment Directive will enhance our understanding of the legislative processes in the EU and put the concept of self-regulation into perspective.38

37 'Directive 98/5/EC of the European Parliament and of the Council of 16 February 1998 to facilitate practice of the profession of lawyer on a permanent basis in a Member State other than that in which the qualification was obtained’.
38 For a more elaborate description of the legislative process concerning the Lawyer’s Establishment Directive see Tobias Nowak and Nicolle Zeegers (2008), Rules for Professional Legal Services: The Same Authors Acting in a Different Arena? In Nicolle Zeegers and Herman Bröring (eds.), Professions under Pressure. Lawyers and Doctors between Profit and Public Interest, Boom Juridische Uitgevers, Den Haag, pp. 47-62.
Fulfilling a request from the Commission

In 1977, Viscount Davignon, the Commissioner for the Internal Market, asked the CCBE to draft a Directive on the establishment of lawyers. This was the beginning of a lengthy process in which the Commission made an initiative for a Lawyers’ Establishment Directive dependent on a draft by the CCBE which had to be supported by a vast majority of CCBE members and the member states. The CCBE formulated several proposals in the early 1980s. The discussion in the CCBE, as well as the discussion between the CCBE and the European Commission, included the questions as to which activities a lawyer would be allowed to perform in the host state and whether the rules for the profession of the host state or of the home state applied. However, the decision making process stalled and it was not before 1988 that the CCBE again seriously discussed proposals for an establishment Directive.

Basically, three versions were produced and put to vote. The 1988 vote on these three versions did not produce a winner. Thus, the CCBE continued to work on a draft for a Lawyers’ Establishment Directive. In 1991 a new draft was put to vote and received eight out of twelve votes. In order to be accepted ten votes were needed. However, in 1992, after some changes had been made to that draft, ten delegations voted in favour of it.

The two delegations voting against the proposal had very different reasons for doing so. The Spanish delegation voted against the draft of the CCBE because it would have liked a more liberal approach. The Luxembourg delegation was of the opinion that adequate means already existed for lawyers from other member states to practise law in Luxembourg.

The proposal of the European Commission

Then, in 1994 the Commission published its own Proposal for a European Parliament and Council Directive to facilitate practice of the legal profession by a lawyer on a permanent basis in a member state other than that in which his qualification was obtained. Although the Commission stressed that its point of departure had been the draft of the CCBE, the Commission’s proposal differed from the CCBE draft on two major points. Moreover, the Commission’s proposal differed on several minor points from the CCBE draft, for example, no reference was made to the CCBE’s Code of Conduct. Why did the Commission depart from the CCBE draft? The CCBE reports that the French delegation to the CCBE had changed its

40 The best known are called Zurich 10/80 and Athens 5/82 according to the dates and places the CCBE adopted them.
41 See Spedding 1987, p. 163.
44 France, Luxembourg and Spain voted against the draft, while Greece abstained (CCBE 2005, p. 31).
45 Toulmin 1993, p. 73, CCBE 2005, p. 31.
47 First, the right of establishment under the home title would expire after five years. Second, the proposal did not require an aptitude test for lawyers who wanted to join the host state’s legal profession.
mind after voting in favour of the CCBE draft.\textsuperscript{48} The Commission then adjusted the proposal in accordance with the French wishes.\textsuperscript{49}

\textbf{Reactions to the proposal of the Commission}

After the European Economic and Social Committee and the EP Committee on Legal Affairs and Citizens’ Rights criticized the Commission’s proposal on several points. In their opinions most of the points on which the Commission’s proposal departed from the draft of the CCBE were criticized. Both committees wanted to return to the original draft of the CCBE on all major points and proposed to amend the Directive accordingly. In June 1996 the European Parliament approved the Commission proposal on the condition that the proposed amendments would be incorporated into the Directive.\textsuperscript{50}

\textbf{The amended proposal}

The European Commission adopted an amended proposal of the Lawyers’ Establishment Directive in September 1996.\textsuperscript{51} The Commission adopted all of the major amendments proposed by the EP. The time limit on practice under home-state title was deleted, and the verification procedure for professional qualifications was included. The European Commission declined to follow the EP proposal only on some minor points. In its explanatory memorandum on the amended proposal the European Commission stated that it followed the suggestions of the European Economic and Social Committee, of the European Parliament’s Committee on Legal Affairs and Citizens’ Rights, and of the CCBE.

However, the Commission did not only follow the suggestions of the CCBE but considered the support of the CCBE as prerequisite for adopting the Directive. Thus, the new proposal was put to the vote in the CCBE on 17 November 1995 in Dresden.\textsuperscript{52} The CCBE made some changes to the provisions concerning the aptitude test and then accepted the proposal by qualified majority. The president of the CCBE, Heinz Weil, informed the responsible Commission official immediately per fax of the outcome of the vote.\textsuperscript{53} In addition, the EP was informed about the decision.

In July 1997 the Council of Ministers adopted a common position on the Commission’s amended proposal.\textsuperscript{54} The changes made by the Council of Ministers to the amended proposal were rather minor. The only member state not in favour of the Directive was Luxembourg.\textsuperscript{55} This common position was approved by the Commission and the EP.\textsuperscript{56} The Council of Ministers finally approved the Directive in its second reading in December 1997 by use of the decision mode of qualified majority. Again the only member state rejecting the Directive was Luxem-

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{49} CCBE, (2005), p. 32.
\item \textsuperscript{50} OJ C 198, 08.07.1996, pp. 68-85.
\item \textsuperscript{51} COM/1996/446/final.
\item \textsuperscript{53} Interview with Commission official.
\item \textsuperscript{54} OJ C 297, 29.09.97, p. 6.
\item \textsuperscript{55} See Council Minutes of 2007th Council meeting and of 2026th Council meeting.
\item \textsuperscript{56} SEC/1997/1206/final and A4-0337/1997.
\end{itemize}
\end{footnotesize}
Conclusions
Even though the history of the Lawyers’ Establishment Directive started in the late 1970s with the Commission asking the CCBE to prepare a draft, the Commission does not seem to have been the driving force behind the drafting and passing of the Directive. The CCBE did thus not react to a threat of the Commission to pass a law that would regulate the establishment of lawyers but parts of the CCBE saw different rules of establishment in the member states as a problem that needed to be tackled. As the CCBE was in itself divided on how to regulate establishment, the formulation and approval of a common proposal was rather difficult. This seems strange at first sight because no other interest group was involved (which brings the issue of representativeness to mind). However, this can easily be explained as the CCBE, like many European interest groups, is composed of many national interest groups with different agendas which makes compromises often difficult.

3.3 Institutionalised self-regulation: Dialogue of the Social Partners

“Because of their representativeness, trade unions and employers’ organisations have a particular role in the shaping of social policy.” Since the Single European Act provisions on the social dialogue can be found in the Treaty. Today Articles 137-139 contain the relevant provisions on the social dialogue. Article 139 makes it possible for the social partners to ask the Council of Ministers to adopt an agreement negotiated by the social partners as legislative act. However, the term social dialogue also refers to the obligatory consultation of the social partners by the Commission found in Article 138 EC and in a broader sense to all kinds of consultation committees involving the social partners. The procedure of the social dialogue as found in Article 138 and 139 EC goes as follows: The Commission has to consult the social partners in the preparation phase of a proposal in the field of social policy. If the Commission decides to go ahead with legislation it has to consult the social partners again on the proposal itself. At this moment the social partners can decide to start negotiations on the proposal. In this case the normal legislative process is stalled for nine months. In case the social partners have reached an agreement, the agreement can be transformed into a directive by the Council of Ministers by Qualified Majority Vote (QMV) or unanimity depending on the issues being regulated. Alternatively, such an agreement can be implemented at a national level ‘in accordance with the procedures and practices specific to management and labour and the Member States’ (Article 139 (2) EC). If no agreement was reached the normal decision-making procedure continues. Note that the European Parliament is not formally involved in this process. However, the Commission keeps the EP informed about the contents of agreements (Benedictus, pp. 28). The Social Dialogue can take place across industries or be restricted to a specific

57 Council Minutes of 2060th Council meeting.
58 The CCBE (2001) has drawn up guidelines on the implementation of the Lawyers’ Establishment Directive. This has been done in consultation with the Commission (interview with Commission officials).
60 The social partners have been involved in a more informal way via committees and working groups in the legislative process since the 1960s. With the SEA the social dialogue found a treaty basis. Article 118b of the SEA (1987) stated that the dialogue of the social partners (management and labour) could lead to agreements. The social dialogue in its contemporary form could first be found in the Agreement on Social Policy of the Maastricht Treaty (1993), it became part of the Treaty with the Treaty of Amsterdam (1999) (Benedictus (2003), p. 19 ff).
sector. We will concentrate on the cross-industry dialogue but will refer to the sectoral social dialogue to illustrate certain points more clearly.

The actors and their reasons

The main participants of the social dialogue are the Commission as supervisor, employees represented by ETUC and management represented by BusinessEurope (called UNICE before 2007), CEEP and UEAPME. The Council of Ministers plays a role as it can adopt agreements of the social partners as Council Directives. A marginal role if any is played by the EP. These actors and their reasons for supporting or criticizing the social dialogue will now be introduced.

The European Commission, or to be more precise DG Employment and Social affairs, supervises the social dialogue. According to Article 138 (1) EG the Commission ensures a balanced support for the parties. The Commission is not directly involved in the negotiations but its proposal forms the starting point for negotiations. The Commission determines which organisations are consulted during the social dialogue. Agreements presented to the Council are first checked by the Commission for representativeness of the parties involved, compatibility with Community law and impact on small and medium sized industries. The Commission considers the social dialogue as a ‘key to better governance’. The social dialogue was introduced by the Commission to reconcile the trade unions with the 1992 programme and to make the social dimension more tangible. The Commission is also the strongest supporter of the social dialogue. Although the Commission surrendered some of its powers under the Social Dialogue procedure to private actors, Obradovic (2001, p. 89 f.) argues that the Commission profits from this procedure because it makes it possible to outmanoeuvre the Council of Ministers.

The ETUC, the umbrella organisation for labour unions set up in 1973, has 82 member organisations from 36 European countries and all fields of industry. This heterogeneity makes internal decision-making difficult. The ETUC is under the control of the national trade unions and negotiation mandates are given to the ETUC on a case-by-case basis by its members. Despite these unfavourable organisational characteristics, the ETUC is normally described as being in favour of the social dialogue procedure.

The Commission recognises three cross-industry employers’ associations as participants in the social dialogue: BusinessEurope, CEEP and UEAPME. BusinessEurope has 40 members from 34 states and can trace its history back to 1949. However, it was not before the 1970s that UNICE started to represent the interests of its members and only at the 1991 IGC that the employers opened up to the idea of bargaining at European level. The reluctance to European level bargaining with trade unions dwindled with the extension of QMV and thus the disappearance of the veto position of any one member state. Under unanimity the employers could

61 Benedictus, p. 31-32.
63 Dolvik, Visser, in Compston/Greenwood p 19.
64 <http://www.etuc.org/r/5>, accessed on 25 November
65 Dolvik/Visser, p. 15.
66 Benedictus, p. 29.
rely on the UK to block any European social policy advances. CEEP represents public and formerly public enterprises as public enterprises that were privatized remained members. Willingness of the CEEP to participate in the social dialogue is considered to be bigger than from BusinessEurope. In social dialogue negotiations CEEP and BusinessEurope coordinate their positions. UEAPME is the employers’ European umbrella organisation for crafts, trades and small and medium enterprises. 83 organisations from 36 states are members of UEAPME. UEAPME is a late-comer to the social dialogue. In 1996, unhappy about its exclusion from the negotiation concerning parental leave and part-time work, it went to the Court of First Instance to gain access. UEAPME asked the CFI to annul Directive 96/34/EC (Parental Leave Directive) because the Directive was the result of a negotiation between ETUC, UNICE and CEEP in which UEAPME was not involved. The CFI ruled that the representativeness of the involved actors was sufficient and declared the case inadmissible because UEAPME was not individually concerned. In 1998, the same year the CFI delivered its judgment, the UNICE and UEAPME signed an agreement on the UEAPME’s participation in the social dialogue. As a result, the UEAPME withdrew its complaint about the Part-Time Work Directive and its appeal concerning the Parental Leave Directive.

In general the Council supports involvement of management and labour at a European level (see Compston, p. 98 ff.). Not one member state was against the social dialogue procedure at the time of its creation, except maybe the UK which did not sign the social protocol. The fact that there is only a very limited number of Directives based on the social dialogue is not due to the unwillingness of the Council but the social partners. In fact, the Council transformed the few agreements that the social partners asked them to transform into Directives without ado. The reasons given for the supportive stance taken by the Council in official documents are rather vague. They stress the need for dialogue between the social partners and that this dialogue is needed to bring about the single market. Compston (p. 106) points out that the concept of social partnership existed in most member states and that the political benefits created by the social dialogue for governments are high (easier implementation, content electorate) and the costs low (it is still the Council which adopts the Directives under the social dialogue procedure).

The most critical towards the social dialogue amongst the institutions is undoubtedly the EP. As it has no formal role in the social dialogue procedure this is understandable. During the negotiations leading up to the Amsterdam Treaty the EP unsuccessfully pushed for a formal role for itself in the social dialogue procedure (Obradovic, p. 91). However, the position of the EP is not consistent over time. Obradovic (p. 93 f.) distinguishes three phases: the EP’s support of the involvement of the social partners in the mid 1980s was followed by a phase in the early 1990s in which the EP was in favour of the social dialogue but at the same time

68 Branch and Greenwood, p. 41 f.
69 Benedictus, p. 30-31.
72 Benedictus, p. 31.
73 Branch/Greenwood, p. 64.
74 Some students of democracy could actually think that circumventing the EP in a legislative process would be a threat to the democratic legitimacy of the acts thus adopted. However, the ECJ knows better. In UEAPME v Council (T-135/96, [1998] ECR II-2335, para. 89) the ECJ argued that it is enough to ensure participation of the peoples in some other way, in this case by involving the social partners under the condition that their representativeness is guaranteed.
demanded a formal role for itself, then, in the late 1990s, the EP started to openly criticise the social dialogue procedure.

