Fraunhofer Institute Systems and Innovation Research

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New Products and Services:
Analysis of Regulations Shaping New Markets

Final Report

Karlsruhe, February 2004

A great deal of additional information on the European Union is available on the internet. It can be accessed through the Europa Server (http://europa.eu.int).

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Foreword

The Fraunhofer Institute for Systems and Innovation Research produced this report on behalf of the Innovation Policy Unit of DG Enterprise in the European Commission in the framework of the Innovation /SMEs programme, which was part of the Fifth Research Framework Programme.

A project team led by Dr Knut Blind produced this report. Dr Bernhard Bührlen was responsible for the case study in the pharmaceutical sector. Professor Klaus Menrad produced the case study in the food sector. Both supported also other tasks of the project together with Sabine Hafner. The case study on environmental technologies was produced by Dr Rainer Walz and Christiane Kotz. I would also like to thank the companies and the other organisations who responded to the survey or were willing to spend some time being interviewed.

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However, responsibility for the final report remains with the Fraunhofer Institute for Systems and Innovation Research.

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Contents

List of Tables

List of Figures

Executive Summary

Introduction

New products and services are the **driving force of** a **dynamic and persperous economy.** Besides the direct public promotion of new products and services, e.g. by public funding for research and innovation activities, framework conditions are crucial for the success of new products and services in the market. In contrast to direct support measures, we focus in this report on **regulations shaping new markets** as indirect, but crucial **framework conditions**, which have often far reaching and ambivalent impacts and are therefore an important topic for policy makers, e.g. as discussed at the World Economic Forum 2004 in Davos. The study "**New Products and Services. Analysis of Regulations Shaping New Markets**" aims to to reduce the lack of adequate, reliable and systematic knowledge on the relation between regulation, including deregulation, on the one hand and the emergence of new markets on the other. On that basis, we aim to develop **suggestions for a regulatory framework** which allows the **emergence of new markets**, and even to use **regulation** systematically as an **instrument to foster innovation**.

The final report contains six parts. After the introduction, a **conceptual framework** of the various relationships between regulation and innovation is presented by analysing the various, often ambivalent impacts of these regulations on innovation. Then, we present an **overview** of regulatory systems shaping new markets, including a **new taxonomy** of product market regulations. Fourth, the **views of stakeholders**, especially **companies**, on the impact of the regulatory framework on innovation are presented. Fifth, the main results of three in-depth **case studies** covering the **pharmaceutical**, the **food** and the **environmental sector** are outlined. In addition, examples of **standards** responsible for the development of new markets are presented. We conclude with an **outlook of future regulatory policies** taking the innovation dimension explicitly into account.

A Conceptual Framework to Analyse the Relationship between Innovation and Regulation

The **complexity** of the **relationship** between **regulation** and **innovation** calls for the development of an adequate **analytical framework**, which takes into account the different aspects of the regulatory framework and the characteristics of the various sectors.

The term **"regulation"** generally refers to the **implementation of rules by public authorities and governmental bodies** to influence the behaviour of private actors in the economy. Such intervention in the market is justified by the goal to maximise

collective **welfare**, including reaching some **distributive goals**. In general, **three types** of regulatory interventions are usually distinguished: **economic**, **social** and **administrative regulations**.

Table 1: Types of regulations and their impacts on innovation

Type of Regulation	Positive Impact on Innovation	Negative Impact on Innovation
Economic regulation		
Antitrust or pro-competition regulation	eases and enforces innovation	prohibits (R&D) alliances
Protection of infant industries (R&D subsidies, barriers to entry)	allows costly and risky innovations	continued protection does not enforce innovative activities
Public utilities: rate of return regulations; pricing at marginal costs	rents available for R&D and innovation	little and biased incentives to innovate
Public utilities: price cap	incentives to reach productivity gains	-
Public utilities: competition	-	price pressure and low profits do not allow to invest in innovation
Protection of selected industries (e.g. aerospace)	funds available for large R&D projects and innovation	no competitive pressure to innovate
Social regulation		
Environmental regulations	create incentives for new processes creating less environmental damage and for the development of new products	restrict innovative activities and hamper the competitiveness and therefore their innovative capacity regarding end-of-pipe technologies
Safety regulations	increase acceptance of new products among consumers	additional restrictions for innovators
Public goods	provide infrastructure for innovative activities	reduced private sources for innovative activities
Administrative regulation		
Product liability	producer liability increases the acceptance of new products among early adopters	too high liability reduces the incentive for producers of innovative goods
Intellectual property rights	additional incentives to innovate	additional protection for monopolies hinders the diffusion of new technologies and products

The impact of regulation on innovation is difficult to assess, because **innovation** is intrinsically a **complex dynamic process** with often contradictory aspects. In this study we focus mainly on product innovations, following the OECD definition of the "Oslo Manual", covering both goods and services introduced to the market which are either new or significantly improved with respect to fundmental characteristics. **Table 1** summarises the **potential impacts of regulation on innovation** following the regulation typology presented above.

Regulatory Systems Shaping New Markets

For a more detailed and comprehensive analysis of regulations shaping new markets, the following **new taxonomy of product market regulations** was developed by screening the directory of the relevant Community legislation and clustering the regulations and directives. The taxonomy is based on the assumption that regulations concern actors or relations between actors and defines the following types of relations (Figure 1):

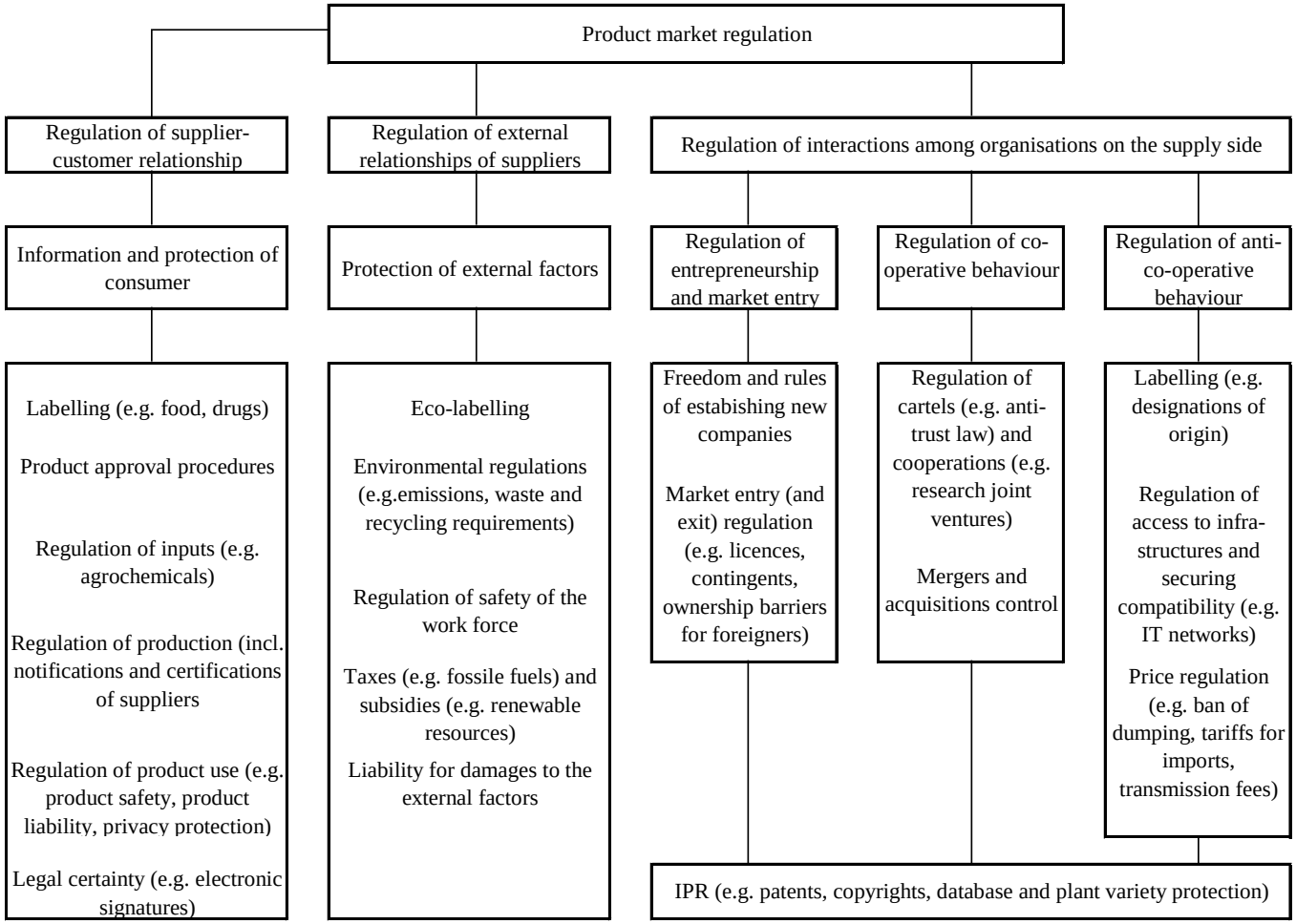
- **Supplier-customer relationships**
- **External relationships of suppliers**
- **Interactions among organisations on the supply side.**

The main objective of regulating the supplier-customer relationship is to **inform** and **protect the consumer**. The second type of relationship is the one between the supplier of goods and services and external factors, which also include the **work force** besides the **environmental resources**. All these regulations aim again to reduce **negative externalities**, e.g. to protect the environment by environmental regulations, e.g. taxes on fossil fuels. Besides the regulation of the relations to customers and the environment, the **actors on the supply side** need to be regulated in order to prevent **negative impacts** for the **consumers** and **society**, such as these caused by cartels.

Based on this taxonomy, we produced an **overview of European regulations** relevant for the introduction of new products and services according to the categories developed above. The overview of regulations with an impact on innovation based on the new taxonomy of product market regulations showed the variety of **different types of regulation** and the **range of possible impacts** on the introduction of new products and services. The main results are the following:

- often the **impact** of product market regulations on innovation is **ambivalent**
- one type of regulations, like **labelling requirements**, are soft framework conditions for the introduction of new products and services
- some regulations give companies **strong incentives** to develop and market new products and services, like:
  - **direct financial support** for the transfer from traditional to organic farming
  - **indirect financial incentives** like the guarantee to have restricted competition (e.g. orphan drug regulation for pharmaceuticals or fixed feed-in tariffs for renewable energies)
- the **liberalisation** of several **network industries** on its own was a meta-deregulation allowing the **market entry** of new companies offering new and often improved products and services.

Figure 1: Taxonomy of Product Market Regulations (Source: own taxonomy)



Following the overview of European regulations, the corresponding review of recent **national regulatory reforms** and its impacts revealed that within the so-called **network industries** the most dramatic changes have taken place also due to the deregulation initiatives of the European Commission:

- We find an impact on innovation in the **telecommunication** sectors by the **entry of new companies** into these markets offering a broad range of **new products and services** – also supported by the development of new technologies –
- In the **energy sector**, the **liberalisation** of the markets is at the **very beginning** and the market entry is still difficult, therefore the **entry** of new companies and the supply of new products and services is **still restricted**
- Within the **postal services** the **incumbents** still **dominate** the market and competition in new products and services is primarily taking place in certain niches
- In **air transport** the traditional European flag carriers came under great pressure from **low cost carriers** which leads more to **cost-saving procedures** and **less** to **new products** and **services**
- There is still **dissatisfaction** with **railway services** and the experience with liberalisation is mixed due to frequent **accidents** in the liberalised markets.

The review of recent regulatory **reforms** in the **USA, Canada and Japan** showed that the **USA** especially has **reduced** all regulatory **restrictions** in some sectors, whereas **Japan** is still at the **beginning of deregulation** in some sectors. In general, regulatory changes leading to a stronger competitive pressure have a positive impact on the prices and quality of products and services, but also on the introduction of innovative products and services.

Although innovation is a rather important impact dimension of regulation from a normative perspective (see Table 1), its factual appearance within regulations is rather limited. Therefore, we analysed in-depth the **objectives** and missions of institutions and **bodies responsible for regulatory policies** in the **European Union, the USA and Japan**. This screening revealed the following priorities:

- The promotion of **innovation** is only an explicit goal for the bodies which are responsible for **competition** issues
- In regulatory bodies responsible for very dynamic sectors, like **telecommunication**, we find the promotion of **innovation** as a further objective
- Most regulatory bodies have **conservation- or protection-oriented missions**, like those responsible for **energy**, the **environment** or **health** and **safety**
- The regulatory bodies in the **USA** are more likely to have the promotion of **innovation** on their **agenda** compared to Europe, but definitely more in relation to the Japanese bodies.

European Survey on the Role of Regulation for Innovation among Different Stakeholders

This section presents results of **surveys** on the role of regulation for innovation **among stakeholders**. First, the results of a company survey are presented, based on the answers of a random sample of more than 250 mostly **European companies** mainly active in **six sectors** (environmental sector, food sector, pharmaceutical sector, mechanical engineering, electro-technology, transport and telecommunication services).