The results of the social dialogue
The cross-industry social dialogue has so far led to the adoption of three Directives concerning parental leave\(^ {75} \), part-time employment\(^ {76} \) and fixed-term work\(^ {77} \) and two agreements concerning temporary workers and teleworking.

In 1996 the Council adopted a Directive regulating parental leave which was the result of an agreement between ETUC, UNICE and CEEP. This Directive grants minimum parental leave rights of three months to working parents on the grounds of birth or adoption of a child. The agreement is generally considered to be rather meager in substance as it only concerns unpaid leave, specification of most issues is left to the national level and most member states had stricter regulations in place already.\(^ {78} \) The significance of this first agreement is thus not its contents but that it was concluded at all. Although the procedure already existed for a number of years no results had been produced and the Commission apparently threatened to remove the procedure at the Amsterdam IGC.\(^ {79} \) With this agreement the social partners showed that they were actually able to reach agreements under the social dialogue procedure.

The second agreement concluded by ETUC, UNICE and CEEP concerns part-time employment and also took the form of Council Directive. In this agreement both unions and employers made considerable concessions. The unions agreed to identify and eliminate obstacles to part-time work (clause 5 (1)). Some unions even withdrew their support of the agreement because of these concessions. The employers, on the other hand, agreed to adhere to the principle of *pro rata temporis* (being in proportion to the length of time involved) (clause 4 (2)).\(^ {80} \) Branch and Greenwood (p. 59) contribute this successful negotiation again to the upcoming IGC. They argue that the social partners wanted to show their ability to use the social dialogue once again.\(^ {81} \)

As mentioned above, UEAMPE felt excluded from the negotiations of these first two agreements and took legal action. However, UEAMPE managed to conclude a cooperation agreement with UNICE in 1998 and is now involved in the social dialogue procedure.

The third agreement that was adopted as Council Directive concerned fixed-term work. Its content is similar to the agreement on part-time work (for example the principle of *pro rata temporis*) and lays down the principle of non-discrimination for fixed-term workers. Again, many issues concerning fixed-term work are to be decided on national level. Branch and Greenwood (57, 59, 62 f.) conclude for all three agreements that UNICE wanted to avoid legislation and/or Commission initiatives and thought negotiated agreements the lesser evil.

\(^ {75} \) Council Directive 96/34/EC of 3 June 1996 on the framework agreement on parental leave concluded by UNICE, CEEP and the ETUC.

\(^ {76} \) Council Directive 97/81/EC of 15 December 1997 concerning the Framework Agreement on part-time working concluded by UNICE, CEEP and the ETUC.

\(^ {77} \) Council Directive 1999/70/EC of 28 June 1999 concerning the framework agreement on fixed-term work concluded by ETUC, UNICE and CEEP.

\(^ {78} \) Dolvik, Visser 27-28. The agreement is also rather short consisting of only four clauses and a number of sub-clauses.

\(^ {79} \) Benedictus, p. 36.

\(^ {80} \) Benedictus, p. 36.

\(^ {81} \) This agreement is again rather short and consists of roughly two pages containing six clauses with a number of sub-clauses.
Besides these three agreements which were adopted as Council Directives, the social partners negotiated in 2002 a legally non-binding agreement on teleworking which lays down the working conditions for these kinds of workers. An ad-hoc group will prepare a joint report on the implementation measures taken. In addition, the social partners issued a number of joint statements covering subjects such as the Community’s strategy for more employment, mobility of workers, vocational training and the social dialogue itself.\textsuperscript{82}

\textit{The sectoral dialogue}  
So far only the inter-sectoral social dialogue has been discussed. However, the same procedure can be utilised by sectoral interest groups. Three sectoral agreements were adopted as Council Directives.\textsuperscript{83} Benedictus et al report that ‘between 1978 and 2002, 230 results have been achieved in the sectoral social dialogue, against 40 in the inter-sectoral dialogue’\textsuperscript{84} Only 20 of these were framework agreements, 210 were joint statements.\textsuperscript{85} The leading sector was the telecommunication sector with 32 results by 2002.\textsuperscript{86}

\textit{Cases in which the social dialogue failed}  
Several attempts for a social dialogue were made which can be described as failed. They concern – without any guarantee for completeness - the European Works Councils, the burden of proof in cases of sex discrimination, sexual harassment, consultation in national enterprises and the regulation of working time. Three of these attempts – namely the European Works Councils, the burden of proof and working time - will be described in short.\textsuperscript{87}

The first attempt to conclude a social dialogue under the Social Protocol concerned Works Councils. Works Councils are meant to facilitate information and consultation of employees in their firms. However, the member states in the Council were divided concerning the necessity of regulating such councils at a European level – as were the representatives of the employers.\textsuperscript{88} Moreover, while employers presented by UNICE preferred a non-binding recommendation, the employees presented by ETUC wanted a legally binding document. However, the Commission was very much in favour of regulating Works Councils at a European level and in 1990 had produced a proposal for a Directive. This pushed management to formulate its own position. If they could not prevent European level regulation at least they could try to make it non-binding. With the introduction of QMV and the exclusion of the UK by virtue of the social protocol and thus an increased chance that a binding Directive would be adopted in the Council, UNICE also became more willing to participate in formulating binding regulations on a European level (Falkner, p. 103). Finally, negotiations between the social partners were started. However, at the last minute UNICE withdrew as a reaction to the rejections

\textsuperscript{82} Benedictus, p. 32 ff.  
\textsuperscript{84} Benedictus, p. 46.  
\textsuperscript{85} Benedictus, p. 48.  
\textsuperscript{86} Benedictus, p. 54.  
\textsuperscript{87} In the cases of sexual harassment and consultation in national enterprises negotiations were rejected by UNICE (Falkner, p. 150).  
\textsuperscript{88} Falkner, p. 98 ff.
of the compromise text by the British employers’ federation and the social dialogue ended before a decision was taken. Nevertheless, in 1994 a European Works Council Directive (Directive 94/45/EC) was adopted by the Council. Despite the fact that the social dialogue in the case of works councils failed, Falkner (p. 107 ff) reports that the Commission’s proposal took the points the social partners had already agreed upon into consideration.

The Burden of Proof Directive (Directive 97/80/EC) can be seen as another failed attempt to bring about legislation via the social dialogue. In 1995, the interest groups representing employees and employers gave their opinion on the proposed Directive. The Union of Industrial and Employers’ Confederations of Europe (UNICE 1995) response to the Commission started with stating that the European employers support the elimination of sex discrimination and the effective application of Community law. They also agreed that plaintiffs could sometimes have difficulties verifying their allegations and that in certain cases “the burden of proof may need to be interpreted with more flexibility to allow proper investigation of the complaint”. However, they did not think that the EU should act on this issue. They argued that there is no reason for such a step because the member states already have systems that modified the burden of proof and that the ECJ case law takes account of the difficulties of plaintiffs. Thus, the proposed Directive would have no added value. The European Association of Craft, Small and Medium-sized Enterprises (UEAPME) took the same point of view as UNICE: “It should not be up to the entrepreneur to prove that he hasn’t discriminated on the basis of sex” an UEAPME official said (European Voice, vol. 2, no. 14, 04.04.1996). The European Trade Union Confederation (ETUC) on the other hand, supported a shift in the burden of proof to the employer (European Voice, vol. 2, no. 14, 04.04.1996). Negotiations between the social partners never started.

Another example is the amendment of the Working Time Directive (Council Directive 93/104/EC). In 2003 the Commission had published a Communication on how to reform the Working Time Directive (COM (2003) 843). The Council of Ministers considered the Communication to be the first step in the consultation process of the social partners. Probably because the Communication of the Commission was not officially directed to the social partners at all, the Commission called upon the social partners to give their opinions on a new Directive which were published in a second consultation paper in May 2004 (SEC (2004) 610). Their opinions on a reform of the Directive were very different. The ETUC was in favour of stopping the practice of opt-outs and against making a twelve-month reference period the norm. Moreover, ETUC was against the introduction of the concept ‘inactive part of on-call time’ into the Directive (SEC (2004) 610, p. 3). In contrast, the other two social partners that would have been part of the social dialogue procedure, UNICE and the European Centre of Enterprises with Public Participation and of Enterprises of General Public Interest (CEEP), were in favour of the opt-out provision, of the twelve months reference period and of defining inactive on-call time as distinct from working time (SEC (2004) 610, p.3-4). The division between employee and employer associations on the reform of the Directive is not restricted to these three organizations. Basically all European employee’s associations that gave their opinion had a similar point of view than ETUC (for example The European Transport Workers’ Federation and The European Federation of Public Service Unions), and all employer’s associations

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agreed with UNICE (for example Comité Européen des Fabricants de Sucre and Hotels, Restaurants and Cafés in Europe) (SEC (2004) 610, p. 5-7). At the end of the consultation paper the Commission invited the social partners to start negotiations on a new Directive. However, the social partners could not agree to start negotiations. The highly incompatible positions of the employee and employer associations seem to have been the main reason for them to not open a social dialogue on the reform of the Working Time Directive. A comprise on the main issues would have been difficult. Moreover, not initiating a social dialogue could therefore be a sign that at least one of the social partners thought that the normal legislative process would lead to a result close to its own position. In the case of the Working Time Directive the odds were in favour of the employers as most member states as well as the Commission signaled that they were in line with UNICE’s position. Thus, the employers’ side understandably preferred the high chance of getting its position through via the normal legislative procedure above having to enter into negotiations with the employees’ side.

Conclusions
Although a number of legal acts resulted from the social dialogue, it is not the success story it is often sold as by the Commission and the social partners. Why does the social dialogue lead such a rather marginal existence next to classical law making procedures? One explanation is the low level of organisation of some industries at a European level and/or disagreement in a sector on how to regulate the sector. In addition, the party which expects a better outcome from classical law making procedures, for example because it has better access to the Commission or it knows important EU institutions share its opinion, has no incentive to agree to open a social dialogue which is after all characterised by compromise.

3.4 A prime example of self-regulation?: The advertisement industry

An example often referred to by the Commission and other actors as representing some kind of exemplary form self-regulation is found in the advertisement industry. In 2004 the advertisement industry represented by the European Advertising Standards Alliance (EASA, not to be confused with the European Aviation Safety Agency which uses the same acronym) concluded the Advertising Self-Regulation Charter (http://www.easa-alliance.org/page.aspx/237). Together with the Statement of Common Principles and Operating Standards of Best Practice (2002) and the Best Practice Self-Regulatory Model (2004) this document is meant to ensure ‘that advertising is legal, decent, honest and truthful’ (briefing of the EASA, June 2008, http://www.easa-alliance.org/Search/page.aspx/18?Request=briefing briefing June 2008, p. 2). The fact that self-regulation of the advertisement industry is often mentioned as a good example of self-regulation on a European level makes it necessary to take a closer look at what the EASA is, what the self-regulation charter contains and whether it is indeed a purer form of self-regulation than the ones described in the previous case studies.

The actors involved
The EASA consists of national self-regulatory organisations and organizations representing the advertisement industry and is based in Brussels. With the establishment of the EASA in 1992 the advertisement industry wanted to prevent the Commission from issuing detailed legislation concerning advertisement. This was a direct reaction to a request by the Commissioner for Competition, Leon Brittan. The EASA’s declared aim is ‘to promote legal, decent, honest and truthful advertising rules.’ The EASA tries to achieve this by coordinating moni-
toring processes, the handling of cross-border complaints and providing best practice recommendations. At the same time, the EASA wants to provide ‘detailed guidance on how to go about advertising self-regulation across the Single Market for the benefit of consumers and businesses’. Today the EASA consists of 33 national Self Regulatory Organisations (SROs)\textsuperscript{90} and 16 advertising industry members (advertisers, agencies, media). The EASA is funded by membership fees and monitoring exercises, special projects and the sale of publications.

The most important interlocutor for the EASA on a European level is the European Commission, more specifically the Directorate General (DG) for Health and Consumers. Not only was it the Commission threatening to regulate the advertisement sector that lead to the establishment of the EASA but also the reports of the EASA are at least implicitly addressed to the Commission. In addition, the EASA does not become tired to stress how satisfied the Commission is with the work of the EASA.\textsuperscript{91} The Commission itself mentions the advertisement industry’s approach to self-regulation as a good example of an efficient self-regulatory system which becomes clear from a report following three discussion meetings between Commission officials, the EASA and other interested NGOs held in 2005 and 2006 (DG SANCO 2006).

The advertising self-regulation at European level

The overarching self-regulation document is the Advertising Self-Regulation Charter in which the EASA stresses its commitments to self-regulation as a ‘the best way to maximise confidence in responsible advertisements – for consumers, competitors and society’. To enhance this confidence the charter suggests that common principles and standards of best practice should be applied throughout Europe. However, at the same time the charter recognises that self-regulation needs to be backed by legislation in order to be effective and vice versa.

The Charter lays down ten principles that should apply to all national self-regulatory systems. Such a system should cover all forms of advertising, be adequately funded by the advertising industry, have a code of practices that has been drafted after consulting interested parties, have ‘due consideration of the involvement of independent, non-governmental lay persons in the complaint adjudication process’ (point 5), have an independent and impartial self-regulatory body which administers the code and handles complaints, handle complaints promptly, efficiently and free of charge for the consumer, provide training and advice to practitioners, contain effective sanctions and enforcement mechanisms\textsuperscript{92} and spread awareness amongst consumers and industry for the self-regulatory system itself. The EASA regularly publishes reports on how the national SRO’s live up to these standards. Two relevant documents of the EASA preceded the Charter: the EASA Best Practice Self-Regulatory Model from 2004 which contains the same principles as the Charter but presents them more comprehensively and the Statement of Common Principles and Operating Standards of Best Practice from 2002 lists similar principles but also contains some principles that cannot be found in the

\textsuperscript{90} SROs handle complaints, normally give copy advice (an ad is submitted voluntarily before publication or airing to the national SRO for evaluation), monitor ads to check that they comply with the code and in some countries they give pre-clearance (in a few countries where submitting an ad before publication to the national SRO is obligatory, for example, Ireland and the Netherlands (radio, TV) in case of alcohol commercials). In the Netherlands this SRO is called Stichting Reclame Code. Not all states that are member of the EU also have such SROs and some have more than one. Thus, not all member states of the EU are represented in the EASA. However, the home country of an SRO does not have to be a member of the EU in order for it to join the EASA (Switzerland, Turkey) nor does it have to be in Europe (Australia, Brazil, Canada, Chile, India, New Zealand, South Africa).

\textsuperscript{91} For example, on the website of the EASA we can read that in 1998 Commissioner Brittan acknowledged that the work of the EASA “had reduced the perceived need for legislative intervention”.

\textsuperscript{92} These sanction and enforcement mechanisms can include, for example, naming and shaming, non-publication and pre-clearance.
other two documents, like the duty for member SRO’s to cooperate or that the constitution and membership of all SRO’s should be published. In addition, reference is made to the International Chamber of Commerce’s Code of Marketing and Advertising Practice. The main guidelines for the advertisement industry contained in this code are: be fair, decent, honest, truthful, responsible, distinguishable (from, for example the editorial part of a magazine), protect children and respect privacy.

Thus, the EASA functions as a link between national SRO’s and the European Commission. With its Charter and the two accompanying documents the EASA gives guidelines what a good national self-regulatory system should look like and with its reports it tries to convince the Commission that the national SRO’s are doing a good job and that therefore no legislation is needed. Moreover, it manages cross-border complaints by putting complainants into contact with the relevant SRO in another state if necessary.

In addition to the Advertising Self-Regulation Charter, the Best Practice Self-Regulatory Model and the Statement of Common Principles and Operating Standards of Best Practice published by the EASA, different sectoral organisations have published guidelines and standards for their members on a European level. In case of the alcohol industry the EASA provided a platform for information exchange on the implementation of these guidelines.

Regulating the advertisement industry by law
Despite the fact that self-regulation in the advertisement sector is rather well developed and used as an example of good practice by the Commission, many issues concerning the advertisement industry have been regulated by Community law as well as national law. The following part introduces some of the Directives regulating advertisement. Only a few have to be listed here in order to show that the often praised self-regulatory system of the advertisement industry is restricted by an increasing number of Directives. This overview also shows that the shadow of the law is very real.


In addition, the member states have different national laws regulating the advertisement industry. France and Portugal, for example, have laws that prescribe the use of the French and Portuguese language respectively. Sweden has an alcohol act that contains, for example, the

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93 For the newest version of this code see http://www.iccwbo.org/policy/marketing/id8532/index.html.
94 For this purpose the EASA provides an online complaint form (http://www.easa-alliance.org/page.aspx/105).
95 Examples are the Common Standards for Commercial Communications from the European Forum for Responsible Drinking (EFRD) and the almost identical Guidelines for Commercial Communications for Beer from The Brewers of Europe.
rule that alcoholic strength must always be specified in commercial communication. Some
national laws demand the pre-clearance of advertisement for certain products and certain
media and some states limit commercials addressed to children.96

Conclusions
The advertisement industry established a coordinating organisation on a European level only
after being confronted with the threat of traditional legislation by the Commission. This
organisation plays a coordinating role bringing the national SRO's together or consumers in
touch with the relevant national SRO. It also represents the advertisement industry towards
the Commission and keeps the Commission satisfied with its reports on self-regulation based
on its code of conduct. Its declared goal after all is to advertise self-regulation. Nevertheless,
a lot of issues concerning advertisement have been regulated by law on a European level as
well as on a national level. Thus, self-regulation in the advertisement sector is limited by
these laws.

4 Conclusions

Officially the EU embraced the concept of self-regulation in order to address some of the per-
ceived deficits of EU decision making. These are the ever reoccurring problems of legitimacy,
transparency and efficiency. The climate for a new approach was good because political ac-
tors as well as the scientific community at that time embraced concepts such as deregulation
and decentralisation in general. Moreover, the Commission, which could gain influence by
sidestepping the other institutions, actively supported self- and co-regulation.

The expected advantages, like reduced decision costs, higher compliance and better partici-
pation, were used as arguments by the proponents to advertise self- and co-regulation. Most
of the arguments used, enjoy only little empirical support. However, the same holds true for
the expected disadvantages, such as lower compliance, lack of legitimacy and legal certainty,
brought forward by critics of self- and co-regulation. These critics can be found in the EP,
which has the most to lose from alternative forms of decision-making of all the EU Institu-
tions, and parts of civil society who worry about the formulation phase (participation) as well
as the monitoring phase (free rider problem, low compliance ) of self-regulatory acts.

To address these points of critique, self- and co-regulation became subject of regulation
through means of the IAA which mainly lays down the role played by the Commission in
processes defined as self- and co-regulation. However, the quantitative overview made clear
that self-and co-regulation play only a minor role in the overall legislative output of the EC.
It seems thus that self-regulation does not offer an attractive new institutional opportunity
for economic and social actors to influence European decision-making. Instead private actors
remain sceptical towards this form of regulation. Voluntary agreements are not necessarily
more effective as strategic options for private actors to attain their goals than active interest
representation in traditional legislative processes.

96 For example, in Greece advertisement for toys on television is prohibited from 07:00 to 22:00 hours, in Sweden, television advertising addressed to
children under the age of 12 is prohibited and in the UK no advertisement of products that are high in fat, salt or sugar.
What then is the result of this regulatory mechanism? Has it blurred further the distinction between public and private sector by transferring rule-making powers to private interest associations? The three case studies show that the line drawn between classical law making by public authorities and self-regulation by private actors is much thinner than is often suggested in official documents and academic literature. In the lawyers case we saw a strong involvement of a private interest group in the formulation phase of a traditional legislative process, resembling in many ways the characteristics of a self-regulatory system. In the case of the social dialogue, self-regulation is based on an institutionalized delegation of public rule-making powers to European associations representing employers and unions. The case of the advertisement industry seems to come closest to the standard definition of self-regulation, as it is initiated by and based on a voluntary agreement of private economic actors. Nevertheless, also here a strong legislative framework exists. Private actor participation in EU policy making remains to be linked to the hierarchical control and command chain, even when it takes the form of voluntary agreements.
Annex

Table 1: Initiatives of Self-regulation and Co-regulation per year (includes cases that have become obsolete)

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* Social Dialogue procedure, Treaty articles 138, 139
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INTERNET GOVERNANCE AND GLOBAL
SELF REGULATION
Building Blocks for a General Theory
of Self Regulation

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The following exposition sets out to identify the basic theoretical and empirical building blocks for a general theory of self-regulation. It uses the Internet as an empirical basis since its global reach and technical characteristics create interdependencies between actors that transcend national boundaries and allow for non-governmental forms of regulation to emerge. The current wave of globalization increasingly creates global interdependencies that open avenues to new forms of self-regulation. A study of the Internet from this perspective provides us with the conceptual tools needed to interpret these developments and develop tools to direct regulatory policies more effectively.

The first part of this exposition provides the theoretical building blocks by analyzing the concept of self-regulation. The second part provides empirical building blocks by analyzing the state of affairs of one of the most contested types of regulation on the Internet, its domain name system. The third part of the exposition integrates the findings of the first and second part of the inquiry and concludes by emphasizing the characteristics of the Internet and by accentuating the relevance of the Internet situation to the development of a general theory of self-regulation in a global context.

1 Theoretical building blocks

1.1 Internet Governance and Self Regulation

Internet governance comprises the institutional and procedural aspects of controlling the behavior of actors on the Internet. In perfect analogy to governance of the world outside the Internet, control of the Internet is based on the power to regulate and to enforce regulations. In both contexts self regulation seems to be an uncomplicated concept referring to situations in which the subjects of regulation are themselves also the creators and/or enforcers of this very regulation. In its simplest configuration, self regulation is the most primitive ordering mechanism of what once has been dramatically labeled the ‘state of nature’. In a more sophisticated form, self-regulation comprises a wide variety of different types of delegation.

The Internet is an information transaction network that is characterized by the prevalence of self regulation. The global and technical features of the Internet responsible for its distinctive
decentralized organization, renders it a perfect research object into self regulative processes. In many ways the Internet at-large can even be considered as one large self regulative system since its global reach renders no organization powerful enough to control the Internet in its entirety. Interaction on the Internet is primarily egalitarian in nature and typically based on the interaction between peers with a common interest. The technical architecture (e.g. Packet switching) and a widespread availability of knowledge and technological resources empower both individual users and private market parties and prevents states from obtaining extensive regulatory and enforcing powers. As a consequence the ability of states to control the Internet is very limited. Notably, the identification of all participating computers, which is essential for worldwide communication on the Internet, is regulated by a private corporation, the Internet Corporation for Assigned Names and Numbers (ICANN). The case of ICANN that will provide the empirical part of this inquiry, therefore serves as a case in point. In addition to providing insight into the specifics of Internet governance, the ICANN case will highlight some complications in the traditional conception of self regulation thus providing building blocks for a more balanced and complete theory of self regulation.

1.2 Self Regulation and Delegation

From a conceptual point of view, the first steps from a state of nature in building a society requires a primitive form of self regulation, that is, small groups of individuals regulating their own behavior, a phenomenon we label original self regulation. As cooperation becomes more complex and involves more people, larger groups tend to benefit from delegating their regulative powers. Delegation can taken on one of three forms; coordinate, superordinate and subordinate delegation. In its simplest form the regulative powers are delegated to a small subset within the group in order to coordinate behavior within the group. This type of coordinate delegation is very common and preserves the self regulative character of the original variety of self regulation. Within the context of public organizations coordinate delegation can take shape as advisory committees. Within the context of the Internet the responsibilities of system administrators and standardization committees are good examples of coordinate delegation. More advanced types of delegation involve delegation of regulatory powers to hierarchically higher level, superordinate self regulation, and delegation to a hierarchically lower level, subordinate regulation. Superordinate delegation is the kind of delegation treated by most classical delegation theories typically involving the delegation of regulative powers by the people to states and by states to organizations of states. On the Internet this type of delegation of regulative power is an exception (keeping the essential difference between actual power and formal authority in mind). The only examples of effective superordinate delegation on the Internet concern purely local affairs taking place within national territorial borders. The Internet shows some apparent examples of global superordinate delegation. One important contribution in the empirical part of this exposition is to show why in ICANN’s case this conclusion is deceptive. In classic delegation theories, subordinate delegation typically concerns the subordinate delegation of powers by organizations of states or by states to subordinate legislative and administrative levels like federal states (US), member states (EU),

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1 The sparse EU directives that are aimed at the regulation of the Internet prove this fact by their lack of real enforcement. E.g. The privacy of Internet users is principally regulated and actually protected by private communication arrangements mainly concerning technology (the architecture of the Internet, privacy enhancing technologies like anonymizing, encryption, relocation and filtering and p2p networking) and not by EU Directives 1995/46/EC on Data protection or 2002/58/EC on Privacy and Electronic Communications. The same holds for most other directives like the Copyright Directive 2001/29/EC.
provinces and counties.\textsuperscript{2} As opposed to coordinate delegation, both genuine superordinate and subordinate delegation cause a transition from self regulation to non self regulation by definition. Therefore, these latter forms of delegation, as the exposition of ICANN will confirm, are merely of indirect interest to the theory of self regulation. However, as the analysis of the ICANN case will show, \textit{quasi} superordinate delegation and subordinate delegation can play an important role in the development of self regulation of the Internet.

1.3 Causes of delegation relevant to self regulation

Delegation of regulative responsibilities can have various causes that appear relevant to self-regulation.\textsuperscript{3} In a number of cases the delegator attributes superior knowledge of or close contact with the subject matter to the delegate. In most cases of coordinate delegation the delegator institutes an internal expert organization to this aim which can take an advisory role or a regulative role, depending on the extent of expertise needed. The delegation of regulative powers to ICANN is an example. Other common arguments are the promotion of common interests (e.g. superordinate delegation to the EU by its member states), the need to match dissimilar interests of different groups of stakeholders (cf the coordinate delegation of regulative powers of domain name system-stakeholders to ICANN), the need to serve the specific needs of local communities (e.g. the subordinate delegation of powers by states to counties and municipalities, but also by the EU to EU states), the need for cost reduction or speed (delegation as an anti bureaucratic measure), and more generally the need for efficient and effective enforcement. The empirical evidence from the ICANN case however suggests that all these different arguments can be reduced to changes in the balance of powers that constitute changing delegator-delegate relations.

As the ICANN case will show in more detail, the complexities involved in these changing power relations can best be described and explained using a market frame of reference as opposed to a state frame of reference in which the processes are depicted as intentional political processes directed by state-based actors.

1.4 Delegation of Substantive, Procedural and Accountability regulations

The specific kinds of regulation that are delegated in all these transfers of regulative powers add even more to the complexity of the subject. An original self regulating group has a broad palette of regulative competences of which any subset can be subject of delegation. In its most extreme form, a group can transfer all regulative powers similar to the transfer of regulative powers in constitutional democracies from the “demos” to the representatives in parliament. In many cases of delegation only the power to regulate the behavior of regular subjects is transferred (substantive regulations). In in other cases, the authority to regulate the behavior of the rule applicants (procedural regulations) or a combination of both is transferred. Delega-

\textsuperscript{2} Modern delegation theories also focus on the delegation (or outsourcing) of regulative powers by private organizations to subordinate organizations.

\textsuperscript{3} The occurrence of these forms of delegation have all kinds of causes (also called reasons, grounds or motives, usually in retrospect) that can be relevant to the understanding of self regulation. Historically, changes (variation) in the actual balance of powers and unintentional (natural) selection processes (e.g. selection towards cooperative behavior) have caused (forced) delegation. In our time and legal culture these consequences are commonly presented as the results of idealistic choices based on fundamental political principles (democratic rights, economic freedom etc.) or as rational choices based on the need for efficient and effective communication, decision making and implementation. As the ICANN case will show the “fundamental” or “rational” considerations are actually dictated by the existing balance of powers.
tion of regulative powers presupposes supervision. This is why delegation involves the creation and enforcement of reporting rules and agreement on the consequences of a breach of the conditions of delegation. These types of rules, commonly referred to as accountability rules, are typically introduced the first time that an originally self regulating community coordinately delegates its regulative powers. As we will see in the ICANN case these accountability rules can also be subject to delegation.