The following **main results** can be reported from the perspective of the **companies**:

- **regulations** have both **positive** (e.g. for the quality) and **negative impacts** (e.g. for the time to market) on aspects related to the introduction of new products and services
- the most **positive impacts** of the regulatory framework for companies introducing new products and services are
  - the protection from **liability claims**
  - the increase of **acceptance** of new products by **consumers and users**
  - the enhancement of the **quality** of products and services
- regulations have especially strong **negative impacts** on
  - labour **costs**
  - energy and material costs
  - costs for the development and the introduction of new products and services
- **fulfilling** governmental or non-governmental **regulations** is among the set of **objectives** (e.g. expansion of market share) for companies to perform innovation activities only of **second priority**
- in relation to other obstacles, the **implementation** of governmental **regulations** is a serious **obstacle** for the introduction of new products and services
- **non-governmental regulations**, e.g. **standards**, are **less restrictive** for innovation
- **health** and **safety** aspects, the **quality** of products and services, and the question of **liability** are the most **important** regulations for the introduction of new products and services
- it has to be noted that
  - specific types of regulation **create market opportunities** for new products
  - **regulations** in general **do not make** the development and market introduction of **new products and services impossible**
- regarding the assessment of specific regulatory issues, we find that a **large consensus** among companies exists that
  - **approval** procedures are both too **costly** and too **long**
  - **public help** regarding the fulfilment of regulations is **not sufficient**
  - the **number** of regulations is perceived to be definitely **too high**
  - the **implementation** of regulations is often **not flexible and transparent**

- due to the obvious dissatisfaction the **companies require** that
  - regulations have to be **regularly adjusted** to the state-of-the-art in **science** and **technology**
  - each new regulation should undergo an **impact assessment**, which also takes into account the market introduction of new products and services
  - policies of different **regulation bodies** should be **better co-ordinated**
  - companies should have to contact only one regulatory body responsible for all regulation-related aspects, a so-called **"One-Stop Shop"**
- there is **no majority** for
  - the **US paradigm** of a **less rigid regulatory framework**, especially regarding product requirements, and **stronger product liabilities**
  - a substitution of governmental regulations by **self-regulation**
- an adequate **regulatory framework** is **not sufficient** for the initial introduction of new products and services world-wide in the sense of a **lead market**, but it may help to increase the **acceptance of consumers** for novelties in Europe.

Regarding the **differences** between sectors, we find that the **food and pharmaceutical companies** suffer more from the **burdens of the regulatory systems**. The answers of the research institutes are similar to those of the companies, but are less sceptical regarding the impact of the regulatory framework on their R&D activities.

Based on open telephone interviews, **other stakeholders**, e.g. consumers, express the following views:

- **Consumer organisations** are in favour of regulations which secure the **safety and quality of products** and argue that regulations are effective in providing incentives for companies to develop products of higher quality and safety.
- **Trade unions** favour in general a regulatory framework which protects the interests of the workforce, especially innovations reducing **risks for health and safety**, but they are also very interested in framework conditions which promote the **innovative capacity** of the respective **industries.**

Besides the different views of the stakeholders, significant **differences between sectors** can be observed:

- Within sectors characterised by strong public interest regarding the **protection of health, safety and the environment**, the regulatory framework is more extensive and rigid. Consequently, the **companies** in the **pharmaceutical or food industry** bear **higher regulatory costs**.
- The **conflicts** between the representatives of the protected objects, like the consumer associations or environmental groups, and industry are stronger, because more protection and **less risk** on the one side leads to **more costs** and less resources for innovation on the other side.
- In contrast, **environmental technologies** are promoted broadly by more **rigid regulations**, because both their **suppliers** and the **environmental groups** win in the form of increasing **market shares** and better **environmental quality**.

Case studies in the **pharmaceutical,** the **food** and the **environmental sector** and on standards complement the general analyses of frameworks and stakeholders.

1. The Impact of Regulation on the Development of New Products in the Pharmaceutical Sector

The pharmaceutical industry is characterised by **high investments** in **R&D** and innovation. In addition, the sector is **highly regulated** because of impacts of medicinal products on health and safety of the consumers. Consequently, the relationship between regulation and innovation in this sector deserves special attention.

However, the **analysis** of the impact of the regulatory framework on shaping (new) markets in the pharmaceutical sector does **not** provide a **clear picture** of the relations and causalities between the regulatory framework and innovative activities, like research and development and the marketing of new products.

The comparison of the **general regulatory framework** relevant for the pharmaceutical sector in the **EU** and the **USA/Canada** shows that the **significant differences** of the past have been **reduced** to some **minor discrepancies** in detailed regulations. In Europe, the **creation** of the **EMEA (European Agency for the Evaluation of Medicinal Products)** and the centralised authorisation procedure were major steps to overcome hindrances caused by conflicting national approval policies.

The companies in the pharmaceutical sector are interested in getting developed **drugs to the market as soon as possible** and developing new or improved drugs for new indication fields or diseases which cannot be treated so far. In contrast, the rationality of the **approval authorities** in the pharmaceutical sector is to **maximise safety**, in the extreme case by blocking beneficial products even with minimal risks.

Although **significant progress** has been made towards more efficient and faster **approval procedures**, the pharmaceutical **industry** both in Europe and in the USA still **complains** about the costly, uncertain and long **approval procedures** from first research to the marketing of new pharmaceutical products discouraging research.

Specific policies for medicinal products have to be mentioned which are related to **rare diseases** (the so-called "orphans") for which the costs of R&D and marketing activities would not be recovered by the expected sales. Therefore, the pharmaceutical industry is rarely interested to develop medicinal products for such diseases. In order to ensure patients suffering from orphan diseases the same treatment as other patients, specific regulations were established to stimulate R&D and market introduction of respective medicinal products. Both in the USA and in the EU the introduction of the **Orphan Drug regulation** had a strong **positive impetus for R&D** activities and the **market approvals** for such products, but it is argued that the lack of competition leads to too high prices for orphan drugs.

2. The Impact of Regulation on the Development of New Products in the Food Industry

In contrast to the pharmaceutical industry, the **food industry** is **less R&D-intensive**. While in the past innovation in the food industry strongly depended on technical developments in their supplying industries, current **innovation activities** are mainly **demand-oriented**, which results in a high number of new or modified products. We observe also in the food sector an increasing **harmonisation of the regulatory framework**. However, in many **innovative fields** relevant for the food industry the **framework conditions in the EU** often **do not keep pace** with **scientific** and **technical** discoveries or **trends** on the **demand side**.

In particular in interdisciplinary-oriented innovation fields of the food industry, e.g. **Functional Food** to prevent nutrition-related diseases, the institutional and administrative framework impede innovation activities, since different competent authorities are responsible for implementation, administration and control of regulations.

Since the mid 1990s, **genetically modified (GM) plants** have been cultivated which can enter the food chain. In addition, genetic engineering approaches are regarded by their protagonists as major tools to increase productivity and efficiency in food processing in future. On the other hand, an **intensive public debate** worldwide concerns the **safety** of these approaches and derived novel foods, their **health and environmental impacts** as well as their wider socio-economic impacts. In contrast to the **USA policy** of **not requiring market approval** for GM (genetically modified) crops, the **EU approach** for environmental release and market approval of GMOs (genetically modified organisms) follows a rather **strict** interpretation of the "**precautionary principle**". Therefore specific regulations have been put into force which require often more complex procedures than for conventional products. In 2001 the Directive 2001/18/EC modified the rules for environmental release and market approval of GMOs significantly, by restricting market approval to ten years and the requirement of post-market monitoring of each GMO, meaning a de facto moratorium on the commercialisation of GMOs.

The definition of standards and the creation of labelling and control procedures for **organic food products** does not seem to be sufficient for an early and fast take-off on the supply side. The high technical and market-related risks impede farmers from converting conventional farms to organic agriculture. Therefore, financial incentives seem to be an adequate instrument to speed up the adoption of new production processes and products.

These three case studies, i.e. Functional Food, GMOs and organic food products, underline the importance of regulations for the development of new markets in the food sector. Unclear competencies and regulations or very restrictive market approval procedures impede new products or even the establishment of new markets.

3. The Impact of Regulation on the Development of New Technologies in the Environmental Sector

Environmental problems are one of the most prominent cases for **external costs** and justify therefore **environmental regulation**. Thus, since the late 1960s, environmental regulation has been a major political issue in all industrialised countries. In almost every country, regulation takes mainly the form of **command and control policies**. However, there seems to be a move toward **market-based instruments** recently in the form of emission taxes or tradable certificates.

The increase in environmental regulation in the 1970s to 1980s was caused in the USA and Europe by an increasing public awareness in several fields of environmental protection. General environmental regulations applicable to all areas of environmental protection have been passed since the late 1980s concerning environmental impact assessment, environmental liability, or the availability of environmental information. In general, the introduction of new and **stricter environmental regulations** has worked towards an **increase in environmental innovations**.

The **water sector** is a sector with rather **conventional environmental technologies**. Therefore at wastewater treatment plants, mostly incremental innovations take place along an existing technological paradigm. In Europe and the USA the foundations of the environmental regulation in the water sector were developed in the 1970s and made stricter in the 1980s. The **technological development** was influenced by environmental regulations, not only by **command and control policies**, but also by **emission charges** on wastewater. Furthermore, long-term policy goals were also very important, providing guidance for the development of water protection technologies.

Wind power is a **new technological paradigm** competing with conventional electricity generation. European countries, e.g. Denmark and Germany, and the USA used **R&D policies** to trigger innovation in the early phase. However, only in Denmark and Germany did the R&D policy evolve constantly. In addition, the predictability of **fixed feed-in tariffs** used in Germany, Spain and Denmark stimulated market growth more than the subsidy and quota systems, e.g. in the USA. The market expansion in the European countries led to virtuous circles which made **Europe** a **lead market** and its producers the key players in wind turbine supply.

The general overview and the case studies underlined that various aspects proved to be very influential in deciding on the innovative effects of environmental regulation: the existence and performance of general economic regulation, the institutional processes which determine the interaction between R&D institutions, suppliers of technology and users to create knowledge spillovers, or the existence of long-term policy goals such as water quality or the doubling of renewable electricity supply.

4. The Role of Standards for Shaping New Markets

Regarding the role of different types of standards for new technologies and markets, the main results are the following. First, finding a **common compatibility and interface standard** allows to build up **critical masses** which are a necessary condition for the emergence of network technologies, like the GSM standard in mobile telecommunication. Furthermore, **compatibility** between existing and new technologies avoids the **lock-in** in old technologies, but increases also the attractiveness of new technologies. Minimum **safety** and **quality standards** reduce transaction costs and protect especially early adopters from risks, which increases the **acceptance** of, and the confidence in, new products and services. **Information standards** have the same impact and allow consumers to assess the benefits of new products more easily and better. In total, all kinds of standards play an important role for the development of new markets, although compatibility and interface standards have a special relevance for the crucial network industries, like telecommunication.

Future Challenges for Regulatory Policy Shaping New Markets

All the different approaches to identify and analyse the role of regulation for shaping markets for new products and services have shown various challenges, problems and shortcomings:

- The **variety of regulations** have **different** and often **ambivalent impacts** on the introduction of new products and services
- There is a significant **lack of awareness** regarding the issue of new products and services within the regulatory bodies
- The various interest groups and **stakeholders** involved in the regulatory process are also often **not aware** of the **opportunities** new products and services can have for their own interests
- The **implementation of regulations** is crucial for the incentives of companies to develop and market new products and services.

Based on these general insights, we present four sets of proposals for regulatory policies shaping new markets.

1. The General Role of Innovation for Regulatory Policy

- **Regulatory bodies** responsible e.g. for the protection of competition, health and safety or the environment, have to adequately **consider** the **opportunities** of new products and services and **innovation** in general for achieving their traditional goals
- Also the **major stakeholders** in regulation, except industry, have to **check** systematically the **positive influence** of **new products** and services on their organisations´ objectives.

2. Approaches to Increase the Quality of the Regulatory Framework regarding Innovation

- **Regulatory bodies** have to **react** more **proactively** to trends in **science** and **technology** relevant for their regulatory framework by:
  - intensifying the **contact** to the science and technology community
  - implementing "**regulatory foresight**" exercises
  - **observing** on-going **standardisation** processes
- The **co-ordination** and the division of work between **standardisation** and **regulation** activities have to become **more efficient**
- The extent of **self-regulation** has to take into account the trade-off between the gains in flexibility and the loss in legitimacy and acceptance among stakeholders
- Regulatory bodies have to focus on those **types of regulations** or shape regulations in a way which maximises the positive and minimises the negative impacts for the development and market introduction of new products and services
- The **impact assessment** approach of the European Commission already takes new products and services into account but needs to be specified and to be accompanied by methodologically advanced impact assessment tools
- The **performance criteria** of regulatory bodies have also to integrate indicators measuring the promotion of new products and services in balance with their other objectives.