Three classes of Self regulation: Original and Delegated (reinstated or introduced)

Following the previous description, delegation of regulatory powers tends to transfer the original self regulative powers of individuals and smaller groups to other individuals and groups. On this account original self regulation served as a precondition for the existence of delegation. In addition, delegation itself can logically be the origin of (non original forms of) self regulation. This class of self regulation can be called delegated self regulation. From a logical point of view, delegated self regulation comes in two varieties. The first variety occurs when a new delegatee group is created by a delegator. This type of delegated self regulation can conveniently be called introduced self regulation. The second variety occurs when self regulation is reinstated to an original group This kind of delegated self regulation can be called reinstated self regulation and is strongly associated with deregulation, the clearest example being a public organization (like a state) re-establishing original self regulation by delegation of regulative powers back to a private group. In order to assess ICANN’s situation adequately it is useful to keep the distinction between these three types of self-regulation into mind.

2 Empirical building blocks

In the previous section we have proposed a number of theoretical concepts and relations that we think are prerequisite to an adequate description and explanation of self regulation on the Internet. As indicated in the previous section, the introduction of a part of these concepts and relations is inspired by an empirical study into the regulative powers of the Corporation for Assigned Names and Numbers (ICANN). We think that ICANN is representative of the most important category of self regulative arrangements on the Internet, as these arrangements are characterized by the regulation of a global public interest by a global private organization, which is managed by the main subjects of the regulation themselves (interested parties or stakeholders). ICANN is a private organization, that regulates an important public issue (the identification of computers and websites on the Internet) and that is managed by its main stakeholders (including states). As a representative case of self regulation, the ICANN example renders initial validity to the proposed concepts and relations. The starting point of the following analysis of ICANN’s regulative powers and regulative procedures is the debate about ICANN’s supposed accountability deficit. An organization serving public interests is usually presumed to be accountable to the public. From a state frame of reference the public

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4 A variant of this introduced self regulation is the introduction of a new delegator to an existing self regulating group or existing self regulating groups, which usually will precede the introduction of a new (composite) delegate group. The situation in which a new delegator just imposes accountability on the existing self regulative group is equivalent to ordinary super-ordinate delegation of (in this case) the power to regulate accountability. The fact that the would be delegator can take the initiative shows that delegation (at least in these cases) is an effect of a changing balance of powers instead the result of idealistic or rational choices of the self-regulating group.

is commonly represented by a state or an organization of states (governmental supervision) and states are mainly accountable to the public through elections. The ICANN case not only shows that governmental supervision and elections are not viable as a part of the self-regulative arrangements on the Internet, but moreover it shows that technical characteristics of the Internet introduce competition.

ICANN’s accountability problem
ICANN manages the Internet’s Domain Name System (DNS). The DNS helps users find their way around the Internet by allowing a (unique) string of letters, the domain name, to be used instead of each computer’s unique Internet Protocol (IP) number. Domain names consist of several parts, representing levels within the naming structure, separated by dots. At the end of the domain name we find the Top Level Domain (TLD) which is divided into Country Code (cc)TLDs representing countries, like .uk and .ir, and Generic (g)TLDs representing general categories like .com and .org. To the left of the TLD we find the second level domain falling under the first and so on, resembling a standard classification system. The system is set up in this way in order to ensure unique naming on the Internet. It also allows for an easier, more efficient and less vulnerable way of translating the names into the IP numbers needed to contact the respective hosts. This process, called ‘resolving’ mimics a hierarchical naming system since it resolves the domain names level by level.

The top of the DNS consists of the root zone file and its ‘authoritative’ servers. The root zone file is simply a list of Top Level Domain (TLD) names and the IP numbers referring to the servers able to resolve the second level domain names falling under this specific TLD. First the TLD name gets resolved and the query gets directed to a server dedicated to resolve secondary level domain names falling under the respective TLD. This one in turn refers to the third level domain name server etc until the complete IP address is resolved and the host can be contacted. The root zone file is the master file from which the DNS gets its data. In effect, controlling the root means controlling the Internet because deletions and additions to this file affect the top of the Internet’s universe. If for example, the cc TLD of the Islamic Republic of Iran, represented by .ir would be deleted, eventually, none of the domain names containing the .ir TLD could be resolved anymore and consequently, the underlying web pages could not be accessed. Since domain names are scarce due to the fact that they need to be unique, and Internet users are affected by choices regarding TLDs, ICANN is said to set public policies.

In Klein and Mueller’s words:

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6 See THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2007b) ICANN general information (factsheet).
7 For the purposes of this paper, this rough sketch of domain name resolving suffices. For a more in depth treatment see NATIONAL RESEARCH COUNCIL (U.S.). (2005) Signposts in cyberspace: the Domain Name System and internet navigation, Washington, D.C., National Academies Press.
8 Authoritative servers are servers that get their information directly from the root zone file.
9 TLDs are divided in to general TLD’s like .org and .com etc and country code TLDs like .uk and .de etc. For an overview of registrations see the VERISIGN INC. (2005) The Verisign Domain Report. The Domain Name Industry Brief.
10 This is a simplification of reality. Caching makes it possible to directly access content avoiding the use of authoritative name servers. The data in the caches however needs to be updated regularly in order to guarantee the validity of the information. Eventually, the caches will also contain updated information regarding the deleted data (see op cit, note 2).
11 ICANN’s decision not to add the proposed .xxx domain name debate forms an interesting illustration, see ICM REGISTRY (2005) The Voluntary Adult Top-Level Domain (TLD) - .xxx. See also THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2007c) ICANN Publishes Revision to Proposed ICM (.XXX) Registry Agreement. ICANN Announcements. The question whether to add this TLD to the root zone file raises implications regarding freedom of speech, protection of citizens, privacy issues and so on. Cf LESSIG, L. R., PAUL (1999) Zoning Speech on the Internet: a Legal and Technical Model. Michigan Law Review. 98.
ICANN makes global public policy in a number of fields. It makes competition policy by controlling business entry into the domain name registry market and by determining the market structure of the US$2 billion industry. It engages in rate regulation, setting the base price for the majority of the world’s wholesalers and retailers of generic domain names. Indirectly, ICANN affects freedom of expression because its rules on trademark protection in domains set limits to public use of words, and its rules regarding registrant data are intended to make anonymous expression on the internet impossible. Many would say that ICANN also engages in taxation; it imposes per-domain fees on domain name registries and the fees have grown sharply over time. Finally ICANN’s powers are open ended; the entities it regulates must commit to implementing any further policies that the organisation should promulgate. ICANN’s regulatory and supervisory activities constitute global public policy of a type usually exercised only by governmental (or intergovernmental) entities.

Indeed, the power to set public policies is commonly held by (inter)governmental agencies. Unlike those agencies, ICANN lacks the appropriate mechanisms to constrain its decision making power and secure its accountability to the public. The following paragraphs examine two exemplary proposals to overcome this deficit and show that inadequate assumptions underlying these proposals caused an inadequate appraisal of ICANN’s accountability mechanisms.

Proposed solutions
Two exemplary solutions have been proposed to solve ICANN’s accountability problem: direct elections of a part of ICANN’s board of directors and intergovernmental supervision. The proposal to directly elect a part of ICANN’s board to reduce the accountability deficit needs to be seen against the background of ICANN’s legitimacy problem. When it was founded in 1998, ICANN’s board consisted of nine technical experts, nine user representatives and a president. None of them were elected by the Internet users. The transference of the DNS management from the US government to the not for profit corporation ICANN soon raised questions regarding its policy setting powers and led to a call to overcome this democratic deficit. In 2000, answering to fierce lobbying pressures, the board decided to have five out of nine user representatives directly elected by the Internet community. Despite its promising outlook, the project failed miserably. Of the estimated 375 million Internet users at the time, less than 0.01 percent actually voted. Failure of the experiment led ICANN to abandon the idea of direct elections in 2002. The second proposal, intergovernmental supervision would solve the legitimacy problem by making ICANN accountable to the international community. The cluster of proposals presented by the UN Working Group on Internet Governance (WGIG) is a recent initiative to this end. This type of proposal is mainly rooted

14 See ibid. note 130 and FROOMKIN, M. Ibid. Wrong Turn in Cyberspace: Using ICANN to Route Around the APA and the Constitution.
18 For ICANN’s post reform bylaws see THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2002, December 15) Bylaws.
19 WORKING GROUP ON INTERNET GOVERNANCE (2005) Report of the WGIG.
in the widespread concern regarding the alleged unilateral US power over the root zone file combined with a strong belief that internationalisation of Internet governance is a first step in overcoming the digital divide. Despite pressures from countries like Brazil, Russia and China at the UN World Summit on the Information Society (WSIS) in 2005 where the Internationalization of ICANN was at the top of the agenda, an agreement was reached to maintain the status quo.

None of the attempts to overcome ICANN’s accountability problem by implementing traditional state-based solutions succeeded. Whereas many causes might have led to the failure of the proposals, the more fundamental question is whether we actually need state mechanisms to control and influence ICANN’s DNS decisions. In the next paragraph we show that DNS context lacks essential conditions for applying a state model to assess and design its accountability mechanisms. In order to see the reason, it is useful to examine these conditions within their traditional context; that of the state.

The State Frame of Reference

Democratic representation is designed to avoid governmental power abuse by monitoring and influencing the decisions that are taken in the public interest on behalf of the people. This principle underpinning the election experiment also forms the basis for the supervision proposals. Intergovernmental supervision influences decisions by holding the organization accountable to the international community, represented by state officials. So both instruments, elections and intergovernmental supervision, are based on the same principle, i.e. to constrain and influence decision making powers. Representation through elections provides the ‘bottom up’ means and intergovernmental supervision provides the ‘top down’ means of achieving this goal.

The reason why citizens require constraints on governmental decision powers is due to their degree of dependency. The lack of alternatives to government decisions made in the public interest requires citizen participation. This is why accountability enhancing mechanisms are built into our constitutions. It also forms the basis for insisting on democratic decision making in general. In ICANN’s case, dependency and a lack of alternatives lie at the heart of the governance debate and have formed the basis for the proposed solutions. The next section shows that it is exactly at this point where the applicability of the state frame of reference breaks down.

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20 The source of the power is; DEPARTMENT OF COMMERCE (USG) & NETWORK SOLUTIONS, I. N. (1998) Amendment 11 to Cooperative Agreement Between NSI and U.S. Government. While NSI continues to operate the primary root server, it shall request written direction from an authorized USG official before making or rejecting any modifications, additions or deletions to the root zone file”. See also MUELLER, M. (2005) US Unilateral Control of ICANN Backfires in WSIS. Pointechbot.
21 See for the UN’s commitment; WORLD SUMMIT ON THE INFORMATION SOCIETY (2003, December 12) Plan of Action.
22 Europe has shown concern about the US position since the ninety’s. At the WSIS Europe held an intermediate position pleading for an independent forum which would act as a platform for all stakeholders, REDING, V. (2005) Opportunities and challenges of the Ubiquitous World and some words on Internet Governance. IN MEDIA, E. C. R. F. I. S. A. (Ed.).
Factual misconceptions

The UN proposals to put the DNS under intergovernmental supervision are based on the assumption that the US controls the root zone file. Since the Internet is a trans-national medium affecting the global public interest, our democratically informed sense of justice tells us that uniform control by one nation is not fair and that every individual should have a say in decisions affecting the global public interest. This is the source of the UN’s call for intergovernmental supervision. In the eyes of many nations, the US seems to have a disproportional amount of power over the root zone file and in fact, it has the last say regarding changes in ICANN’s root zone file\(^{27}\). Whereas the root zone file is not much more than a telephone directory listing names (TLDs) and IP addresses of authoritative servers, it does form the spine of the DNS. It is the informational source of the 13 authoritative TLD name servers, i.e. the servers that obtain their information directly from the root zone file. In addition to this, the US role seems strengthened by the fact that ten of these thirteen authoritative root zone servers are located on American soil. Three of these servers are even run by the American government.

Appearances however, are deceptive. The US power over the root zone file is rather overrated. The availability of alternative root zone files and root zone servers systems operating independently from the US/ICANN based system diminishes the US’ power significantly. From a political point of view the most interesting alternative is the European Open Root Server Network\(^{28}\) (ORSN), which consisted of 13 independently operating root zone servers thus providing a European alternative counterbalancing US power. The ORSN had two operating modes. The ICANN based operating mode served as the normal mode and involved daily synchronization with the ICANN based system with one exception. Removed TLDs are not removed from the ORSN root. For example if ICANN for political reasons would remove a country code TLD on instigation of the U.S. this TLD would not automatically be removed from ORSN. The ICANN independent mode did not synchronize automatically and was to be activated whenever the political situation required this, for example, when a possible modification or downtime of ICANN’s root appeared or was expected\(^{29}\). The ORSN servers were primarily placed in Europe. The interesting point about this alternative is that a possible US power abuse by deleting TLDs, e.g. .ir, from ICANN’s root zone file would not prevent the ORSN users from reaching the deleted domains\(^{30}\). The moment that the .ir TLD name was deleted from ICANN’s root zone file, Internet Service Providers could (and pressured by their customers probably would) switch to the ORSN operated DNS servers and their users would be able to reach the Islamic Republic of Iran without difficulty. The ORSN tells us something about the way in which power imbalances are dealt with on the Internet (by private actors). The fact that after six years of service the project was put to a halt due to a lack of financial resources suggests a changing conception of the threat and dominance of US power on the Internet.

The US power over the root zone file however, is not the only overrated issue in the current Internet governance debate. There is an even more persistent and fundamental assumption

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\(^{27}\) Op cit. note 23.


\(^{29}\) Ibid.

\(^{30}\) Apart from the ORSN, there are many satellite servers (copies of the authoritative server). It remains to be seen how many of them are likely to copy unwanted US deletions in the root zone file.
which is also part and parcel of the US power debate. It concerns ICANN’s sovereignty, or monopoly (if put in market terminology) regarding the DNS. The issue at stake is (again) determination of the root zone file content, and its focus is on possible additions to the root zone file\textsuperscript{31}.

In order to maintain uniform resolvability, i.e. guaranteeing that every connection, whether in Spain or Alaska, has equal access to identical information, maintaining one single root zone file is elementary. At the moment ICANN manages 18 gTLDs and slightly over 240 ccTLDs\textsuperscript{32}. ‘The Internet however, is no longer the kind of thing where only six guys in the world can build it’\textsuperscript{33}, and ICANN has been very slow in expanding the domain name universe with additional TLDs. As a result, alternatives have been developed catering for the increased demand for new TLDs. As from 1996 onwards, companies have been offering competing TLDs and hence complete domain names\textsuperscript{34}. The most important commercial TLD providers simply offer an alternative system of root zone servers that include ICANN’s root zone file. On their own root zone server system they offer registration for additional TLDs and complete domain names. In order to increase access to the newly registered names they contract ISPs thus providing access to the ICANN independent TLD’s.

One of these companies, New.Net\textsuperscript{35}, had contracted Tiscali with over 4.8 million active European users\textsuperscript{36}, Earthlink (Atlanta) also with over 4.8 million active subscribers\textsuperscript{37} and Tutopia in South America with 2.7 million registered users\textsuperscript{38}. New.net was just one of many companies offering alternative domain name services on the TLD level. Other exampled offering alternative root server systems were for example UnifiedRoot\textsuperscript{39} and Public-Root\textsuperscript{40}. In addition, China also operates on this market. It has launched alternatives to .com domain names using Chinese characters\textsuperscript{41} that are directly accessible to 110 million Chinese internet users\textsuperscript{42} and are not accessible outside China without configuration changes\textsuperscript{43}.

In sum; the assumptions informing the proposals to implement traditional state-based mechanisms in order to monitor ICANN’s operations are based upon factual misconceptions. Neither the US power over the root zone file, nor ICANN’s power regarding the Domain Name System (DNS) in general, are strong enough to justify the implementation of classic state based accountability mechanisms. The availability of alternatives makes the state model inadequate as a frame of reference by which to judge and design ICANN’s accountability.

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\textsuperscript{31} The debate regarding the US domination of the root zone file focuses mainly on the possible deletions of existing TLD’s due to US influence.
\textsuperscript{34} AlterNic, eDNS and Iperdome for example were early alternative DNS providers.
\textsuperscript{36} TISCALI (2007) About us.
\textsuperscript{38} RIGHTNOW TECHNOLOGIES (2005) RightNow Powers CRM For Top Latin American Network Services Provider.
\textsuperscript{39} UNIFIED ROOT (2006) FAQ.UnifiedRoot also works on a commercial basis in order to promote the liberalisation of the domain name market. It has also contracted Tiscali in order to provide access to their extended universe see also; TECHREPUBLIC STAFF (2005, November 26) Dutch tech firm want to rid the Web of the .com. TechRepublic.
\textsuperscript{40} PUBLIC-ROOT (2003) Public-Root (homepage). Public root offers its global root server system as well to alternative domain names. It has recently launched a TLD system in Turkey see TDN STAFF (2005, June 23) Top Level Domains Launched in Turkey. Turkish Daily News. Istanbul.
\textsuperscript{41} PDO STAFF (2006, February 28) China Adds Top-Level Domain Names. People’s Daily Online.
mechanisms to the public. In the next paragraph we propose an alternative, more promising frame of reference and discuss its advantages in assessing the DNS market and ICANN’s accountability mechanisms.

The market frame of reference as an alternative
The availability of alternatives has caused the State frame of reference to break down as a viable model to asses and design ICANN’s accountability mechanisms. The availability of alternative root server systems and competing TLD providers renders the need for traditional political accountability mechanisms superfluous. There is however another widely accepted, traditional model available that does seem to fit ICANN’s situation perfectly. The market model is able to provide us with a better understanding of the economic reality, i.e. the expanding competitive environment, in which ICANN operates. The accompanying notion of accountability might shed a new light on ICANN’s accountability requirements and its curious hybrid organizational structure.

In a market situation the notion of accountability to the public takes on a completely different form. The traditional State-based principle of accountability to the public gives way to an accountability mechanism through which citizens influence decision making not by representation but by voting with their feet. As opposed to political accountability, market accountability is based upon informal economic mechanisms rather than highly formal hierarchical control types of accountability. On the market place the ability of a company to maintain and attract customers is the main indicator of the company’s accountability to the public. On a market the principle of political accountability is replaced by a company’s ability to respond to their consumer needs. Actual customer choices are the key constituents of the main accountability mechanism of the market. On the Internet, the actual competitive character of the TLD- and root server systems markets forces a shift in conceptual frame of reference upon us. Consequently, ICANN needs to be assessed using a market rather than a State frame of reference. In the previous paragraphs the focus has been on an adequate description of the DNS and the supply side of the services involved. The next paragraph focuses on the demand side of the DNS services and shows that ICANN’s current stakeholder model is a new organizational arrangement based on market principles and a variety of consumer demands.

ICANN revisited
The analysis thus far established that ICANN is a market party. Instead of using a normative model in order to examine the adequacy of ICANN’s accountability mechanisms, this paragraph will provide a description of ICANN’s actual accountability to the public by focusing on the role that States and private Internet users play within ICANN’s organisational structure. The latter part of this paragraph explains ICANN’s hybrid structure in the light of the market model.
As Figure 1 above shows, ICANN’s board is its central policy making body. It consists of a President and fourteen directors deciding by a majority vote. Eight directors are appointed by the (board-independent) Nominating Committee (NC) based on the criteria of geographical diversity and technical skills. Two directors are appointed by the Address Supporting Organization (ASO), two by the Generic Names Supporting Organization (GSNO) and two by the Country Code Supporting Organization (CCSO). These fourteen directors in turn, annually elect the President.

Within ICANN, the Internet users are represented in a variety of ways. ICANN’s prime provision for empowering the global individual Internet users is the At Large Advisory Committee (ALAC). Operating on the same level as the technical advisory committees (the Security and Stability Advisory Committee, the Root Server System Advisory Committee and the Technical Liaison Group), the ALAC is purely advisory in nature, informing ICANN’s board directly about the Individual user’s concerns.

Similar to the ALAC, the governmental concerns are addressed by the Governmental Advisory Committee (GAC) consisting of representatives of national governments, governmental organisations, and regional bodies like the European Commission. Its task is to provide advice on public policy issues affecting governments. Like the ALAC, the GAC’s influence is advisory and informative. Since ICANN’s board is obliged to search for a mutually acceptable solution in the case of diverging views, it seems to be more powerful than the ALAC.

44 Art II, Section 1 Bylaws ICANN at THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2002, December 15) Bylaws.
45 Ibid, Art. VII Section 4 and 5
46 Ibid, Art. VI Section 2(1)
47 Ibid. Art XIII Section 2
49 THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2007a) Governmental Advisory Committee (homepage).
51 Op cit, note 44, Art XI, Section 2(1)(j)
The scope of its advice however, concentrating on the interaction between ICANN’s policies and national laws or international agreements\(^{52}\), limits the GAC’s power significantly\(^{53}\).

The ALAC is not the only way in which the Internet users are represented. Within the NC they occupy half of the voting seats\(^{54}\). As such they have a large say in the appointment of eight ICANN directors. In addition, the NC also appoints half of the CCSO’s Council responsible for developing ccTLD policies, which in turn appoints two ICANN directors\(^{55}\). They are also represented by nine out of the twenty-one voting members in the GSNO which is responsible for developing gTLD policies\(^{56}\) and again, the appointment of two ICANN directors. In short, the Internet users are directly involved in the appointment of ICANN’s directors and the development of TLD policies.

The inclusion of both users and state representation within ICANN poses difficulties for the State frame of reference. Specifically the inclusion of Governmental representation and ICANN’s commitment to mutually acceptable solutions is a breach with a fundamental feature of a modern state, namely its sovereignty\(^{57}\). From a market perspective the inclusion of both governments and private users is also unusual, but it does allow for a natural explanation.

As was noted before, on a market, the accountability to the public is simply constituted by the organisation’s capacity to attract customers and its ability to maintain to serve them according to their needs. Since States are generally more inclined to foresee conflicts with national legal frameworks affecting national citizens, they obtained a specific status within ICANN. The strategic relevance of government and individual user inclusion can be seen in the light of ICANN’s awareness of potential competition and its fear of Internet splits\(^{58}\). Since on the Internet decisions regarding the DNS can have implications for national legislation and existing treaties, keeping in line with the legal frameworks has several advantages. It improves ICANN’s responsiveness to the governmental needs and reduces the chance of premature splits of the Internet along territorial lines. As a consequence it helps ICANN to maintain its market share.

Inclusion of individual customer representatives within ICANN’s organisational structure is also in line with the market model. It provides the most direct way to monitor consumer needs. In fact, the incorporation of both private users and governmental organisations as customers within its formalised organisational structure actually takes the notion of responsiveness one step further. Instead of the traditional sales monitoring, relying on market survey’s and customer satisfaction reports (generally outsourced to other companies), customer participation in company decision making is quite a revolutionary way of keeping in line with

\(^{52}\) THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS Governmental Advisory Committee (about).

\(^{53}\) For an example of public policy discussed within the GAC concerned the cooperation of law enforcement with regards to the potential .xxx TLD, see THE INTERNET CORPORATION FOR ASSIGNED NAMES AND NUMBERS (2006, March 28) GAC Communiqué -Wellington, New Zealand. Wellington.

\(^{54}\) Op cit, note 48, ICANN’s bylaws, Art VII, Section 2

\(^{55}\) Ibid, Art IX, Section 3(1)

\(^{56}\) Ibid, Art X, Section 3(1)

\(^{57}\) See United Nations Charter Art. 2(1)

the customer’s needs. In effect, ICANN has taken the market’s prime accountability concept, responsiveness, to a higher level in its need to maintain and increase its market share. In this sense, judged from a market frame of reference, ICANN’s accountability mechanisms are substantially advanced and sophisticated, and judged by its market share they are rather effective as well.

Conclusion
The origin and the development of ICANN’s regulative powers can be described and partly explained by the theoretical concepts introduced in the first paragraph. Originally the identification of computers on the Internet was regulated by the users (military and scientists) of the Internet themselves (original self regulation). Soon the expanding dimensions and diversity of the Internet brought about coordinate delegation of this task to system administrators (e.g. Jon Postel and the originally informal organization IANA). In 1988 the Internt Assigned Numbers Authority (IANA) was contracted by the US ministry of defense and in 1998 ICANN was established and contracted by the US ministry of commerce. The first contract did not suppose delegation of regulative powers to the US government because of its narrow scope (national defense research). The second contract (the Memorandum of Understanding (MOU) between the US department of commerce and ICANN) does presuppose superordinate delegation of the regulation of the DNS. More than that, the MOU stipulates that the permanent transition to private sector DNS management requires that the private sector will first acquire the capability and resources to assume the responsibilities related to the management of the DNS. As we have seen, this presupposition of superordinate delegation denied the actual balance of powers characterized by a multitude of stakeholders (many of which are non US and a number of which are states). Paradoxically, ICANN’s actual organizational structure, although based on the MOU and on cooperation with the US department of commerce (both suggesting a supervisory relationship), almost completely reflects this actual balance of powers. The US government evidently acknowledges an ideal (and realistic) balance of powers but dictates that ICANN has to install adequate accountability provisions before the actual subordinate delegation of regulative powers can take place. Until such adequate provisions have been installed ICANN is accountable to the US government.

What the exposition outlined above shows is that the installation of new accountability mechanisms fails, that the actual US power over the DNS is overrated and that ICANN is subject to competition. This means that the supposed superordinate delegation of regulation of the DNS to the US never took place and consequently that the proposed subordinate delegation of regulation of the DNS to ICANN never will take place. The MOU actually introduces the US as a delegator and ICANN as a ‘would be’ delegatee. ICANN is a newly defined conglomerate of stakeholders which actually comprises a broader representation of stakeholders than IANA did. This introduced self regulation will just function as long as ICANN is representative of the ‘self’ composed of all the global stakeholders. The competition that occurred in the DNS services suggests that ICANN has not been fully able to represent all stakeholders (to satisfy all its customers), a development that will force ICANN to adapt to such an extent as to reflect the real balance of powers and thus reinstate full self regulation. The fact that the ORSN initiative has been withdrawn and the fact that many new domain name services providers

59 Actually, very recently, the privatization of ICANN has been finalized by expiration of the contract between ICANN and the US on the 30th of September 2009.
have not developed into permanent competitors shows that ICANN is slowly adjusting to new power relations under the threat of competition.

In sum, ICANN turns out to be a TLD provider and a root server system provider amongst competitors. Consequently, a market- rather than a state frame of reference is therefore more appropriate to describe the economic reality of the competitive market in which ICANN operates. Using the market model’s accompanying accountability concept based on responsiveness, a rather different picture emerges. Assessment of ICANN’s accountability mechanisms actually shows a very successful organization. Its hybrid structure in which both governments and individual users are incorporated as stakeholders presents a novel and rather effective way in which to organize a not for profit company eager to preserve its market share in a global environment. With the rising number of Internet connections world-wide, the demand for additional TLDs will continue to grow. In addition, the general availability of techniques to set up root server systems and to register domain names stimulates competition between DNS services providers. A uniformly resolvable DNS as was envisioned when ICANN was founded is already an idea of the past. With a growing demand for Chinese and other internationalized domain name systems, the number of Internet splits (either technically or effectively) is likely to increase. The interests of Western countries associated with the Internet are varied. The ideals of fair trade and human rights have traditionally been high on the agenda, but the rise of Internet connections also create new opportunities for Western companies to enter emerging foreign markets. In order to safeguard and pursue these Western interests on the Internet it is necessary to re-examine the state’s role in regulating the Internet. This analysis of the DNS forms a necessary first step towards such a re-examination and paves the way for further research developing more effective state policies.