3. Coordination of Policies of Regulatory Bodies to Foster Innovation

- Since innovation is a complex process, the promotion of innovation by regulatory policies requires a **comprehensive approach**, **co-ordinating** or even integrating the **regulatory policies** of all the regulatory bodies, e.g. it is not sufficient to set a favourable framework for research, it is also necessary to stabilise the demand for new products and services
- Shaping the regulatory framework for new products and services should also take into account windows of opportunities to establish **lead markets**, i.e. combination of favourable supply and demand conditions, which may generate trade advantages and are therefore a source of future growth.

4. Improved Implementation of Regulations to Foster Innovation

- The **implementation** of regulations has to be **harmonised** in order to reduce the risk and the costs of companies introducing new products and services
- **Approval times** have to be **reduced**, since they are very negative for the expected return of investment in long-lasting and expensive R&D resulting in innovative products and services
- The transition of **regulatory bodies** into **service providers** for the general public, but also for companies, represents a promising strategy also to promote their general support for the introduction of new products and services.

1. Introduction

The question of regulation, innovation and their impact on competitiveness in global markets has been discussed for decades, but is still of high relevance. For example, at the World Economic Forum 2004 in Davos, one major issue is regulation with innovation in mind. However, little has been done to understand the effect of regulation on the capacity of European industry to develop new technologies and to introduce new products and services to the market. The debate has taken place at the level of anecdotal evidence and poor systematic empirical foundations. In addition, most of the approaches assume a static framework, not recognising the long-term dynamic feedback loops between regulation and technical progress and new markets. Finally, the majority of the expressed statements, especially from industry, come to the conclusion that the negative impacts of regulation outweigh the positive effects.

The study "New Products and Services. Analysis of Regulations Shaping New Markets" aims to bridge the gap between the challenge to shape a regulatory framework, which allows the emergence of new markets, and even to use regulation as an instrument to foster innovation on the one hand, and to reduce the lack of adequate, reliable and systematic knowledge on their interrelationship, by applying a methodological approach which considers the complexity and interdependence of the multiple parameters and stakeholders. Regulation can vary between private self-regulation of the involved stakeholders and governmental mandatory regulation. This variety will be taken into account, as well as the interfaces of regulation to other spheres of public frameworks, like competition law. The optimal solution, that means achieving an adequate balance between an environment fostering the introduction of new products and services and securing consumer safety and environmental protection, depends on several aspects, like the respective technologies involved and products or services supplied.

The report contains six chapters. The second chapter presents a conceptual framework of the relationship between regulation and innovation. In the third chapter, we review regulatory systems relevant for new markets applying a revised taxonomy of product market regulations. Then we give an overview of those European regulations, which are relevant for innovation and the market introduction of new products, followed by a review of regulatory reform in the network industries in the Member States and recent regulatory reforms in the USA, Canada and Japan with an impact on innovation. We conclude the chapter with an overview of the priorities of institutions responsible for regulation in Europe, the USA and Japan. In chapter four the views of stakeholders on the relation between regulation and innovation are presented. First, the results of a survey focussing on European companies in selected sectors are presented. In addition to the views of companies, we show also the results of a survey among research institutes asking about the impact of the

regulatory framework on their R&D activities and of interviews with other stakeholders like consumer associations. In chapter five, we present the results of three in-depth case studies covering the pharmaceutical, the food and the environmental sector and selected technical standards. In addition selected success stories of technical standards shaping new markets are displayed. The concludes with an outlook how in future the innovation dimension can be better integrated into regulatory policies.

2. A Conceptual Framework to Analyse the Relationship Between Innovation and Regulation

2.1 Introduction

This introductory chapter aims to provide a conceptual framework for the analysis of the general relationship between regulation and innovation, especially focusing on the impact of the regulatory framework on the development and diffusion of new products and the emergence of new markets.[1] Since there is no comprehensive theoretical framework for the regulation-innovation relationship, we must rely on the very few studies which have also focused, besides other aspects, on the issue we address in this report. This chapter tries to organise the partial insights drawn from various contributions in order to construct a concept which allows us to analyse the relationship between regulation and innovation in a systematic way.

Except for some specific topics (Intellectual Property Rights) and for some specific sectors (environmental regulations), very few studies have been performed which explicitly focus on the link between regulation and new or modified products and services or innovation aspects in general. Often, these insights are by-products of broader studies, mostly on competitiveness of specific industries or national economies. This observation should not be explained by the restricted relevance of the issue, but by its high complexity and the difficulty to comprehend it in a simple framework. This difficulty is caused both by the complexity of the regulatory framework, which is many-sided and has various – often contradictory – impacts, and the complexity of the innovation process, which is not just linear from basic research to market introduction of new products and services, but interactive with multiple feedback loops and involves many actors and institutions, linked through numerous and different relationships. Consequently, one of the major results of the literature is to underline that it is impossible to draw any simple and general conclusions about the link between regulation and new products and markets. It cannot be postulated that a specific regulatory measure will lead inevitably to more innovation, since there are many subtle variations within each category of regulations. Moreover, most regulatory requirements generate contradictory effects on innovation, being both positive to certain phases or actors in the innovation process and negative regarding other phases or economic actors.

This two-sided complexity calls for the development of an adequate analytical framework, which can be applied and tested for various sectors and regulatory frameworks. This would allow us to gather stylised facts to reach a better understanding of the relationship. One essential reason for the difficulty to establish a link

1 This chapter draws significantly on Brousseau (1998) and the literature cited there.

between the two phenomena is, indeed, the lack of specific, dedicated studies on the topic. In order to remedy this lack, a systematic assessment of the impact of various dimensions of regulations on the diverse aspects of the innovation process is needed. It would enable the gathering of the necessary information to build an adequate analytical framework to help to develop public policies aimed to encourage innovation in form of new products and services or even new markets.

In order to reach this aim, the chapter is structured as follows. First, the variety of regulations and the complexity of the innovation process will be outlined in order both to clarify the concepts and to derive some methodological insights. Then, the most important conclusions about the causal links between regulation and innovation will be presented.

2.2 Types of Regulation

The term regulation generally refers to the implementation of rules by public authorities and governmental bodies to influence market activity and the behaviour of private actors in the economy. Such intervention in the market is justified by the goal to maximise collective welfare, including reaching some distributive goals. In economic literature and by the OECD (1997), three types of regulatory interventions are usually distinguished.

2.2.1 Economic Regulation

This type of regulation refers to public interventions to remedy market or competition failures. The basic assumption behind this concept is that competitive markets are the best way to achieve economic efficiency in the tradition of neo-classical economic theory. However, markets sometimes do not work efficiently, because:

- the market mechanism generates inefficient adaptation processes,
- market equilibria are not stable,
- competition destroys competition leading to monopolies,
- competitive markets (many suppliers) are less efficient than non-competitive ones (few suppliers).

These different reasons lead to a certain degree of public or governmental intervention, even in very liberal economies, in order to ensure efficient performance of markets. We can differentiate between the following two types of economic regulation.

Pro-competitive or Antitrust Regulations

Pro-competitive or antitrust regulations aim to avoid impediments for competitive markets by competition itself. This type of regulation is mostly directed at the supervision of firms' behaviour, like mergers and acquisitions, pricing policies, general selling conditions, relationship between suppliers and consumers, and to the repression of anti-competitive ones. It must be pointed out that sometimes this type of regulation induces public authorities paradoxically to erect barriers to entry or to reduce the competitive intensity.

Regulation of Natural Monopolies and Public Utilities

In traditional economic literature, it is generally considered that in some sectors with specific cost structures in the production process, a single producer – a monopoly – is the most efficient solution, because economies of scale or because some strategic resources, like military equipment or energy suppliers, deserve to be excepted from the principle of competition. In those markets, public authorities try to avoid a rationing of the markets and rent capturing by monopolistic behaviour like overstated prices. Public authorities can therefore legitimately restrict and supervise private or independent operators.

2.2.2 Social Regulation

Social regulation refers to public intervention necessary to correct externalities in general. Externalities arise when economic agents do not fully bear or appropriate the consequences of their actions because market mechanisms are missing or just not possible. Due to physical or institutional constraints, like the non-existence of property rights on certain resources, many economic activities have side effects. These side effects or externalities cause a difference between the private and social cost and benefit of actions, like the production and distribution of goods, that results in a misallocation of resources. Two types of regulations are appropriate for effects caused by externalities.

Internalisation of Externalities

The internalisation of externalities tries to provide an incentive scheme that induces economic decision-makers to make the best decision according to the collective interest. Whether the internalisation of externalities is inspired by the Pigovian tradition based on taxes or subsidies (in case of positive side effects) or by the Coasian paradigm based on an appropriate definition of property rights and private negotiation, the aim of this regulation is to lead economic agents, producers and consumers to fully bear the consequences of their decisions and actions. It includes the protec-

tion of the environment (Kemp 1998), public health, and protection of buyers from risky, poor or defective goods and services. Public policies are generally more concerned with negative than with positive externalities, since the former cause generally more damage for social welfare than the latter. However, since positive externalities are characterised by the same feature of an incorrect incentive structure, public authorities can correct them in order to generate an increase of social welfare, for example by subsidising the production of non-marketable goods which generate positive externalities or by public procurement schemes, which favour new technologies with less negative impacts on the environment.

The Provision of Public Goods

Collective or public goods represent a special case of extreme externalities which are not divisible among consumers (Samuelson 1954). For pure collective or public goods, it is not possible to exclude any individual after it is produced (non-excludability) and its use by additional consumers does not reduce the consumption or welfare of the other, already consuming agents (non-rivalry in consumption). Since the production of a public good by an individual agent makes it – at least theoretically – available for all the members of a society who cannot even be forced to pay for it, public goods are extreme cases of externalities. Therefore, they generate serious free-riding problems and market mechanisms fail to cause sufficient incentives for their private production. Consequently, public authorities are often either directly involved in their production or they commission a private company with its production and charge all members of the society with mandatory fees, mostly in form of taxes.

2.2.3 Administrative or Market-organising Regulations

In the tradition of institutional economics, public authorities are not only responsible for a most efficient performance of existing markets, but also for the general organisation of markets.[2] More precisely, they or even other non-governmental public institutions have to enable private agents to use resources and to transfer them among each other. Collective governance devices and inter-individual agreements both influence the design and implementation of resource usage rights and ensure their transfer among economic agents (North 1990, Williamson 1985). Economic agents must spend resources to define the boundaries of the resources they use and to exclude unauthorised parties from access to these resources. When these resources are transferred from one agent to another, the transferred user's rights have to be specified and the transfer has to be made effective according to the trans-

2 The OECD classification defines a third type of regulation as administrative regulation (OECD 1997). Some of these, especially those with relevance for innovation, belong to market-organising regulations.

fer agreements. The effectiveness and the efficiency of the institutional framework influences the costs of using and transferring resources for the individual. Therefore, the institutional framework is one of the major factors for the efficiency – both in a static and in a dynamic sense – of the economic system.

Consequently, many rules issued by governmental bodies as well as by organisations responsible for their implementation are instruments through which public authorities can influence economic efficiency. This is especially the case for the legal framework dedicated to the organisation of property rights and the boundaries of contractual practices. These allow markets to emerge and to work. However, the assessment of legal rules can only take place if their implementation also is acknowledged, which is in the responsibility of implementing institutions.

2.3 The Assessment of the Impact of Regulation on Innovation

The impact of regulation on innovation is difficult to assess, because most assessments perform an evaluation based on static efficiency criteria, although innovation is intrinsically a dynamic process. Furthermore, innovation is a complex phenomenon and it is difficult grasp all of its – sometimes contradictory – aspects.

In this study we focus on product innovations, following the OECD definition of the "Oslo Manual", covering both goods and services introduced to the market which are either new or significantly improved with respect to fundmental characteristics. However, often process innovations in the form of new or significantly improved technology are crucial for the production or the supply of new goods and services. Therefore, we restrict ourselves not only to product, but take also into account relevant process innovations. Innovation in general should be based on the results of new technological developments, new combinations of existing technology or utilisation of other knowledge by firms.

The assessment of regulation is mostly based on static efficiency criteria instead of dynamic ones, since the latter approach would require long-term observations of the behaviour of the affected economic agents. Economic regulations are judged on the basis of the generated improvement of social welfare estimated by changes of production costs, prices, and turnover. The efficiency of social regulation is estimated on the basis of the remaining level of externality, e.g. environmental pollution, or of the volume (and costs) of available resources. Finally, the efficiency of administrative regulations in the sense of institutional and legal framework conditions is assessed through the level of the so-called "transaction costs", which often cannot be directly measured but only by proxies.

Besides the methodological shortcomings, it has to be stated that assessments of economic regulations are often reduced to the analysis of theoretical models without a direct application to concrete regulatory changes. An exception is the regulatory impact assessment programme of the United States of America (OECD 1999). Furthermore, innovation is a phenomenon which is difficult to grasp. In general, the impact of regulation can be measured either by the input or the output of the innovation process.