3 Theoretical and empirical building blocks

Systematically thinking through the life cycle of self regulation, using general legal concepts (like governance, delegation and regulation), inspired by an empirical examination of new regulative arrangements like that of ICANN, shows where delegation theory should be extended to meet the descriptive and explanatory requirements of self regulation.

First, Internet governance is dissimilar to other forms of governance (like government and governance by businesses) because of the state of self regulation on the Internet, which mainly consists of original self regulation maintained by coordinate delegation as a consequence of the global, decentralized and technical characteristics of the Internet. We still do not know if this is just a first phase in the natural development of the organization of the medium, or put

60 See for the Chinese additions c.f. op cit, note 40.
61 Starting with original self regulation, developing into delegated self regulation and finally into introduced or reinstated self regulation.
62 There actually is no general delegation theory. Delegation has been extensively studied in many different disciplines, each discipline employing its own partial perspective. The study of law focuses on the formal aspects of delegation, political science on the role of the state (Hobbes, Burke), behavioral sciences on organizational aspects (e.g. Weber, bureaucracy), political economy, business management and economics since the early seventies of the last century on the consequences of delegation for the promotion of the interests of the delegator (referred to as principal by agency theory) and the rules that define the accountability of the agent etc. The inadequacy of these partial theories for describing and explaining self regulation on the Internet is obvious. Agency theory for example hinges on asymmetry of information (the information deficiency of the delegator), which is just one of many causes of self regulation (and by definition is not a problem in a world dominated by self regulation) and on the regulation of accountability, which is provably absent in representative cases of self regulation on the Internet.
differently if it will be followed by the subsequent phases of (1) delegation to a superordinate organization (to a global/intergovernmental Internet governing organization), (2) subordinate delegation to formal constituents of the superordinate organization and finally (3) deregulation as we have consecutively seen in the development of state based governance. The findings in the ICANN case strongly suggest that the development of governance on the Internet will take another course. Instead of superordinate delegation of regulation we see the extension of the life cycle of self regulation by introduced and reinstated self regulation.

Secondly, the dynamics of self regulation can only be described and explained adequately if we account for the continual changing power relations and the accompanying continual changing locus of regulation. The ICANN example (amongst others) shows that the dimensions and composition of the self regulating group continuously changes and with it the locus of regulation. This change is brought about by changes of the actual balance of powers, not primarily by changes of the formal authority to regulate. The ICANN case furthermore showed that the change in power balance on the Internet, can best be explained by using a ‘market’ model in which stakeholders, that is, the subjects of and therefore interested parties in the regulation, choose and consequently define the ‘self’ and the locus of regulation on the basis of changing circumstances. If the ‘customers’, or ‘electorate’ in a state frame of reference, want the delegated task to be performed in another way they form new alliances and change delegates. As a consequence, self regulation and delegation on the Internet cannot be described as a top down intentional process. Actually, a bottom up unintentional process is a better description of what we see on the Internet. We need concepts like reinstated self regulation and introduced self regulation to describe and explain these dynamics.

Thirdly, as a consequence of the actual state of self regulation on the Internet (mainly original self regulation, mainly coordinate delegation) and the described dynamics of self regulation the introduction of accountability regulations by a superordinate organization which is an essential feature of delegation theory, takes an unfamiliar shape, that of implicit accountability (to the stakeholders). Both stately and business organizations are used to hierarchic regulation processes that tend to be dominated by superordinate and subordinate delegation, and recently by reinstated (non original) self regulation (deregulation). Consequently they tend to be subject to intentional introductions of explicit accountability regulations. As we can see in the ICANN case the US (and indirectly other states) fail repeatedly in their attempts to introduce regulations to make ICANN more accountable to its global stakeholders, a phenomenon that can be attributed to ‘conflict behavior’ of states. Their behavioral repertoire is not adapted any more to a world of original self regulation. They continue to behave as conventional superordinate and subordinate delegators and delegates, unaware of the fact that they have become (be it large) stakeholders in conjunction with other producers and consumers of information on the Internet (i.e. quasi superordinates and subordinates). This latter development renders the conventional (stately) explicit accountability mechanisms obsolete and has led to their replacement by an implicit accountability mechanism (once labeled the ‘invisible hand’).

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63 Specifically, available services (technologies) and competition (alternative providers of services)
64 Actually the aggregation of many individual intentional processes determines the outcome (cf an election process), so one could speak of an aggregated or induced intentional process
A theory of self-regulation cannot afford to miss the insights rendered by a thorough investigation of the Internet. First, because the Internet has become an integral part of society at-large, and secondly, because it exemplifies a world characterized by global interdependence. Hence in addition to providing us with new insights relevant to a general theory of self-regulation, the Internet and its associated modes of organization and regulation may even provide us with the tools needed to address new developments in the regulatory configuration of the world. Consequently, this contribution, in providing new essential building blocks, reaches beyond the Internet context and is indispensable to the development of a sophisticated general theory of self regulation in a globalized context.
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MIXED REGULATION IN INTERNATIONAL SECURITY POLITICS:
The Case of Iran’s Nuclear Program

Paul Rusman

1 Introduction

How does the world’s government interfere in world society with legal instruments? This question is obviously wrongly posed. There is no world government. On the other hand, there is a plethora of international regulatory instruments that impact on international relations, and the number is growing by the day. Are states in the final analysis the issuers of these instruments? Are the trends governing this process comparable with the ones at the national level? Such questions we cannot even begin to answer, given the state of research into the matter. Yet a case study of a contentious piece of international rulemaking can lay bare some of the essential characteristics of present-day international regulation, and hopefully the changing role of the world of states that accompanies it.

It is assumed here that a concentration on a joint public-nonpublic product would too much restrict the subject matter. This contention is explored in some detail in the first paragraph. After dealing with that question, the concept of international regime is introduced. The case studied concerns the crisis over Iran’s apparent plans to acquire the know-how and equipment critical for nuclear weapons production, while purportedly staying within the nonproliferation regime. It is argued that, since Iran denied to be bound by the relevant regulations, an international-legal obligation for Iran to change course in this matter had to be specifically created. This part of the chapter starts by explaining the nonproliferation regime in some detail, in order to demonstrate what additional regulation was called for. It then lays out the Iran case in broad strokes, concentrating on the 2002-2007 period.

Concluding remarks attempt to highlight some differences and similarities with domestic mixed regulation.

2 Mixed regulation in international politics

If, domestically, mixed regulation fans out from ex post consultation to ex ante consultation via forced co-regulation and co-regulation proper, to self-regulation in its pure form, all forms of consultation, and possibly also co-regulation, presuppose the existence of a capable and strong state to do the consulting and co-regulating. In the international sphere itself, that quasi-statal capability and strength are more often than not lacking, certainly outside the domain of well established international institutions like the EU. Ever since the Westphalian Peace of 1648, state sovereignty has been absolute and indivisible, and all regulation self-
regulation by the state. Only explicit exceptions in the form of international agreements are recognized. Yet again, practice yields a different picture. Economic globalization, the rise of global electronic networks, and especially the freeing of global finance after the cold war, have undercut government control of the national economy and national life. New regulators have sprung up. They range from intergovernmental to nongovernmental international organizations to private organizations and companies. Subjects that have seen important regulatory inputs of the latter are as diverse as the post-cold war sale of superfluous weapons by Western defence ministries (successfully taken up by the British NGO Campaign Against Arms Trade), the trade in blood diamonds by African rebels and thugs (resulting in the so-called Kimberley Process, an initiative by governments, industry and civil society to stem the flow of blood diamonds), but also global warming (the scientific evidence of which is assessed on a continuous basis by the Intergovernmental Panel on Climate Change, basically a band of independent researchers), the release of bioaccumulative toxins into the environment (successfully campaigned against by the World Wildlife Fund), or unacceptable labor conditions in the sweatshops of the apparel industry (successfully targeted by the International Labor Organization as a cause in need of regulation).\(^1\) Hence, an important role is played by grassroots organizations.

But an overconcentration on regulatory cases with marked nongovernmental input threatens to miss vital points. Some of these are (1) Most international regulation is firmly controlled by governments, and subject principally to the international distribution of power. This means that some states occasionally do lay down the law for other states, either by virtue of their leadership of a defensive alliance or their economic and cultural hegemony. An alliance leader usually shouldering part of the defence burden of others, cementing his claim to leadership. An economic hegemon usually bribes third countries by opening up his home market for them. With leadership comes a dominance in regulatory activities: think only of the US role in composing the IMF and UN Charters as examples. (2) Governments themselves increasingly speak for special interests, so why should direct rather than indirect contributions by these interests to international arrangements represent a fundamental difference? The fact that direct contributions may be on the rise results more from a need to control the costs of cooperation than anything else: governments simply lack essential know-how of the low-politics issues they seek to regulate (3) International regulations typically suffer from relative under-provision, non-participation by important parties, a lowest common denominator-approach, and a lack of enforcement mechanisms.\(^2\) Does ‘private’ regulation fare any better? In many cases it does not, one may think e.g. of the poor record of the Kimberley process in halting the trade in blood diamonds. (4) In many areas of international regulation, network analysis would appear to be more fruitful than analyses strictly along private-public lines. Already in the case of highly institutionalized international decisionmaking like that of the EU, scholars advocate arena analysis and deemphasize the public-private divide,\(^3\) and this may be even more true in some less highly institutionalized settings. (5) In roughly half the number of a sample of regimes, substantial roles are played by non-state actors. However, the state is almost always involved in regime formation,\(^4\) thus there is at least co-regulation, never privatization of rulemaking.

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\(^1\) a.o. Lipschutz and Fogel 127-129
\(^2\) Barrett, 2007
\(^3\) Van Schendelen....
\(^4\) Spector 2003, 68
The case at hand is chosen for a few reasons. It is a case of rulemaking which, in spite of general agreement on the need for these rules, designing, making and implementing them may be extremely difficult. Iranian nonproliferation cries out for regulatory activity because the political costs of no regulation appear sufficiently high to warrant a large amount of political activity to avoid these costs. Thus regulatory output, if any will result, will be the product of coercive diplomacy rather than negotiation. It is also a showcase for the ability of the planet to solve its most pressing problems. It also is a rich case, with global players involved, and fierce turf battles of domestic and international bureaucrats. Hopefully some insights will emerge that serve our understanding of mixed regulation per se.

3 The nuclear nonproliferation regime

Ever since the cold war ended, calls for an improved international regulation of nuclear non-proliferation have grown louder. Evidently, the international legal order, though reasonably adequate to the task in a world divided into two camps, has had difficulty preventing the spread of nuclear weapons once the stalemate was ended. The results of this crisis in the legal order have been devastating. Neither of the two wars with Iraq since 1990 might have been fought, had not this country implicitly threatened to upset the balance, and dominate the Middle East, by trying to acquire weapons of mass destruction. Similarly, there have been two nuclear crises since 2002, over Iran’s apparent plans to acquire the know-how and equipment critical for nuclear weapons production, and North Korea’s open efforts to obtain these weapons. Other than in the Iraq case, an international-legal obligation for Iran to change course in this matter had to be specifically created. This chapter deals with that process.

The legal basis for the world’s efforts in this field is the nonproliferation regime. In order to explain the meaning of this concept, we use the most often cited definition, the one offered by Stephen Krasner, which reads:

‘International regimes are defined as principles, norms, rules, and decision-making procedures around which actor expectations converge in a given issue-area.’ Note that this definition meshes well with Black’s definition of self-regulation as cited in the Introduction: ‘A situation of a group of persons or bodies, acting together, performing a regulatory function in respect of themselves and others who accept their authority’, a description that deliberately extends the scope of self-regulation beyond ruled that are legally binding. As long as the regime works, it is relevant. This has to do with the very basic truth that in international relations there is no overarching authority from whom legal power emanates. If at all there is an international Rex acting as law-giver it is the community of states. Only on limited grounds can the United Nations Security Council make binding decisions. But in these cases it is questionable whether the Council can create new rules. As a rule, international regulation is created by states that voluntarily enter into obligations. In international relations, regulation is principally self-regulation. Coercion is a problematic strategy to achieve rule-creation, since aggressive war is illegal (according to the UN Charter), costly and too blunt an instrument, and sanctions are notoriously difficult even to ensure compliance, let alone voluntary self-regulation. Co-regulation is therefore the normal state.

5 Krasner 1982
International regimes are constructs designed to overcome such game theoretical anomalies as the Prisoner’s Dilemma and the Chicken Game, which severely hamper perfect information (under the aggravating circumstance of the ultimate lack of world political authority and the huge costs of the functioning of the world system, i.e. the costs of regulation, security, bribery and extortion, all that it takes to make the world turn socially; cf. Coase 1960). Without international regimes, outcomes are bound to be suboptimal, at least theoretically. International regimes seem to flourish as a breed, since their number has been exploding after WWII. Evidently, globalization is responsible for much of this, as the density of today’s world’s issues calling for transnational regulation increases continuously. But how do they come about? There are broadly two views on this. Some believe that, to have regimes, you must have a hegemon with sufficient power resources and ambition to bring them about. Others point out that regimes may spring up between states that find one another essentially trustworthy, which, it can be demonstrated, may be entirely the product of the interaction between self-interested parties [Axelrod 1984]. In both cases, international regimes are the product of historical happenstance, and, like gardens or good marriages, need constant attendance. One lesson learned from the study of existing international regimes is that ‘comprehensive and fair agreements that enjoy wide participation and acceptance in the beginning tend to break down over the course of the regime’s life and need to be renewed and renegotiated’  

Being an artifact of international relations, a regime is a stand-alone construct, that carries the genetic instructions needed for its own reproduction. It does not only contain the prerequisites of rules, i.e. principles, norms and decision-making procedures according to Krasner’s definition, but can be defined even broader. It presupposes a domain consisting of a welter of guidelines, interfaces between different groups working on the problems from different angles which creates the differentiated interpretation, guidance and feedback needed with respect to the rules in real life [An example being the seminars of civil servants, international bureaucrats and university researchers set up to interpret and assess UN Security Council resolution 1540]. As these things are part of a layer of interactions and culture that is never in doubt on the national level (indeed, national rules are written with these practices in mind), they must exist on the international plane as well for regulations to be effective  

How can the nonproliferation regime be characterized? It is composed of distinctive hard and soft law elements, betraying its pedigree as a regime that experienced several historically and politically distinctive phases. At least the distinction can be made between the phases of bipolar, East-West confrontation, and of the post-cold war, multipolar, North-South competition.