Innovation also requires physical and human resources like a production process. It is performed in a first stage by formal processes of R&D and by informal and sometimes unintentional processes of learning-by-doing or learning-by-interacting. In order to generate economic effects, the results of the R&D process have to be adapted to the needs of potential users and have to be promoted by marketing activities. As a consequence for the analysis, the inputs into the innovation process cannot be reduced just to R&D expenditures. Especially in the service sector, new services are generated by a close interaction between the consumers and the service providers, whereas R&D activities are of minor importance. Finally, innovation processes are characterised by a high level of uncertainty, which makes it difficult to identify a close link or causality between inputs into the innovation process and its final result.

The measurement of innovation by output has to take into account that it can take place at the level of new products, new services or even new markets, but may include also process innovations like the application of new technologies and organisational innovations caused by changes in the management. Some of these aspects can be more easily observed than others, but often they are interconnected. Furthermore, radical innovations can be observed better than incremental innovations which are characterised by gradual changes of products, processes or organisations. However, the latter type of innovation is much more frequent than the first, more spectacular type. A final problem for the observation of process or organisational innovations, which are not so relevant for this study, is the fact that they are often kept private and not disclosed by a product announcement or a patent application. Summarising the characteristics of the output of innovation, it is easier to observe completely new products and services than improved processes or organisational changes.

In addition, studies about the impact of regulation on innovation should take into account how regulations affect the various aspects of the complex process of innovation. Since innovation is a process of search, discovery, development, improvement, and adoption of new products and processes, it is also a cumulative process, that produces an increasing amount of knowledge.

This has consequences for the analysis of the impact of regulation, which cannot be based on a simple linear and mechanistic stimulus-response model, since this does

not take into account the complex interdependencies between regulatory policy measures and the manifold aspects of innovation:

- First, since an innovative process requires the co-ordination of very diverse operations, its efficiency is influenced by the dynamic articulation of these various tasks as much as by the individual performance. It must therefore be pointed out how regulations affect the ability of economic agents to articulate these tasks within and among firms, and finally how it impacts on the speed of the innovation process, as well as on its quality in terms of the fitness of the results to the needs of the users and of the appropriability by producers.
- Since an innovation process leads not only to new products or processes, but also to knowledge, it is essential to determine how regulation affects the production and diffusion of knowledge.
- Third, innovation implies the co-ordination of various parties within and among firms, the impact of regulation on this co-ordination including inter-firm collaboration has to be taken into account.
- Fourth, since innovation is a dynamic process, the causal relationship between regulation and innovation may change over time. Therefore, the assessment of the impact of regulation has to acknowledge its various impacts on the diverse phases of an innovation process.

2.3.1 The Impact of Economic Regulation on Innovation

Most of the existing literature on this issue is dedicated to the analysis of the impact of antitrust regulation on innovation. Recently, the approaches have become more differentiated and go beyond simple monopoly regulation towards more efficient incentive regulation, also taking into account stimulating effects on innovation.

In general, it has to be underlined that the effect of economic regulation on innovation is very controversial. Therefore, one cannot analyse the relationship on an abstract level, but must investigate concrete variants of regulation. Nevertheless, regulatory constraints generate contradictory effects for innovation. It is central to take into account that a very pro-competitive regulation scheme forces companies to innovate in order to reach a competitive advantage. However, this scheme may forbid strategies and organisational arrangements, like close collaborations between firms, which are necessary to introduce new technologies and new products into the market successfully. However, if the regulatory regime tries to protect infant industries and firms in order to develop new markets, then the consequence could be the persistence of a protected industry, which will not become competitive with foreign, unprotected industries.

These two examples make clear that it is necessary to analyse the impact of the various types of economic regulation on the various aspects of innovation and innovative processes.

Antitrust or Pro-competition Regulation

The link between pro-competitive regulation and innovation has been discussed since Schumpeter's seminal contributions. Four issues have to be taken into account. First, regulation and innovation mutually affect each other. Second, there are two very contradictory positions about the impact of regulation on innovation. Third, this antagonism is mainly caused by a divergent understanding of competition that leads to very contrasting implementations of pro-competition or antitrust regulation.

It is generally accepted that not only does regulation influence innovation, but that innovation also has an impact on regulation, since in many industries the so-called de-regulation or liberalisation processes have been induced by technological innovations. The best example is the telecommunications industry, which was formerly a natural monopoly, but triggered by technological change (e.g. digitalisation of transmission) into an industry with "normal" production cost structures. Therefore, the regulatory framework adequate for a natural monopoly had to be adapted to the new situation caused by technological innovations. We have observed not only in telecommunications, but also in other industries that the technological development drove the evolution of regulation towards highly pro-competitive regulation.

The other way round, it is confirmed that pro-competitive policies affect the likelihood to innovate. De-regulation of markets leads in most cases to a price decrease. Reduced prices force companies either to make production processes more efficient by searching for new innovative technologies, or companies have to introduce new products into the markets, which may be superior to the existing one. Consequently, de-regulation often allows formerly regulated companies to expand their product and service assortment by the introduction of new products and services.

There are two antagonistic views about the impact of regulation on innovation. On the one hand, pro-competitive frameworks are supposed to be favourable to innovation. Since companies are allowed to choose their strategies and actions without restrictions, innovation activities should be easier to perform. In addition, in a highly competitive environment, firms are strongly forced to innovate, because both product and process innovations allow them to survive in the long run by being ahead of the competitors. In a Schumpeterian perspective, innovating firms enjoy a temporary monopoly that provides them with rents. In sum, competitive environments caused by pro-competitive regulations are positive for innovation.

However, the empirical evidence is rather ambivalent, not only for methodological reasons, but because it is based on theoretical approaches, which assume that inno-

vation requires both the close co-operation between firms and significant resources. On the contrary, pro-competitive policies reduce the ability of firms to form strong alliances, especially in the R&D stage. In addition, innovation is costly and leads to temporary inefficient resource allocation. Only in the long run can the broad distribution of new products or the broad application of new technology make it possible to recover the investments in the early stages. Consequently, innovation processes should deserve some kind of protection in their infancy stage, which is realised by patent protection. However, protection does not necessarily mean a direct public intervention, but only that innovators should be able to protect their innovation as they want, including the formation of strong company alliances – often the target of antitrust investigations. Besides this liberal approach, evolutionary economists even plead for a direct protection of industries and innovators in their infancy by subsidising R&D, erecting barriers to entry or admitting some anti-competitive practices, including mergers leading to high market concentration. In total, all these trains of thought postulate that pro-competitive regulation damages innovation.

The explanation for these two antagonistic views is based on differences regarding the understanding of competition. Based on neo-classical economics, markets should be competitive in the sense that as many firms as possible should supply a market with their goods. This excludes a supplier structure with only a few or just even one dominant firm – a monopolist. Consequently, regulatory bodies have to prohibit an integration between firms via mergers and acquisitions, which leads to a high level of concentration and just a very small number of suppliers inclined to adopt monopolistic behaviour, like price increases or little innovation activities. Or if markets are dominated by very large firms, regulatory bodies have to break them down into many small firms.

From a dynamic point of view, competition is a selection process that in the long run selects the most efficient techniques, commercial strategies and organisations. During this selection process, firms with dominant, even monopolistic positions can emerge. This is not a problem from the dynamic efficiency criteria, as long as these positions are contestable by new entrants (Baumol et al. 1982). This entry threat leads the dominant firms to be efficient and not to exercise monopoly power. Consequently, dominant positions have not to be forbidden, but their abuses.

In relation to innovation, pro-competitive policies have to take into account that in their infancy innovation processes are not efficient and "competitive", but they are necessary to ensure competition in the long run. As a consequence, during the formation phase of a technological or product life cycle, while companies build up new capacities, pro-competition authorities should tolerate most firm practices including cross-subsidisation, market restriction, and barriers to entry. In the long run, such practices should be forbidden, since they enable firms to escape from competition, leading to inefficient resource allocation, a slowdown of technical progress, a reduction of innovative activities and a rationing of consumers.

Monopoly and Public Utilities Regulation

Under the regulatory framework in the 1960s and 1970s, monopolies and public utilities had no strong or biased incentives to innovate. Therefore in the 1980s, the United States started to implement regulations in order to motivate them to make productivity gains and realise innovations. However, these new regulatory principles reduced the rents of the regulated firms they formerly captured and often used for large R&D projects and other innovation activities. Therefore, an incentive-financing dilemma emerged for some public utilities.

Especially network-based services, like telecommunications, water and energy supply, were regulated under the old regulation principles, which consisted either in rate of return regulation or pricing at marginal costs. Under the rate of return regulation, the monopoly should reach a profitability not higher than the average firm in industry. Under marginal cost pricing, the monopoly was forced to price its products according to two-part tariffs (Ramsey-Pricing).

In relation to innovation, these regulatory schemes were responsible for the low or biased technical progress towards capital intensive production (Averch-Johnson Effect) and little innovation in some of the regulated industries, like telecommunication and the energy sector. Based on the progress of the economics of information (Stiglitz 1975), appropriate incentive schemes have been developed to overcome the information asymmetries between regulated companies and regulatory bodies. This led to the implementation of new regulatory schemes based on the idea that there is a "revealation-incentives" dilemma that can be solved by a fine tuning via "price cap" regulation. Price cap regulations are based on contracts between the regulator and the regulated firm, which require minimum quality and fixed maximum prices. If productivity gains can be appropriated – at least – partly by the regulated firm, then this scheme causes incentives for innovation, especially in the direction of productivity gains. If the regulatory body wants to capture all productivity gains, the regulated firms have no incentive to innovate. The same is true if the regulatory framework tries to implement a competition, which allows multiple suppliers with inefficient cost structures in their production. Consequently, they try to increase their market shares by price competition, which reduces their profits and does not allow them to invest in R&D and innovation.[3]

3 The high competitive pressure among the deregulated electric utilities led to the recent energy shortage in the USA, due to too little investment in new power plants.

2.3.2 The Impact of Social Regulation on Innovation

The impact of social regulations on innovations is not as often analysed as the impact of economic regulations. However, it is also less controversial.
Most of the existing literature on social regulations and their impact on innovation is focused on the analysis of the impact of environmental regulation caused by the increasing importance of environmental issues (Kemp 1998). In addition, new environmental regulations have discarded existing machinery and equipment and enabled new entrants to introduce new production techniques in industry. Environmental regulations have caused the emergence of new industries, as in the case of the "environmental industry" and of new products with less or almost no negative impacts on the environment. The counter-hypothesis postulates that environmental regulations restrict the firms in their innovative activities and cause additional costs, which have a negative impact on their competitiveness and consequently also on their capability to innovate. It is consensus that the regulation of end-of-pipe technologies has these negative effects, whereas the regulation of integrated environmental protection may be ambivalent for innovation. Kemp (1998) introduces a further dimension of the relationship and proposes to use regulation as a modulator of technical change, i.e. social regulation may change the direction of technical change into innovations with less negative impacts on the environment.

In empirical studies, Jaffe et al. (1995) find no support either for the conventional wisdom that environmental regulations have large adverse effects on competitiveness or that they stimulate innovations.

In sectors with strong ethical dimensions and a high importance of externalities as in the matter of health, the activities and strategies of the involved actors are so bound by regulations, that the link between regulation and innovation is obvious and close. Safety regulations may on the one hand prohibit innovations, if the public authorities forbid presumably risky products. On the other hand, safety regulations increase the acceptance of new products and services among consumers, since they can rely on some minimum product safety. However, especially the health sector is affected by various other means of intervention (Day et al. 1993). Consequently, the perspective has to be broadened from the single regulation to the institutions that surround the regulatory framework.

Concerning public goods, most of the public policies fit into the logic of direct intervention rather than the logic of regulation. Nevertheless, the provision of public goods fosters innovation if it represents a physical (road system) or intangible (education) infrastructure, which only allows innovative activities. However, individual economic agents are deprived in their innovative activities, because they have to transfer funds via taxes to public institutions.

2.3.3 The Impact of Administrative Regulation on Innovation

Besides single economic and social regulations, the institutional framework implemented by administrative regulations is essential for the analysis of regulation and innovation. Two approaches have been developed to link the legal framework to innovation.

The economic analysis of law has also focused on the way the legal environment influences economic efficiency, including innovation. Especially the impact of liability rules on innovation, particularly in the domain of product safety has been analysed. Too strong liability rules lead innovators not to introduce new products and services in the market, because the risks are higher, the expected revenues decrease, and the users of the products decrease their self-protection efforts, leading to more accidents. Viscusi and Moore (1993) are able to confirm empirically that very high levels of liability have negative effects on product innovation. However, without product liability, the acceptance of new products among consumers is reduced and that may prohibit their success at the market.

The best analysed link between administrative or institutional regulation and innovation is the impact of Intellectual Property Rights (IPRs), especially patents and copyrights, on innovation. As Besen and Raskind (Besen et al. 1991) pointed out, the fundamental dilemma lies between invention and diffusion. On the one hand, a strong patent protection encourages innovation. On the other hand, a weak one favours a rapid and wide diffusion of inventions, which leads then to innovations and to growth for the whole economy. Appropriate licensing schemes may be a good way to reach the two goals simultaneously. Since the innovation processes differ by industries, optimal IPR rules should also vary from industry to industry from a purely economic point of view, but this is not practicable for the legal system.

2.4 Summary

The discussion of the different types of regulation, the difficulty to identify and define innovation and the ambivalent impact of regulation on innovation has shown that simple approaches are not adequate to analyse this issue and no clear-cut results of such an analysis can be expected.

Table 2.4-1 summarises the different types of regulation which have been discussed in the previous sections. We have focused on those regulations which are supposed to have an impact on innovation in the sense of the development of new products and the emerging of new markets.

Table 2.4-1: Typology of regulations

Economic Regulation	Social Regulation	Administrative Regulation
- pro-competitive or antitrust regulation - price control, entry barriers - regulation of natural monopolies and public utilities	- internalisation of externalities (environmental, health and safety regulation; consumer protection) - provision of public goods	- property rights - contract law

Source: modified according to OECD (1999b): Regulatory Reform in the United States, Paris: OECD.

Table 2.4-2 summarises the discussed types of regulations and their possible impacts on innovation, in the sense of the development of new products and services. Due to the complexity of both the regulatory framework and the innovation activities, a differentiated approach is needed to analyse this relationship.

Table 2.4-2: Types of regulations and their impacts on innovation

Type of Regulation	Positive Impact on Innovation	Negative Impact on Innovation
Economic regulation		
Antitrust or pro-competition regulation	eases and enforces innovation	prohibits (R&D) alliances
Protection of infant industries (R&D subsidies, barriers to entry, mergers)	allows costly and risky innovations	continued protection does not enforce innovative activities
Public utilities: rate of return regulations; pricing at marginal costs	rents available for R&D and innovation	little and biased incentives to innovate
Public utilities: price cap	incentives to reach productivity gains, if regulated company can capture parts of the gains	-
Public utilities: competition	-	high price pressure and low profit margins do not allow to invest in innovation
Protection of selected industries (e.g. aerospace)	funds available for large R&D projects and innovation	no competitive pressure to innovate
Social regulation		
Environmental regulations	create incentives for new processes creating less environmental damage and for the development of new products	restrict the innovative activities of firms and hamper the competitiveness and therefore their innovative capacity regarding end-of-pipe technologies
Safety regulations	increase acceptance of new products among consumers	additional restrictions for innovators
Public goods	provide infrastructure for innovative activities	reduced private sources for innovative activities
Administrative regulation		
Product liability	producer liability increases the acceptance of new products among early adopters	too high liability reduces the incentive for producers of innovative goods
Intellectual property rights	additional incentives to innovate	additional protection for monopolistic practices is an obstacle for the diffusion of new technologies and products

Source: own overview based on Brousseau (1998).

3. Regulatory Systems Shaping New Markets

3.1 Introduction

As seen in the conceptual framework for the analysis of the relationship between regulation and innovation, most regulations have only an indirect and often ambivalent impact on innovations and new markets. For a more detailed and comprehensive analysis of regulations shaping new markets, first of all a taxonomy of regulation relevant for development and market introduction of new products has to be developed[4], which is more specific than the rough OECD classification of economic, social and administrative regulations. Furthermore, the OECD taxonomy of product market regulations is based on very specific types of regulations and aims to provide quantitative indicators in order to perform comparisons between countries and sectors.

Consequently, the following section 3.2 develops first a new and more comprehensive taxonomy of product market regulations. Section 3.3 will focus on a selection of those recent regulations of the European regulatory system, which have an impact on innovation and on the development of new markets following the taxonomy developed in section 3.2. Since the current regulatory reforms in the network industries have the most tremendous impact especially on the market introduction of new products and services, we review these activities and impacts in the Member States in section 3.4. Then, we present some recent regulatory reforms and their impact on innovation in the USA, Canada and Japan. In a further section, we review the priorities of institutions responsible for regulatory policies in European Union, the USA and Japan. The chapter concludes with comparative summary of regulatory systems relevant for the introduction of new products and services.

3.2 A Taxonomy of Product Market Regulations

The OECD divides regulation according to its own rough classification into economic, social and administrative regulation (see box below). However, it is necessary to differentiate more precisely between different types of regulations relevant for the development and introduction of new products and services.

The OECD developed a taxonomy of product market regulations (Figure 3.2-1) based on indicators derived from the evaluation of answers to qualitative questions

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4 In order to make the following text more convenient to the reader, we will use in the following as e.g. OECD the term "product markets regulations" for those regulations, although some regulations are included which do not directly deal with the product market.

about the public ownership, price regulations, administrative burdens and antitrust rules (Nicoletto et al. 2000). This classification can serve only as background for those regulations which are directly relevant for the development and the introduction of new products and services, because the taxonomy is neither complete, e.g. labelling is missing, nor consistent, in the sense of imprecise demarcations between the subcategories. Besides the OECD taxonomy no other internationally accepted schemes exist which we can refer to. Therefore, we have developed a new taxonomy of product regulations.

Definitions:

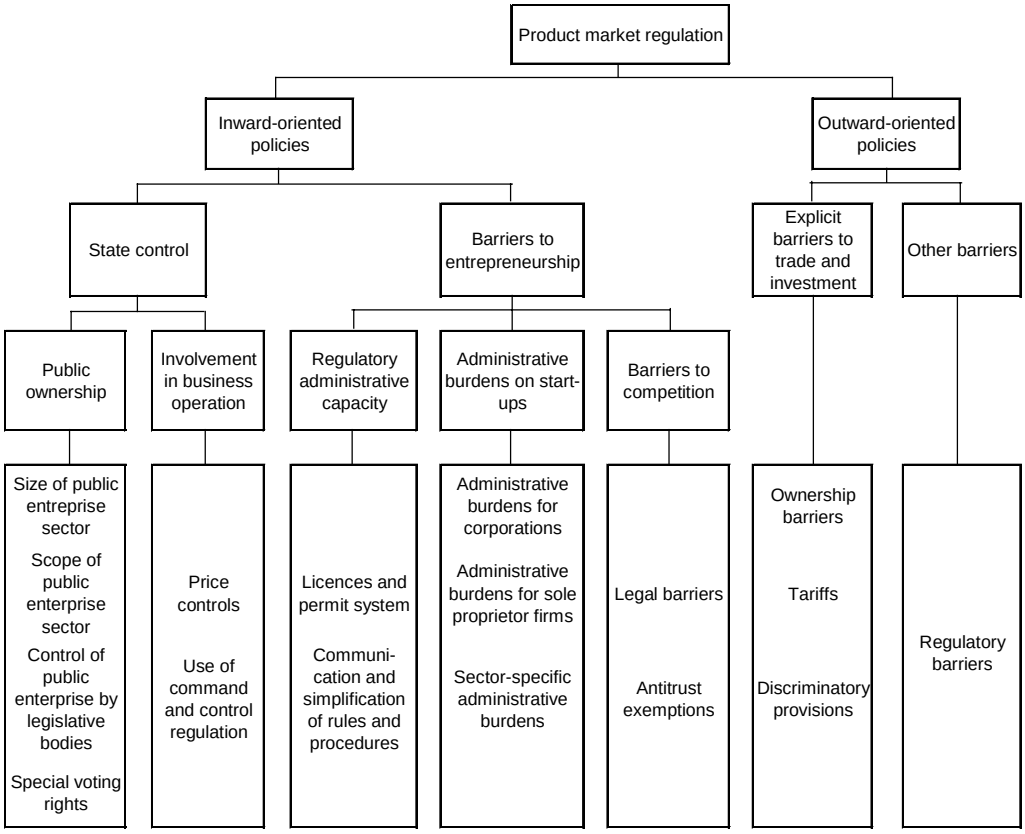
Regulation in total refers to the diverse set of instruments by which governments set requirements of enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of *government* (incl. EU), and rules issued by *non-governmental* or self-regulatory bodies to whom governments have delegated regulatory powers (e. g. standards development organisations, industry confederations). Regulations fall into three categories: ***Economic regulations*** intervene directly in market decisions such as pricing, competition, market entry, or exit. ***Social regulations*** protect public interests such as health, safety, the environment, and rights of workers. ***Administrative regulations*** are paperwork, qualification requirements and administrative formalities ("red tape") though which governments collect information and intervene in individual economic decisions. They also accompany economic and social regulations.

Source: OECD (1999b): Regulatory Reform in the United States, Paris: OECD.

The following new taxonomy of product market regulations was developed by screening the EUR-Lex directory of the Community legislation. In conformity with its mission, which is to publish the whole body of European Union law, and in particular the legislation and the case law, as well as the decisional procedures between the Commission and the other institutions, the EUR-Lex website is the single entry point to the complete collections of EU legal texts in all the official languages. It provides direct access to the official document repositories managed by the institutions or by the Publications Office, as well as other institutional documentary sources.

The search functions permit searches in specific types of documents or across all documents using free text, and contains explanatory texts on EU legislative procedures. Applying free text search using the keywords "innovation", "new", "product", "service" and "market", we generated lists of documents, e.g. regulations, directives, decisions. Then we selected those documents, especially regulations and directives, which are relevant for the introduction of new products and services.

Figure 3.2-1: OECD taxonomy of product market regulations



Source: Nicoletti, G., Scarpetta, S. and O. Boylaud (2000): Summary of Indicators of Product Market Regulations with an Extension to Employment Protection Legislation, Economics Department Working Papers No. 226, Paris: OECD, p. 25.

These regulations have been clustered according to the issues on which they are targeted and not as in economics textbooks according to the type of instrument, e.g. taxes, liability or command and control regulation. This procedure produced both thematic clusters e.g. around the food sector or the ICT sector and some cross-sectoral issues, like product safety and competition issues. Based on an approach to construct a typology for standards (De Vries, 1999), which is based on the assumption that standards concern entities or relations between entities, we defined the following types of relations:

- regulation of supplier-customer relationship
- regulation of external relationships of suppliers
- regulation of interactions among organisations on the supply side

These additional dimensions allowed us, also taking into account the above OECD taxonomy, to come up with the new and modified taxonomy (Figure 2.2-2). The main objective of the regulation of the supplier-customer relationship is to ensure

freedom of choice of the consumers by adequate information as well as protection of consumers´ health and well-being, while the protection of the suppliers does not play a key role, although fraud by consumers is a problem e.g. in the insurance industry. The relevant areas and instruments cover:

- the labelling of products,
- approval procedures,
- rules for the input of production,
- regulation of the production of goods, e.g. meeting quality standards,
- regulation of the usage, especially in case of accidents through product safety and liability rules,
- protection of privacy, e.g. of individual user behaviour,
- legal certainty, e.g. in contract issues.

The second type of relationship is the one between the supplier of goods and services and external factors, which also includes the work force, besides environmental resources. All these regulations have again the objective to reduce negative externalities, i.e. to protect the production factors, like the environment and the workers, by:

- eco-labelling, promoting the usage of environmentally friendly products,
- environmental regulations, e.g. ceilings for pollution,
- regulation of occupational safety
- taxes, e.g. on fossil fuels, and subsidies for the usage of renewable resources
- liability for damages to the external factors.

Besides the regulation of the relations to customers and the environment, the interactions among organisations of the supply side need also to be regulated in order to prevent negative impacts for the consumers and society as a whole. One can distinguish three types of activities which are relevant in this aspect. First, the establishment of companies and their entry to the market need some rules which

- secure the freedom and support of establishing new companies,
- regulate market entry and exit, e.g. licenses.

The interaction between companies can be characterised as co-operative or anti-co-operative. In order to prevent negative consequences for customers, e.g. high prices and reduced variety, co-operative behaviour has to be regulated by

- regulation of cartels (e.g. antitrust law) and co-operations (e.g. research joint ventures)
- mergers and acquisitions control.

However, also anti-co-operative behaviour needs to be regulated in order to secure a sufficient level of competition and to prohibit the distortion of competition by:

- labelling requirements, e.g. origin of destination,
- regulation of access to infrastructures, e.g. IT networks, and securing compatibility, e.g. interoperability between networks or software,
- price regulation, e.g. ban on dumping, tariffs for imported goods, transmission fees.