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6 Spector 2003, 79
7 Spector and Zartman 2003, 284ff
The Trigger List was drawn up in response to the Indian nuclear test explosion of 1974. It lists goods and know-how essential for nuclear engineering, with an eye to regulating their flow unilaterally on the part of the nuclear *haves*. The Dual-Use List replaced the COCOM list and was drawn up to regulate the flow of technologies with both civilian and military applications. The Additional Protocol produces control mechanisms and obligations additional to those created in the Nonproliferation Treaty. It was drawn up for NPT parties to enter into as a response to the Iraqi efforts to acquire weapons of mass destruction, that had fully come to light after the 1991 war over Kuwait. The Proliferation Security Initiative (PSI) of 2003 is a collaboration mechanism of seafaring nations in order to facilitate the interdiction of seaborne proliferation actions (the concentration of shipping within a few insignificant flag states makes this a worthwhile exercise). UN Security Council Resolution 1540 of 2004 tasks all UN member states to create effective controls against proliferation of NBC weapons and delivery means (these controls are of course useful for nonproliferation measures against states as well). Both measures were reactions to the North Korean and Iraqi efforts after the Iraqi war of 2003. All but the NPT, its Additional Protocol and Resolution 1540 were unilateral measures taken by the nuclear ‘haves’ to control nuclear technology. This means that much of the necessary flesh on the bones of the treaty consists of unilateral rules that are nonbinding on the countries suspected of proliferating behavior. During the cold war this was the second-best solution, but after the cold war it made for a glaring weakness in the nonproliferation regime.

The traditional distinction made in international law between soft law and hard law is not very helpful in this case. Soft law elements are both older and younger than the hard law ones. Positive law elements are essentially the NPT and to a lesser degree its Additional Protocol and Res. 1540. All other arrangements could be called soft law, but their rigor varies. For instance the COCOM List was the most typically non-positive-law and thus soft of all these regulations, but in reality it proved the most rigorous of all, being an cold war product of the Western alliance and meticulously policed by its American leader. Although not initially designed to regulate nuclear transfers, national legal instruments drawn up to implement COCOM because of their flexibility could be made to accommodate regulation of all strategic transfers. The lists with proscribed goods and technologies based on COCOM were essentially instruments to guard the 26 Western members’ oligopoly of militarily critical technologies. The number of their adherents changed greatly after 1990, when these countries were joined by countries of the former East. It made them broader in scope and thus ‘harder’, but the point can still be made that only the NPT qualifies entirely as hard law. This however does not make the NPT a perfect treaty.
A useful tool to investigate the degree to which regulations are actually fit to play the roles they are designed for is the concept of legalization. According to criteria drawn up by Ab- bott et al. [2000, 401-419; see also Jojarth, 2009, 29-58], the point at which a particular set of rules finds itself on the hard-soft law continuum is gauged with the aid of three dimensions: obligation, precision and delegation.

The type of obligation entered into when a country joins. The NPT is legally binding, its obligations are specific and unambiguous, and its scope is well-defined. However, withdrawal from the treaty is relatively easy and can be done on short notice (6 months). And although there is independent regular monitoring by the International Atomic Energy Agency (IAEA), for compliance mechanisms such as sanctions the treaty depends on ad hoc measures taken by the UNSC.

The precision of the NPT is generally good, as most of its provisions are nonambiguous. However, the IAEA Council, the multi-nation authority that oversees its operations, is not authorized to settle disputes. The NPT also has an element of incoherence, as its rules regarding denuclearization of the five nuclear weapon powers, vital for its nondiscriminatory character, are ambiguous and declaratory rather than precise. Although they go further than merely serving as ‘recommendations’, they contain no rules, conditions or time-paths for denuclearizing activities.

The delegation contained in the NPT is unprecedented. The IAEA is an important international organization with a large expert staff. Up to a point it is capable of setting its own agenda, albeit in accordance with the potentially powerful Council, which operates by majority vote and has a rotating membership and is therefore difficult to stalemate by the great powers. Its Director-General has a reasonably long term of office. However, its decisions are not legally binding upon the parties in matters of dispute and non-state actors cannot be plaintiffs.

Also, the IAEA is not independently funded and it funds are at present inadequate fully to discharge its responsibilities. It follows that in many respects the NPT’s level of legalization can be described as moderate.

The IAEA has nevertheless been successful throughout in carrying out its chief function of NPT watchdog. There are manifold possible reasons for this, including:

By being branded a proliferator, a country is conspicuously singled out, while gaining little by doing so. The NPT is almost universally adhered to. India e.g. has never succeeded in convincing explaining why it should on moral grounds be able to single itself out as a non-party, and certainly as a nuclear weapon possessor. The discriminatory character has not met with major criticism on the part of the vast majority of possible possessors. When in 1995 the treaty came up for a statutory review, not a single country abrogated it.

Some 35 countries can be regarded as possible NWS [the preamble to the Comprehensive Test Ban Treaty defines 44 countries as having sufficient nuclear know-how to be regarded as at least an outside risk of becoming a NWS; 35 of this number are not currently NWS], but most of these possible possessors are content with being virtual rather than actual NWS, as actual use of NW is pretty unthinkable (making time being less of the essence), and extended deterrence looks reasonably secure.
The mechanism of the NPT is stronger than it looks, as uranium possession is virtually impossible outside the NPT framework.
The proliferation of NW technology, including enrichment, must be very broad and deep for an actual NW design to stand a chance of becoming reality, unless the receiving country illicitly obtains drawings, blueprints, and specialized technologies especially designed for the purpose of being incorporated into NW.

Only a country that can negotiate these barriers can become a proliferator. Iran and North Korea can. They have uranium deposits, they are aided by specialist technology proliferators, chiefly Pakistan (in particular the maverick scientist Khan) but also China, and have been able to use that opportunity. They also have a strong security motive: both have a long history of feeling militarily insecure. Psychologically they are willing to defy the rest of the world, as both are revolutionary regimes. They have a proven track record in this regard. Iran has almost demonstratively shot itself in the foot, by refusing to make peace with Iraq in 1982, and subsequently by ignoring the technical demands of its oil and gas sector. In fact, only with Western, and specifically American support will Iran be able to keep its oil output at reasonable levels, and its gas reserves will not be exploited if Western technology and capital remain unavailable. But Iran’s strength is also a weakness, as the rest of the world is likely to regard its acquisition of NW as a major problem.

4 The Iran case: coercive diplomacy in the service of rulemaking

In August 2002 a clandestine Iranian opposition group disclosed the existence of a large, secret Iranian nuclear program, the components of which pointed in the direction of a nuclear weapons program. It turned out that Iran worked on uranium enrichment, using ultracentrifuge technology it had obtained from Pakistan. It had started building an underground factory in Natanz, where both engineering research and large-scale enrichment operations, using over fifty thousand centrifuges, were planned. Centrifuge enrichment is technically very difficult and is done in but a few places in the world. Iran had also developed two uranium mines, together with a uranium conversion plant in Esfahan, slated to produce UF6, the gaseous feedstock for the enrichment plant. Combined, these plants would give Iran a closed nuclear fuel cycle, but also an independent capability to build uranium bombs. Iran also planned a heavy water plant and a 40 MW rated power plant in Arak, with construction starting in June, 2004, the only feasible object of which was to obtain plutonium for Nagasaki-type atomic weapons (Iran unconvincingly said that it planned to export the heavy water). There were also subterranean laboratories which the IAEA was not, or only, partially, allowed to inspect, while one suspicious installation was erased before an inspection was granted. Past programs included one for Polonium-210, used almost exclusively in some nuclear weapon designs, and one for uranium enrichment using lasers. US intelligence later found indications that Iran even had had a specific nuclear weapons technology program, which was however probably halted in 2003. On top of all this, Iran had a broad array of missile programs, all of which were only marginally useful militarily except as nuclear weapon carriers. As of 2002, no nuclear weapons (NW) design was known to be going on, but from a nonproliferation point of view the crucial step is the acquisition of an enrichment capability. Western intelligence had earlier concluded that Iran headed for a NW capability, a.o. on account of a nuclear power station being under construction in Bushehr and of Iran’s program for advanced mis-
siles, which were only marginally useful militarily. But the newly bared projects, their having been kept secret for eighteen years, and Iran’s advanced missile program, pointed towards a willingness to breach the NPT’s chief rule not to acquire nuclear weapons. However, the NPT neither supplies the authority nor the coercive means to halt such a full-scale weapons program in its tracks. It does not even provide for inspections of nuclear installations that do not yet have uranium feedstuff introduced to them. Technically Iran was in violation of the NPT because it should have notified several of the activities to the International Atomic Energy Agency (IAEA), the executive arm of the NPT. For example, to get an early start, the country had imported 1.8 tons of uranium shale, together with an unknown quantity of UF6 from China, neither of which had been reported to the IAEA, as they should have. At the heart of Iran’s legal position lay its interpretation of the IAEA rules covering members’ duty to report nuclear installations with an eye on the Agency’s ability to monitor them. In 1978 Iran had signed the standard safeguards agreement, under the so-called subsidiary arrangements of which, a bilateral document stating rules between the Agency and Iran, which obligated it to notify the Agency of an impending introduction of nuclear material into an installation no later than 180 days in advance. In the early 1990’s the IAEA had brought this obligation forward to the point where the design had been made. Iran had agreed to the new rule, Code 3.1, in a letter exchange in 2003, after the Natanz factory had been accidentally discovered before nuclear material had been introduced into it, but had withdrawn from Code 3.1 in 2007. Since the safeguards agreement and subsidiary arrangements did not contain a procedure for unilateral withdrawal, one can argue that the non-notification of Natanz was difficult to fault legally, and that only the non-notification of the uranium enrichment installation in Qom, brought into the open in September 2009 by the Western powers, represented an actual breach of the obligations under the NPT.

The West, already suspicious about Iran’s nuclear ambitions, reacted to the Natanz program with an effort to stop it in its tracks. The strategy was to approach Iran with coercive diplomacy in lieu of direct military threats. Coercive diplomacy, i.e. backing up diplomacy with an at least implied threat, has worked against the Soviet Union in the framework of the cold war competition, but not quite as well in other contexts. The motivation and commitment of the coercer and the credibility of its threats are vital to its success. Initially the Iraq war had served as an exemplary use of force to Middle Eastern proliferators like Libya and Iran. Libya had succumbed to the pressure and made a turn to the West, terminating its entire program of weapons of mass destruction. Iran according to later US intelligence analyses, had at least terminated the direct weaponization part of its nuclear program. But the later US mishaps in Iraq threw doubt on its motivation and credibility to push through its wishes in Iran. While the West regarded its coercive diplomacy against Iran’s proliferating behavior as defensive in nature, Iran started portraying it as blackmail, thus offensive in character, as aggressive elements gradually gained the upper hand in the Iranian leadership. It did so chiefly to shore up its domestic credibility. The trouble in Iraq also informed the strategies of Iran’s opponents, the US, the EU, Russia and China. There are several strategies in coercive diplomacy: ultimatum, tacit ultimatum, “try-and-see” approach, “gradual turning of the screw,” and “ While the US preferred an ultimative approach, calling the bluff of the other permanent members by

8 IAEA 1974
9 IAEA 1972
10 [IAEA 2007]
11 [George 2000, 70-71]
bringing the matter immediately to the level of the UN Security Council (UNSC), with the implied threat of harsher methods whenever coercive diplomacy would prove to be unworkable, European countries preferred the carrot and stick-approach of, essentially, negotiating with Iran.

The IAEA Board of Governors (IAEA BoG) is the competent body to handle apparent violations of the NPT. It cannot sanction violators, but is statutorily obliged to refer violations to the United Nations Security Council (UNSC) when they are not suitably explained and redressed. The UNSC has several sanctions at its disposal and can even use force when international peace is threatened. However, no statute explicitly gives the Council the right to deny member states the employment of uranium enrichment technology. Through its infractions against the NPT Iran was technically in breach of its obligations, but in proliferation terms they were in fact minor compared to its legally harmless enrichment plans; neither did the planned plutonium production plant in Arak in itself constitute a breach of the treaty. One would have to define Iranian enrichment as an act likely to endanger peace under Title VII of the United Nations Charter, in order to be able to restrain Iran’s right to indulge in it. That is not an impossibility (after all the UNSC in 1977 instituted a mandatory arms embargo against South Africa’s Apartheid policies for the preservation of regional peace and security) but it would be a departure from normal practice. During the second half of 1990’s, France and Russia made pleas for the lifting of the embargoes on Iraq, in spite of that country’s non-cooperation with the various committees instituted by the UNSC to monitor the mandatory destruction of its weapons of mass destruction programs. The fact that the US and UK as permanent UNSC members vetoed lifting the embargo probably contributed much to Russia’s reluctance to cooperate with the US in the matter of Iran. For Russia, although it had no intention of helping to create new nuclear states, Iran was an important regional power with which it wanted to establish a good relationship. Russia has powerful incentives to follow the US on nonproliferation issues, for instance to protect its equal standing with the US as a nuclear power. Yet this does not mean that nonproliferation is the top priority in its foreign policy).