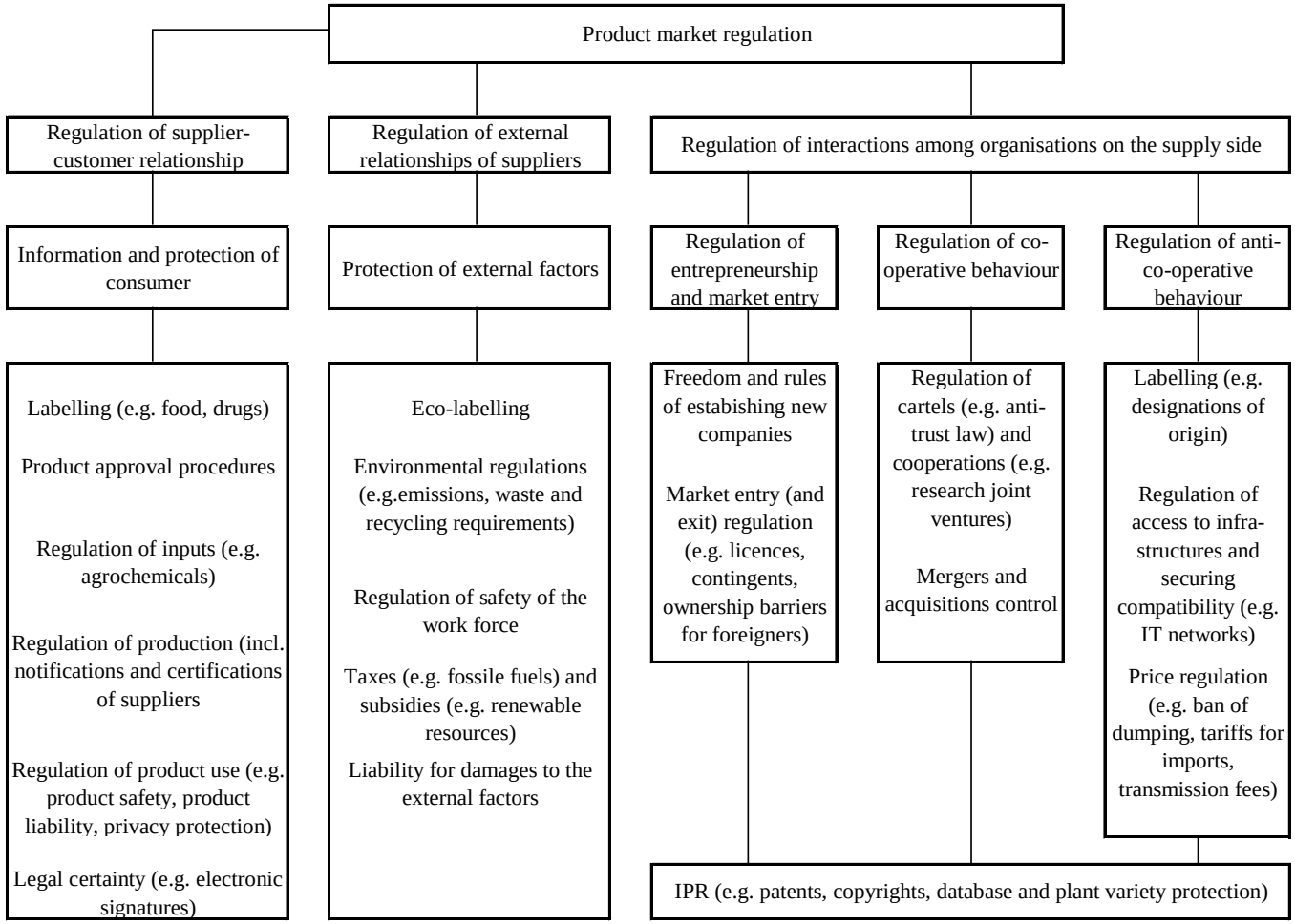
Across all the three categories, property rights are essential, not only for the creation of new companies, but also for the co-operative and anti-co-operative activities of companies. Assuming that property rights in the general sense are understood and accepted,

- intellectual property rights (IPR), like patents and copyrights,

are especially important not only for the development, but also for the market introduction for new products and services.

This taxonomy is independent of sectoral aspects and covers the different instruments available for regulation of product markets, ranging from information requirements to strict command and control regulations. Not all of these regulations have an impact on the introduction of new products and services. If one considers cartel policies, they focus more on the activities of established companies competing in restricted markets, like e.g. cement, vitamins and amino acids, with a small number of large companies. Others, like labelling policy, are more relevant for the introduction of new products and services, since they can increase the acceptance of new products among consumers. In the following chapter, we present an overview of the most important European regulations relevant for shaping new markets.

Figure 3.2-2: Taxonomy of Product Market Regulations (Source: own taxonomy)



3.3 European Regulatory Reforms Shaping New Markets

Based on the taxonomy presented in chapter 3.2, we proceed with an overview of European regulations relevant for the introduction of new products and services according to the categories developed above. We concentrate mainly on directives and regulations released in recent years. In some instances, we also cite regulations published in the 1990s. Furthermore, we do not claim to cover all regulations, but try to provide a comprehensive picture by presenting selected examples of product market regulations having an impact on new markets by referring to important specific regulations.

3.3.1 Regulation of Supplier-Customer Relationship

The regulations relevant for shaping new markets for innovative products and services under the category of "Regulation of Supplier-Customer-Relationship" try to protect the customer from uninformed decisions and possible risks and damages (e.g. health risks) using the following instruments:

Labelling

Labelling regulations are most prominent among pharmaceuticals (Directive 2001/83/EC on the Community code relating to medicinal products for human use) and food, like the Directive 2002/46/EC on food supplements and Commission Regulation (EC) No 223/2003 on the labelling requirements of organic production method for feedingstuffs, compound feedingstuffs and feed materials. Further regulations address labelling requirements for foods intended for use in energy-restricted diets for weight reduction (Commission Directive 96/8/EC), for processed cereal-based foods and baby foods for infants and young children (Commission Directive 96/5/EC, Commission Directive 91/321/EEC) and for dietary foods for special medical purposes (Commission Directive 1999/21/EC).

A long regulatory tradition of labelling requirements can also be observed for dangerous substances. It started with Council Directive 67/548/EEC, which has meanwhile been adapted to technical progress for the 28th time in the Commission Directive 2001/59/EC.

The main intentions of these regulations are to inform and protect the consumer. They promote the introduction of new products and services only in an indirect way by trying to increase their acceptance among the consumers and to reduce information asymmetries which are especially high in the case of new products and services.

Product approval procedures

Product approval procedures are very crucial for the introduction of new products to the market, since the producers have to meet the requirements of the respective regulations. These procedures are very prominent for products which have a strong impact on the safety and health of the consumers. Important examples are food and pharmaceutical products. Directive 98/79/EC on in vitro diagnostic medical devices and Directive 2001/83/EC on the Community code relating to medicinal products for human use define the respective rules and guidelines for approval procedures. The Regulation (EC) No 258/97 concerning novel foods and novel food ingredients aims to provide a framework for producers and consumers and therefore has an important impact on this emerging market (see Part C for details). For the service sector, Directive 2001/34/EC on the admission of securities to official stock exchange listing can be mentioned, which describes the requirements for the introduction of innovative financial products.

The priority of all these directives is the protection of consumer interests. They do not explicitly concern the innovation dimension, although the acceptance of consumers is raised by approval procedures during which the safety of the products is checked and therefore potential health risks of consumers are minimised. As an important peculiarity one has to mention that the objective of the novel food regulation is to construct a framework for a new and emerging market with a whole class of new products.

Regulation of inputs

More rigorous than labelling regulations are the regulations of inputs and materials used in the production process. They also aim to protect the consumer by restricting the opportunities of the producers to use inputs which may harbour risks for the consumers. We find examples again in the agricultural sector in the case of agrochemicals, e.g. Directive 2003/68/EC, and in the food sector, e.g. Commission Regulation (EC) No 466/2001 which set maximum levels for certain contaminants in foodstuffs or Directive 2002/32/EC which defines undesirable substances in animal feed. Furthermore, the pharmaceutical sector is restricted in this sense, like by the recommendation on the prudent use of antimicrobial agents in human medicine or Directive 2003/15/EC on the approximation of the laws of the Member States relating to cosmetic products. Finally, producers also face restrictions in the use of certain hazardous substances in electrical and electronic equipment (Directive 2002/95/EC).

Again, all these regulations intend to protect the consumers and users from potential risk and damage. Consequently, they are less appropriate for the promotion of new products and services.

Regulation of production

The production process itself can also be regulated, not only for the protection of the consumers, but also in order to protect other citizens, the involved work force or the environment. Good manufacturing practice is required especially in the production of medicinal products and regulated in Commission Directive 2003/63/EC and Directive 2001/83/EC. Another example also covering the R&D phase in the pharmaceutical sector is Directive 2001/20/EC which defines analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (see Part B for details). One further example is Council Directive 2002/99/EC, which lays down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

The regulations concerning production have only an indirect impact on the market introduction of new products and services by restricting the production process which may have a negative impact on the opportunity to produce new products or to deliver new services. Strong positive impacts on new products and services cannot be expected.

Regulation of product use

Despite conformity to the safety regulations for the inputs and to the production process itself, the use of products can damage the health and safety of the consumers. Therefore, Directive 2001/95/EC on general product safety tries to ensure a high level of consumer protection through a horizontal Community legislation introducing a general product safety requirement and containing provisions on the general obligations of producers and distributors on the enforcement of Community product safety requirements. European standards complement the product safety directive by providing guidelines for the safety of products. The directive does not take new products explicitly into account. Consequently, the product safety directive supports the introduction of new products only in an indirect way by increasing the consumer acceptance of new products, which have also to follow the rules of the directive.

If – despite all the previous regulations – an accident happens because of a defective product, Directive 85/374/EEC and Directive 1999/34/EC regulate the liability for such products. These directives do not only protect the consumer, they liberate also the producers and distributors from unjustified liability claims in case they followed the rules for the production and distribution of goods. Consequently, this regulation not only strengthens the rights of the consumers, but allows the supply side to produce and distribute new products according to the existing regulations and the state-of-the-art in science and technology. In total, liability rules increase legal security

not only for the consumer, but also for the producer, and provide therefore the framework for the introduction of new products.

Besides these cross-sectoral regulations, several sectoral regulations for product and service use exist. One new regulation of a traditional service is the Commission Directive 2002/25/EC on safety rules and standards for passenger ships reflecting recent accidents. For new service markets Directive 97/66/EC and Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the telecommunications and electronic communications sector have to be mentioned, which protect the consumer by restricting the use of information about his use of the information and telecommunication services. In some Member States citizens are rather critical about the potential threat of misusing their communication profiles. These directives accompanied by Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services tried to increase consumer acceptance for new communication services. Especially in network industries it is crucial to generate a minimum number of users, the so-called critical mass, which allows network goods and services to be marketed without producing deficits. Therefore, all the regulations which reduce the perceived risks among early adopters foster innovations in network industries.

Legal certainty

Legal certainty is a general framework condition for market transactions. However, with the increasing use of the Internet as a platform for trade, new requirements arose. Directive 1999/93/EC provided a Community framework for electronic signatures, which fosters the reduction of transaction costs. This reduction is essential for some new electronic products and services to evolve. As already said above, this is fundamental for the acceptance of the important early adopters of new network related products and services. In addition, Directive 2000/31/EC tries to clarify certain legal aspects of information society services, in particular electronic commerce in order to protect consumers, but also to allow new services to be offered. Legal certainty is the basic requirement not only for existing markets, but especially for new and emerging markets. Consequently, all regulations which contribute to legal certainty not only on the demand, but also on the supply side are crucial for the prosperous development of new markets.

3.3.2 Regulation of External Relationships of Suppliers

The regulations which concern the external relationships of the suppliers aim to minimise unintended negative externalities for society as a whole, but especially for the environment and the work force. We distinguish three types of instruments. First, regulations which require the producers to provide information about the envi-

ronmental impacts of their products.[5] Second, command and control regulations may define limitations for emissions and other impact dimensions. Third, financial incentives, like subsidies, and sanctions, like taxes, are able to influence the activities of producers. Finally, liability rules may force the producers to anticipate possible risks for society, the environment and the work force and to start precautionary measures.

Eco-labelling

Already in 1992, the European Commission published Council Regulation (EEC) No 880/92 on a Community eco-label award scheme. The voluntary Community eco-label scheme intended to promote environment-friendly products during their entire life cycle and to provide consumers with accurate, non-deceptive and scientifically based information on the environmental impact of products. A revised Community eco-label award scheme was published in 2000 (Regulation (EC) No 1980/2000).

Recently, also Community energy efficiency labelling programmes for office equipment (Regulation (EC) No 2422/2001), household electric ovens (Commission Directive 2002/40/EC) and household air-conditioners (Commission Directive 2002/31/EC) have been implemented.

The first objective of all these labelling programmes is the protection of the environment. However, they indirectly foster the development of new environment-friendly or energy-efficient products, because they allow producers to highlight the specific "environmental quality" of their products. Nevertheless, labelling is only a "soft" instrument both for the protection of the environment and the support of the introduction of new products.

Environmental regulations

The regulation of environmental issues aims primarily to protect the environment and the natural resources from damages caused by the production and consumption of goods and services.

There is a long tradition of European environmental regulations (see for details chapter 2 in Part D). We provide just some examples for emission and pollution regulations, like:

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5 The Community eco-management and audit scheme (EMAS) allows companies to signal to customers their environment-friendly production by the use of environmental performance indicators.

- Council Directive 96/61/EC concerning integrated pollution prevention and control,
- Council Directive 1999/32/EC relating to a reduction in the sulphur content of certain liquid fuels,
- Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations,
- Directive 2001/81/EC on national emission ceilings for certain atmospheric pollutants,
- Directive 2001/80/EC on the limitation of emissions of certain pollutants into the air from large combustion plants,
- Directive 2002/88/EC relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery,
- Directive 2003/17/EC relating to the quality of petrol and diesel fuels.

The recent Directive 2002/96/EC on waste electrical and electronic equipment and Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment are addressing the increasing problem with waste electrical and electronic equipment.

Further recent activities are targeted to noise reduction. For example, Directive 2002/49/EC refers to the assessment and management of environmental noise, Directive 2002/30/EC relates to the establishment of rules and procedures with regard to the introduction of noise-related operating restrictions at Community airports and Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors.[6]

The objective of all these environmental regulations is primarily the protection of the environment. They neither explicitly address innovation aspects nor foster the market introduction of new products and services. However, they have two general indirect impacts on the innovation activities of companies. The restrictions imposed by the regulations lead to additional burdens for companies and may hinder their innovation activities. However, they may force them also to search for innovative solutions to fulfil the requirements of the regulations. Second, the regulations force the producers of machinery and vehicles which pollute the air with emissions or the environment with noise to develop new products which fulfil the requirements. The latter aspect is an example for the view that stronger environmental regulations force companies to find new and innovative solutions either by developing them,

6 Finally, one has to mention Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. This directive is fundamental for the future market of genetically modified organisms and is presented and discussed in-depth in Part C of the report.

themselves or by transferring the regulatory pressure especially to the suppliers of intermediate goods and machinery they use within their companies.

Safety of the work force

Besides the environment in its various dimensions, the work force is the second important "external factor" whose protection has to be considered, because it is involved in the protection process accompanied by various forms of risk.

Recent safety requirements regarding the exposure of workers are focusing on the risks arising from noise (Directive 2003/10/EC) or vibrations (Directive 2002/44/EC) of machinery, so called physical agents. The Directive 2003/18/EC tries to protect workers from the risks related to exposure to asbestos at work. These regulations make obvious that similar hazards threaten both the environment and the work force. A very specific risk for the work force is the aspect that the employer becomes insolvent. In this case, Directive 2002/74/EC protects the rights of employees.

The evaluation of the regulations aiming to protect the work force is similar to environmental regulations. At first, they impose restrictions on the use of production materials, like chemicals, and the production process itself which may hinder also the development of new products and services. Secondly, the requirements of the regulations can also force the companies to invent new solutions, like substituting materials or modifying the production process. Consequently, the regulations protecting the external factors have in general similar impacts on the development of new products and services.

Taxes and subsidies

Besides the command and control regulations, market based incentives like taxes or subsidies for certain goods, can change relative price ratios which are able to direct the demand of consumers to new goods and services.

Taxes and subsidies are mostly implemented in those cases in which the government seeks to support the development of technologies and products less harmful to the environment. There are several examples in the case of energy production. On the one hand, the use of fossil fuels is heavily taxed in order to internalise the negative externalities on the environment and to promote the development of "cleaner" technologies. Directive 98/69/EC relating to measures to be taken against air pollution by emissions from motor vehicles and Directive 98/70/EC relating to the quality of petrol and diesel fuels enable the Member States to tax vehicles or fuels which have more negative impacts on the environment more heavily. Directive 2002/51/EC allows Member States to implement tax incentives in order to promote

the reduction of the level of pollutant emissions from two- and three-wheel motor vehicles. On the other hand, renewable resources, like wind and solar energy (see part D), are subsidised either by direct payments for the development and instalment of wind parks or solar cells or by guaranteeing fixed prices for such kinds of energy or by tax exemptions, like regulated in Directive 2003/30/EC on the promotion of the use of biofuels or other renewable fuels for transport and Directive 2001/77/EC on the promotion of electricity produced from renewable energy sources in the internal electricity market. Regulation (EC) No 1382/2003 permits the granting of Community financial assistance to improve the environmental performance of the freight transport system. Another example is the support of the conversion of traditional farms into organic farming implemented by Regulation 2078/92/EC (see part C for details).

The direct change of relative prices by taxes and subsidies is an effective instrument to give incentives for the development and market introduction of new products and services. However, efficiency especially of subsidies is questionable if they are paid without time restrictions, because then it is not guaranteed that the markets for these goods, like renewable energies, are sustainable without state aid.

Liability for damages to the external factors

As for the protection of the consumers through product liability the external factors can also be protected by liability law. We focus on environmental liability, because of a recent initiative. In January 2002 the Commission adopted a proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage (European Commission (2002b)) by applying the "polluter pays" principle.

The operators potentially liable under the directive for the costs of preventing or restoring the environmental damage are the operators of the risky or potentially risky activities. These include activities such as releasing heavy metals into water or into the air, installations producing dangerous chemicals, landfill sites and incineration plants. However, activities related to genetic engineering, nuclear power plants and oil production are not covered by this directive. Finally, the proposal includes provisions concerning transboundary damage, financial security, its relationship with national laws, and a provision for reviewing the regime. Qualified entities (public interest groups, including NGOs), alongside persons who have a sufficient interest, i.e. who have suffered damage, can request the competent authority to take appropriate action, and challenge the competent authorities' action or inaction. This allows the public to oversee and influence the role played by competent authorities as trustees of environmental assets.

The proposal foresees some exemptions and defences, which are justified by the need to ensure legal certainty and safeguarding innovation. For instance, emissions

that have been authorised will not give rise to liability. Activities and emissions which are believed to be safe for the environment according to the state of scientific and technical knowledge when they occur are also not covered by the proposal. This additional exemption proposed by the Commission aims to reach a better balance between environmental goals, on the one hand, and economic and social ones, on the other. In particular, the Commission's proposal should better preserve incentives for innovation, since it does not penalise innovative activities retrospectively.

This proposal for a European liability law aims at first to protect the environment. However, the exemption clause explicitly mentions the innovation dimension. Furthermore, it is claimed that the proposal is also likely to foster investments in preventive technologies and practices capable of leading over time to more efficient levels of prevention. This kind of preventive innovations would achieve high standards of environmental protection with fewer resources, thus freeing up resources and facilitating higher growth.

Nevertheless, this proposal of a European liability law defines rather comprehensive liability claims which increase also the risk of companies when implementing new processes or producing new products. Therefore, as in the case of environmental regulations, it is rather ambivalent whether this liability approach will have a positive impact on innovation or not.

3.3.3 Regulation of Interactions among Organisations on the Supply Side

In addition to the regulations covering the relationships of the suppliers with their customers and the external factors, numerous rules exist in order to co-ordinate and control the interaction of supplying companies. We differentiate four dimensions. First, both the establishment of new firms undergoes certain procedures and especially the entry into specific markets is regulated. Second, companies intend in some instances to co-operate in a way which has negative drawbacks for the consumer and the society, like by building cartels. Third, there is the possibility that companies compete with each other in a way which is negative – at least in the long run – for the welfare of the consumers. Therefore, these activities have to be controlled and regulated. Finally, intellectual property rights are crucial both for the foundation and market entry of companies, their competitive strategies and their collaborations.

3.3.3.1 Regulation of Entrepreneurship and Market Entry

Entrepreneurship in the form of founding new companies, but also the free entry to markets, are crucial factors for the development of new markets and the dynamic change of existing markets. Both factors are driving forces for the market introduc-

tion of new products and services. In the following, we concentrate on those regulations which have an impact on the foundation of new companies and the entry into new markets. The few regulations affecting the exit of companies are not relevant for the development of new markets and are not taken into account.

Freedom and rules of establishing new companies

Very often the development of new markets is accompanied by the foundation of new companies, e.g. in the case of science- and R&D-intensive products often as spin-offs from research institutes and universities. Therefore, the framework conditions for the establishment of new firms are a basic requirement for the development of new markets with new products and services. Already in 1997, Commission Recommendation 97/344/EC tries to give guidelines on how to improve and simplify the business environment for business start-ups.

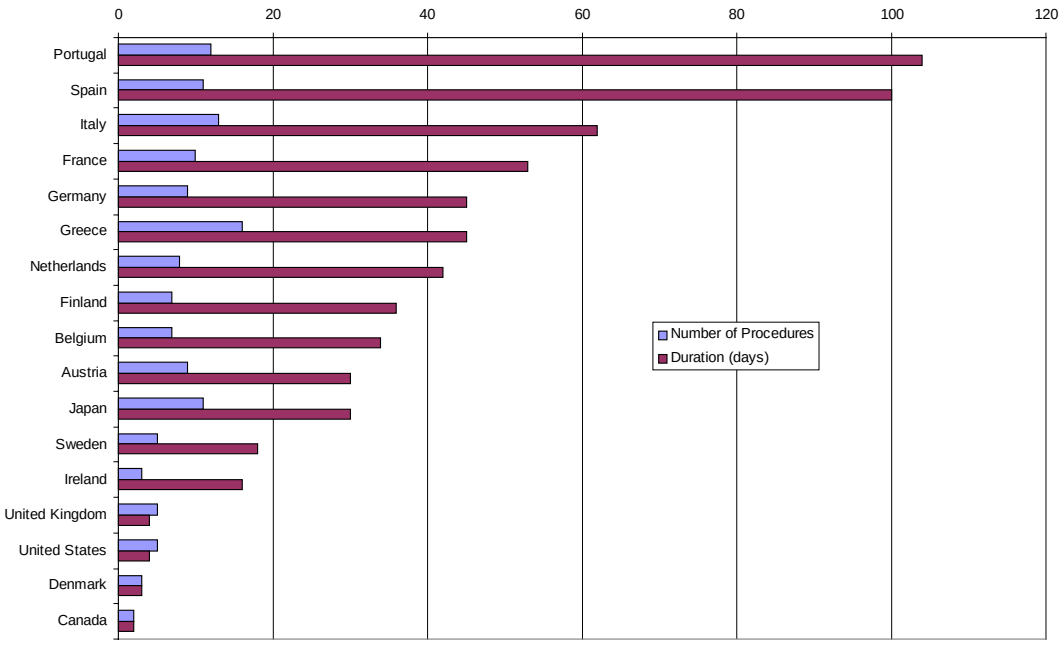
Market entry and exit regulation

Whereas the company-supporting schemes try to ease the foundation of companies, there are several sectoral regulations, especially for the strongly regulated insurance industry which restrict the foundation and therefore also the market entry of companies in order to protect the consumer. The recent Directive 2002/92/EC on insurance mediation lays down rules for the commencement and pursuit of the activities of insurance and reinsurance mediation. A first step to facilitate the exercise of freedom of establishment and freedom to provide services for insurance agents and brokers was made by Council Directive 77/92/EEC. In addition, Directive 2002/83/EC concerning the establishment of new companies in life assurance must be mentioned. For the financial sector, Directive 2000/12/EC regulates the taking up and pursuit of the business of credit institutions and Directive 2000/46/EC regulates the start-up, pursuit and prudential supervision of the business of electronic money institutions. In the transport sector Council Directive 96/26/EC regulates the admission to the occupation of road haulage operator and road passenger transport operator. Especially by the mutual recognition of diplomas and certificates it was intended to facilitate the right to freedom of establishment in national and international transport operations for these operators.

In all, these market entry regulations have the objective to protect the consumer from fraudulent suppliers of services threatening their wealth, and in case of transport, their health. However, these regulations also protect the credible companies and allow them to introduce new products and services which may find a higher acceptance among the consumers. Nevertheless, their positive impact on the market introduction of new products and services is rather small.

The Worldbank has produced a database about entry regulations and the time they require. The database contains information of more than 100 countries. The following Figure 3.3-1 presents the results of the Member States and Japan, the United States and Canada. In contrast to the time-consuming procedures in southern European countries, it is much faster to register a new business in Canada, the United States and Japan. However, Denmark and the United Kingdom have also to be mentioned with less than ten days necessary to register a new company.

Figure 3.3-1: Entry Regulations (Numbers and Days needed) in the Member States, Canada, the United States and Japan



Source: Worldbank (2003): Starting a Business - procedures to start a business (http://rru.worldbank.org:80/DoingBusiness/SnapshotReports/EntryRegulations.aspx).

After the liberalisation of network industries, licence schemes had to be developed in order to manage the scarce infrastructures or frequencies, like by Directive 97/13/EC on a common framework for general authorisations and individual licences in the field of telecommunications services, or Directive 2001/13/EC on the licensing of railway companies. The intention of these regulations is to guarantee an efficient use of the existing infrastructures avoiding congestion which hurts the availability and quality of network-based services.

This second type of entry regulation has a positive impact on innovation only if a licence scheme is applied which generates a more efficient use of the existing network infrastructures and a higher degree of competition. Then it is possible that a higher number of companies enter the market with a broader range of products and

services, and the more intense competition forces these companies to be more innovative, compared to a situation with only a few or even just one supplier underutilising the existing infrastructures. The experiences of the liberalisation of the telecommunication market – at least for the long distance calls – is a good example that a controlled entry of companies had positive impacts on competition and the development of new products and services. The insufficient opening of the local loop as a negative example caused so far no significant competition and consequently also no major innovations in local telephony.