As happens in domestic legal settings where the judiciary usurps the power of lawmakers to legislate when the latter fail to do so, the UNSC was essentially asked to create an extension of the NPT, a rule saying that whoever was distrusted could not obtain enrichment technology. It would come down to applying the unilateral parts of the nonproliferation regime to all subscribers of the multilateral part, i.e. all parties to the NPT. This would put the UNSC under suspicion of assuming legislative powers that it does not really possess. Not that the UNSC is adverse to doing so when there is a demonstrable need to. Its resolution 1540, which demands of all countries active engagement to contain the spread of nuclear technology to terrorists, testifies to that, but it is criticized for abusing the Charter. Proscribing enrichment would prove harder, as it deems to constrict governments, not terrorist organizations. Brazil and South Africa, countries with independent enrichment capabilities have resisted proposals made in subsequent years by the US and the IAEA to freeze enrichment capabilities and concentrate the technology in ‘neutral’ hands, a kind of Baruch Plan revisited, and these same countries tacitly supported Iran in its case against the IAEA and the UNSC. Japan only went

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Wallander 2006

Joyner 2006
along in principle because its own position would not be at stake. But Iran all along clearly stated it would never relinquish its ‘right’ to enrich. Formerly, American coercive diplomacy against would-be proliferators like Brazil, Argentina and Taiwan had worked, but Iran had escaped the US sphere of influence in 1979. The two countries did not have diplomatic relations, and the US had long tried to isolate Iran. Neither could Russia be trusted to coerce Iran, for the reasons mentioned above. The US even distrusted Russia re Iran until it had become convinced that Iran had acquired its technology via the Khan route. Particularly after the 2003 Iraq invasion, the US could no longer take unilateral preemptive military action that did not meet the “global test” of world legitimacy. Thus it needed the UN to put Iran in the wrong legally, broaden the unilateral strategic and trade embargo, and if need be sanction military action. Moreover, since, in VP Cheney’s notorious words, the US did not “talk to evil”, others had to do the talking. This task befell the European Union, which created a steering committee consisting of Britain, France and Germany, the EU3. Germany’s cooptation was natural, since it was the EU’s largest country, had the largest trade interests by far with Iran, and advocated foreign policy principles that left little if any room for the use of force. This in fact widened the circle of the permanent members of the UNSC, the P5, to a P5+1. The US did not applaud the creation of the EU3 channel. It preferred multilateral action in the UNSC, for which purpose it planned to ask for a referral by the IAEA BoG. But the EU3 channel foreclosed this avenue for an extended period, during which European rather than American policy options prevailed. Although Iran policy was coordinated within the Western bloc, it would take all of the Bush Administration’s first term to arrive at a reasonably common policy. Germany and France had declined to support the Iraq war in the UNSC, and the prime minister of the third country, Tony Blair, suffered irreparably from his decision to support Bush and left Iran policy almost completely to his foreign minister, Jack Straw, who enjoyed the support of the left wing of the governing Labour party. As a result, Germany’s traditional strong advocacy of a foreign policy without the use of force gained credibility. The EU3 was in fact set up to demonstrate that serious disputes of this nature could be solved peacefully, yet effectively. The next step was to get Russia and China, the non-Western permanent members of the Security Council, on board, and since the IAEA BoG as a matter of habit works on the principle of unanimity it even took a major effort on the part of the US to get the Board to refer the matter to the UNSC. Russia was fully aware that Iran very likely conducted a weapons program in the guise of a civilian effort, but could comfortably clothe its reluctance to act in the demand that this time around, the proof would have to be entirely convincing. I say ‘comfortable’ because Russia could always count on the willingness of the US to take swift and decisive military action, should Iran be proven to be in the wrong.

The next two and a half years, from July 2003 to January 2006, were spent in trying to find a solution by the EU3. In 2003 a 164-centrifuge cascade had been installed at Natanz, but at the urge of the EU its operations had twice been ‘postponed’. Instead, talks had been held in the intervening 30 months with the object to accommodate the EU’s objections. It took almost the entire period for the EU3 to get the US on board. Only in the spring of 2006 did Washington consent to cooperate in a joint offer to Iran, after an earlier EU-only offer, unsubstantial because the US had been unwilling to back it, had failed. While from the beginning Iran had made clear that the halt in its ‘research program’ would only be temporary, the newly elected

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14 So called by e.g. John Kerry in a 2004 election debate with Bush; Bolton 2008, p.131
15 Albright and Hinderstein 2006
president Ahmadinejad had made it even clearer that compromise was out of the question. Iran had also clearly negotiated in bad faith, reneging on its obligations several times. In the intervening period Russia had laid out a detailed plan for Iran to do its enrichment in Russia, but Iran had insisted that some small-scale enrichment would still have to be conducted in Iran itself, so that the larger nonproliferation issue, the acquisition of the enrichment technology itself if not the industrial capacity, would be decided in Iran's favor.

Before Iran even had in so many words rejected the new offer, the UNSC in June 2006, acting under Article 40 of Chapter VII of the United Nations in order to make mandatory the IAEA requirement that Iran suspend its uranium enrichment activities, the Security Council issued resolution 1696 threatening Iran with economic sanctions in case of non-compliance. The balance had at the same time tilted slowly against Iran. India, an important potential ally, had deserted Iran and voted with the West in the decisive vote in the IAEA BoG, after the US had agreed in principle in July 2005 to sell nuclear technology to India. The great majority of countries within the region that harbored potential nuclear ambitions, like Turkey, Egypt, Saudi Arabia and the other members of the Gulf Cooperation Council in 2006 made known their intention to set up nuclear research or energy programs. Saudi Arabia leaked none too subtly that it would activate its Pakistani connection, Egypt turned to the US for support for a pilot nuclear program. And the US had finally convinced Russia and China that Iran had been conducting actual weaponization work, using a wealth of data on the harddisk of laptop acquired by US intelligence. But this had taken many months of behind the screen bargaining. Even Resolution texts containing elaborately veiled threats like “continued enrichment-related activity would add to the importance and urgency of further action by the Council”, and an even tamer follow-up proposal (“continued Iranian enrichment-related activity would intensify international concern”) had been deemed unacceptable by Russia. In the end, Resolution 1696 completely avoided any implication of use of force in the future. In December 2006, the UNSC finally issued Resolution 1737 which contained a minimum of punitive sanctions but again did not include a statement that use of force would be warranted in case of non-compliance. In each of the following years, other UNSC Resolutions were adopted, with additional sanctions representing a very slight turning of the screw that put the coercive diplomacy intended in very low gear. To make up for this, the US and its Western allies have added unilateral measures that had more bite, particularly financial and investment sanctions, but these will take a few years to show their ultimate impact. Thus the 2003-2009 period has shown the weakness of coercive diplomacy as a means to change legal regimes, even if virtually all participants find them of basic importance.

What does this teach us about mixed regulation in international relations?

It is useful to repeat what was said earlier about the weaker forms of mixed regulation, such as consultation: these appear functional when a strong quasi-statal apparatus is the driver, such as the European Union. Co-regulation, the stronger form of mixed regulation, is more typical in international relations, where the issuing institutions and governments have relatively little grip on matters at hand.

What do these co-regulators do? According to modern regime theory, the interfaces between the regime and national implementation are often not very elaborate, and communities of in-
interested parties must build networks which can play coordinating roles\textsuperscript{16}. How does this play in the nonproliferation regime? First, you have international civil servants like the director-general of the IAEA, Mohamed ElBaradei and the High Representative for the Common Foreign and Security Policy, Secretary-General of the Council of the European Union Javier Solana. They have much freedom to play a personal role. ElBaradei edited the reports of the IAEA to the BoG, and thus subtly steered the direction the discussion took in the all-important matter of whether, and to what degree, Iran had broken its obligations, inadequately informed the IEAE, and the like. He also undertook a major effort in the summer of 2007 to get all outstanding questions, which had bogged the discussions for so long, off the table before it would be too late and the bombs started falling. It did not touch the main point however of whether or not Iran was allowed to enrich uranium. Solana paid many visits to Tehran and inevitably, through his intimate knowledge of the dossier, made his mark in the appreciation of the matter by the EU3, and must have made a definite impression in Tehran of a restless seeker of opportunities to engage. Secondly, you have the inner circle of the IAEA Board of Governors and the governments that issue instructions to the members of this Board. They may seem inconsequential, but in the case of Iran the fact that the American member did not see eye to eye with the more radical neoconservative elements in the Bush administration was of importance in that it made it easier for the other players to continue on their chose paths. Third, you have the inner circle of governments, the ones with real power like the P5. Typically the hegemonic player among them orchestrates the action taken. Here, too, the fact that international institutions are rather sparse, and much of the action must come from national governmental non-governmental inputs, plays a role. Fourth, the hegemonic player is usually given a lot of leeway to create and implement rules, by political and other means of pressure. In this case, however, it met with a lot of opposition or downright indifference, even from trusted allies like Tony Blair. Yet the US was still a hegemonic player, as is most clearly witnessed by the fact that the bottom line of the Bush administration that an Iranian atomic bomb was ruled out entirely as a possible outcome was never challenged even indirectly by the other players.

An important form of coregulation is the administration by the International Atomic Energy Agency of its relationship with the NPT state parties. The states that have nuclear installations have to enter into bilateral agreements with the Agency, which regulate the IAEA’s rights to move through the country, enter nuclear premises, take samples, etc. As said before, the IAEA, its DG and the BoG in fact have semi-judicial (and thus semi-legislative) powers in that their finding that a particular country is in conflict with NPT-based rules cannot be contradicted, only overruled by the UNSC.

In many international security questions the UNSC principally works with a delegation of authority, usually empowering a national government to take the lead in a specific operation. The UN is simply too sparsely equipped and too underfunded to be able to deal with actual emergencies. Particularly the intelligence capabilities of the great powers are all-important in assessing whether a country is in the wrong. Although after 9/11 cooperation between intelligence agencies has increased dramatically, the intelligence assets of almost all countries are dwarfed by those of the US, and the same is true for other pertinent capabilities. Particularly the US expertise in nuclear weapon affairs outruns that of all others, including Russia (alt-

\textsuperscript{16} Spector and Zartman 2003, 285
hough it must be said that part of this is gradually being lost with the reductions in and ageing of the nuclear arsenal). The US already plays a pivotal role in the unilateral portions of the nonproliferation regime, like the Nuclear Suppliers Group; as said it also uses bilateral relations with most countries to influence their behavior. Last of all, it is an interesting outcome of this case that the UNSC is in danger of becoming rudderless in nonproliferation affairs when the hegemonic leadership of the US is in doubt.

The nonproliferation regime revolves around trust. The regime is not well endowed with enforcement means, indeed like most regimes it knows few sanctions or inducements to comply (Barrett 2007) A party to the regime that risks, even encourages, distrust, in a away has already abandoned the regime. Only one maverick country has up till now abrogated the NPT, or any treaty banning weapons of mass destruction for that matter. It is more comfortable to allow yourself to be regarded a fence-sitter or virtual weapon possessor, since you can do many of the things possessors can do, like deterrence, without having to bear the brunt of generalized criticism or even ostracism that possessors are exposed to. It therefore pays off to examine why a country like Iran would want to become at least a virtual possessor. According to most theorists, not only strategic but also psychological motives play a role here. Strategically, Iran’s decision to acquire nuclear weapons was more understandable at the time the first step towards it was taken (around 1985) than it is today. After all the 2003 Iraq war eliminated the threat of Saddam Hussein, an exceptionally well-entrenched dictator and former aggressor against Iran, and replaced him with a Shiite majority government. It also ended the rule of the Taleban in neighboring Afghanistan. The US is on its way out of Iraq and will be less of a threat. Russia has been forthcoming in its policy towards to Iran. Iran’s strategic and political position in the Gulf would be much improved, but its reputation would suffer damage. Thus the psychological motive to breach the nonproliferation regime probably carries much weight. Iranian culture despises being told what to do (William O. Beeman). The fact that Iran construes itself as being up against the most powerful country in the world (instead of the world community, acting through the UNSC), which because of its central position has a lot of sway in the UNSC, could reflect genuine dissatisfaction by a culture that normally already despises being told what to do (Beeman 2000). Interestingly, the Iranian regime in its domestic dealings has particularly stressed elements such as pride (in Iran’s technological achievements) and being victimized (as Iran’s inalienable right to enrich uranium is in danger of being breached by the US, which desires to keep Iran underdeveloped). It could be worthwhile to investigate further how these psychological constructs change the way in which the rules regarding nonproliferation are experienced psychologically. Ahmadinejhad’s populism may reside in the fact that he himself shares these feelings and experiences which other, more cynical and manipulative, government officials may only feign. It is also interesting to note that ayatollah Khamenei, the Iranian, who as Faqi or Chief Jurisprudent has final responsibility for foreign and security policy, is said to have been aggrieved by the European accusations of double-dealing after Iran had resumed its enrichment program, purportedly because Iran had made clear on several occasions that it had halted it only temporarily.

As put in the Introduction to this book, regulation beyond the state will often take place in the shadow of state activity. This proves to be true at the international relations level as well. States are the life-givers (and life-takers) of international regimes. Their task is to either keep post-agreement negotiation processes going in order to maintain regime effectiveness (Spector and Zartman, 4) and/or provide institutions with resources. Because states are the end-all
of international relations, possessing authority, power and a resource base, their role is continuous. This confirms the view of the role of the state in international relations as a hybrid body, embracing both state and non-state sources of regulation. It takes a separate theory of globalization, though, to understand the role of the state in future international relations.

Looking back, we identify at least four meanings of ‘selfregulation’: (1) the national state makes the rule although the problematic clearly is transboundary and asks for an internationally binding rule (2) an international rule is fleshed out at the national level, usually by civil servants with much freedom (3) an international rule is fleshed out at the international level, sometimes by civil servants, sometimes by a hegemonic power, or a group of influential states or even a cartel of states (4) ‘free radicals’ (e.g. temporary project functionaries flesh out the rules). A second level of agents competing in the rulemaking business can be found in countries where jurisdictions are shared between domestic actors, like Congress and the administration, or between the administration and the judiciary. The fact that civil servants are predominant in examples 3 and 4 is important, since it can be argued that their peer groups contain many academically trained people in other walks of life who do similar work in other capacities (journalism, academic, parliament, think tanks, action groups). These people are sometimes brought on board via seminars, brainstorm meetings, workshops, etc., or work is farmed out to them under short-term contracts.
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