Finally, one has to mention a very special and unique entry regulation, the Commission regulation (EC) No 141/2000 on orphan medical products. This regulation restricts the market entry of pharmaceutical companies in the case of rare diseases in order to stimulate R&D investments (see part B for details). In case of rare diseases the potential demand is so small, that no positive return is expected without entry restrictions. The history of orphan drug regulations confirms that this type of regulation is able to create incentives for the development and market introduction of new drugs for small groups of patients, whereas the other entry regulations with the exception of the liberalisation of the network industries have only little impact on the market introduction of new products and services.

3.3.3.2 Regulation of Co-operative Behaviour

The regulation of co-operative behaviour between companies is necessary in order to ensure competition and to prevent dominant market positions which can be achieved by cartels or co-operations between companies or by the mergers and acquisitions of companies.

Regulation of cartels and co-operations

In order to establish a system which ensures that competition in the common market is not distorted, Articles 81 and 82 of the Treaty must be applied effectively and uniformly in the Community. Council Regulation No 17/62, the first regulation implementing Articles 81 and 82 of the Treaty, allowed a Community competition policy to develop that has helped to disseminate a competition culture within the Community. The recent Council Regulation (EC) No 1/2003 sets rules on how to meet the challenges of an integrated market and a future enlargement of the Community.

This general regulation intends to guarantee legal security and tries indirectly to promote innovation. A further indirect impact on innovation is by securing a certain level of competition forcing companies to be innovative by introducing new products and services into the market. The direct impact on innovation and the development of new markets is rather limited.

The European regulatory framework has been favourable to R&D co-operation agreements, recently confirmed by Commission Regulation (EC)No 2659/2000. Joint R&D may only raise problems if companies are moving for joint production afterwards. Worries may still arise when competitors are engaged in joint R&D projects where one of the partners is claiming property rights over the output of the R&D. If the joint share of competitors in the relevant market remains around 25 %, the positive benefits of joint R&D will probably outweigh the negative effects. The only R&D co-operation that will be forbidden is where parties are competitors, and where the joint share has a significant impact (more than 25 %) on the relevant market. The results of R&D joint ventures are also positive for innovation by providing ideas and technological know-how which may not have been produced by R&D of single companies because of lack of critical mass or positive synergies.

Mergers and acquisition control

The regulation of mergers between and acquisition of companies is based on Council Regulation (EEC) No 4064/89. Its objective is to ensure that competition in the common market is not distorted by mergers or acquisitions of companies which may lead to a market-dominating position with the consequence of negative impacts on the consumers, like price increases or quality reductions because of insufficient competition. This regulation is also crucial for the market introduction of new products and services, because it guarantees a sufficient degree of competition which forces companies to innovate in order to survive in the market. However, this regulation may also have a negative impact on the development of new markets if this requires large investments by dominant companies with high market shares which can bear the risk of high and risky investments.

3.3.3.3 Regulation of Anti-co-operative Behaviour

Besides the threats of too much and too close co-operation among companies, there are anti-co-operative strategies between companies which can also hurt the interests of consumers and need therefore to be regulated. We distinguish between regulations of labelling, of access to networks and compatibility, of prices and tariffs on imports.

Labelling

Labelling requirements have already been discussed in the context of the supplier-customer relationship, but it is also relevant for the interaction between suppliers in order to protect products with special characteristics, like Council Regulation (EC) No 692/2003 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs. In the case of wine, Commission Regulation (EC) No 753/2002 lays down certain rules for applying Council Regu-

lation (EC) No 1493/1999 as regards the description, designation, presentation and protection of certain wine sector products. The general labelling of foodstuffs is regulated by Directive 2000/13/EC. Furthermore Commission Regulation (EC) No 223/2003 defines the labelling requirements related to the organic production method for feedingstuffs, compound feedingstuffs and feed materials.

All these labelling requirements support producers to supply their products with special product characteristics at the market by demanding a price premium in comparison to average products. This kind of regulation is able to support the introduction of new products and services, but it is only a necessary and no sufficient requirement for the successful market introduction, like in the case of organic products (for details see part C).

Regulation of access to infrastructures and securing compatibility

In addition to market entry regulation, one has also to consider the regulation of access to infrastructures and of compatibility, because of the recent liberalisation of network industries which like telecommunications play a major role for the European industries. A crucial characteristic of these industries is that especially service providers rely on the access to network infrastructures.

For the purpose of adaptation to a competitive environment in telecommunications, Directive 97/51/EC was published amending Council Directives 90/387/EEC and 92/44/EEC. Already in 1995 Commission Directive 95/51/EC abolished the restrictions on the use of cable television networks for the provision of already liberalised telecommunications services. Directive 97/33/EC on interconnection in telecommunications ensured universal service and interoperability through application of the principles of Open Network Provision (ONP).

Because of several problems, Commission Directive 1999/64/EC has to ensure that telecommunications networks and cable TV networks owned by a single operator are separate legal entities. Regulation (EC) No 2887/2000 regulates the unbundled access to the local loop. The recent Framework Directive 2002/21/EC provides a common regulatory framework for electronic communications networks and services accompanied by the access Directive 2002/19/EC, the authorisation Directive 2002/20/EC and universal service Directive 2002/22/EC.

All these regulations provide framework conditions which enable competition by first opening the market for telecommunication services and second by guaranteeing the access to the infrastructures needed to provide telecommunication services. The primary objective of these regulations is to enable competition, but they also allow new companies to enter the market for telecommunications services using the telecommunication infrastructures. The liberalisation of the telecommunication sector has two impacts on innovation. First, the more intensive competition provided in-

centives to develop new infrastructures and therefore a competition between infrastructures, like traditional telecommunication networks and cable television networks. Second, the stronger competition between telecommunication services increased the pressure to introduce new and better services.

After the liberalisation of the telecommunication sector, further initiatives have been started to open up the following further network markets. Already in 1996 Directive 96/92/EC established common rules for the internal market in electricity, which was repealed by Directive 2003/54/EC. Directive 2003/55/EC defines common rules for the internal market in natural gas. Regulation (EC) No 1228/2003 regulates the access to the electricity network for cross-border exchanges in electricity, accompanied by Directive 2003/54/EC on common rules for the internal market in electricity. Finally, Directive 97/67/EC aims to regulate common rules for the development of the internal market of Community postal services and the improvement of quality of service. As already argued for the telecommunication sector, these regulations aim to allow competition, but by increasing the level of competition, not only the incumbent companies but also the companies entering the markets are forced to develop advanced technologies superior to the existing network technology and to introduce new services into the market. This positive impact on new products and services can be observed in the telecommunication market. However, depending on the technical progress in network technologies and restricted by the degree of possible product differentiation, like in the case of energy, this impact may be smaller in other network industries.

Finally, there are also directives which regulate the compatibility between networks, like Directive 2001/16/EC on the interoperability of the Trans-European conventional rail system. Another kind of regulation ensures that within a network the terminal equipment is compatible, like by Directive 1999/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. This kind of regulation defines common interfaces between components of networks or between different networks and supports thereby the benefits for the users. The direct impact on competition is not so strong and therefore only a limited impact on the development of new products and services can be expected.

Price regulation

There are several types of price regulations. One type of regulations sets price ceilings, others require a minimum price. However, the objectives of price regulations are either the protection of consumers by setting price limits, especially for companies with a monopoly or market-dominant position. Setting minimum price levels aims to protect industry from dumping offers, especially from abroad.

Price-cap regulations restrict companies to fully exploit their market power and therefore limit their profits and the funds available for the development of new

products and services, on the one hand.[7] Especially in the pharmaceutical sector, price regulations are widely applied in form of reimbursement regulations, co-payments, discount rates for health insurers, positive or negative lists of marketable products and budget limits (see also the case study on pharmaceuticals). On the other hand, price-cap regulations increase the pressure on companies to realise productivity gains, e.g. by process innovations. Consequently, the impacts on innovation remain rather ambivalent.

Fixing minimum prices via regulation protects companies from cut-throat competition and has at least no positive impact on innovation activities. All the screened regulations do not aim to promote innovation. However, one aspect has to be mentioned. For new medicinal products Directive 2001/83/EC on the Community code relating to medicinal products for human use, a Community code allows to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them. This is an example that companies should be allowed to promote their new products and services by giving away samples free of charge. Minimum prices may also have a positive impact for environmental innovations, because they may be relevant for the environmental sector in the case of renewable energies, like wind energy, which may guarantee producers a certain price for their energy produced (see also the environmental case study). However, there is no regulation at the European level regulating this issue.

3.3.3.4 Intellectual Property Rights

The fundamental basis for competitive markets is an effective property rights system. For new products and services especially Intellectual Property Rights (IPR) have a high relevance. Consequently, all regulations ensuring an effective and efficient IPR system have a positive impact on the introduction of new products and services by protecting the inventor or the innovating company from imitation by competitors.

Besides traditional IPR, like patents, other kinds of IPR are gaining importance meanwhile. Directive 98/84/EC protects services based on, or consisting of, conditional access, like radio and television broadcastings. Council Regulation (EC) No 6/2002 and Commission Regulation (EC) No 2245/2002 regulate Community designs. The Community trade mark was already implemented in 1995 by Commission Regulation (EC) No 2868/95 implementing Council Regulation (EC) No

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7 Excessive transmission prices in the case of network industries can also hinder the development especially of markets for services which rely on infrastructures, and there is an intensive debate between network operators and services provides about the "right" transmission fee. Since there is often no competition between infrastructures, regulators have to ensure that excessive prices do not prohibit competition.

40/94. Another new aspect of IPR is the legal protection of databases by Directive 96/9/EC. The traditional copyright gained new importance in the information society regulated by Directive 2001/29/EC harmonising certain aspects of copyright and related rights in the information society. Finally, it is still under discussion whether patenting should be extended to software-related inventions or biological materials/organisms.

In general, we observe an extension of IPR to new fields. Although stronger IPR create stronger incentives to invest in R&D and are positive for the market introduction of new products and services, the intensive discussion about pros and cons of software patents for innovation makes obvious that too strong and too many IPR make innovation also more difficult and risky (see for example Blind et al. 2003).

Besides the expansion of IPR, we observe increasing infringement of IPR which is caused by the increasing world trade with imports of pirated goods from developing countries and the opportunity to distribute digital content world-wide via the internet. Consequently, respective regulations have been implemented. Council Regulation (EC) No 241/1999 defines measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. Council Regulation (EC) No 953/2003 allows to take measures to avoid trade diversion into the European Union of certain key medicines. Finally, the recent Council Regulation (EC) No 1383/2003 defines customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

All these regulations have a very strong impact on the innovation activities of companies in the Member States, because they attribute IPR to the output of their R&D activities. Due to the increasing importance of the service sector, new rights have been implemented to protect innovative services and service contents. In addition to additional IPR, measures have been undertaken to regulate the increasing number of infringements. Both the possibility to acquire IPR and the effective persecution of infringements provide the necessary incentives for companies to invest in R&D and to bring new products and services to the market and are a main component of the regulatory framework with relevance for innovation.

3.3.4 Summary

The survey of regulations with an impact on innovation based on the new taxonomy of product market regulations showed the variety of different types of regulation and the range of possible impacts on the introduction of new products and services. Very often the impact of product market regulations on innovation is ambivalent. However, we are able to distinguish between regulations, like labelling requirements, which are soft framework requirements for new products and those kinds of

regulations which give companies strong incentives to develop and market new products and services. Here we have to mention direct financial support, e.g. for the transfer of traditional farming to organic farming, and indirect financial incentives like the guarantee to have restricted competition in the case of orphan drugs or the tax exemptions for renewable energies. Another important recent trend is the liberalisation of several network industries. The opening of the market alone caused the market entry of new companies offering new and often better products and services. However, further regulations had to be implemented in order to achieve sustainable competition because of the dominant market position of the incumbent companies.

Although there are only relatively few regulations which consider innovation explicitly, we observe that recent regulations address the innovation dimension. However, for the future it is required that despite the close relation between the objective to secure competition and to foster innovation, the impact of regulation on the latter should be more adequately addressed in new regulations. Furthermore, regulations with the aim to protect health and safety should also be open for innovative products which may contribute to this objective.

3.4 Regulatory Reforms in the Member States: The Case of Network Industries

3.4.1 Introduction

Since we have seen that there have been major changes in the European regulatory framework for the so-called network industries and we also observe major changes and innovation in these industries due to the liberalisation of these markets, we will concentrate in the chapter on the progress of the regulatory framework in the Member States and the consequences for the market structure and innovation. In addition, the screening of the recent OECD country reports on regulatory reforms revealed that except for these industries in almost no other sectors the regulatory reforms aim directly for the promotion of innovation or shaping new markets.

Based on the national reports on structural reforms, the observations are unambiguous.[8] Due to the liberalisation of network industries and public utilities work, production is becoming more efficient, prices are lower than they would have been otherwise, and consumers face a greater choice of services and quality is improved. And there are no signs that universal service obligations are compromised in liberalised markets, or that efficiency is achieved at the cost of increased inequality. Despite the favourable results so far, reforms of network utilities have been relatively

8 All national reports and overviews can be found under http://europa.eu.int/comm/economy_finance/epc/epc_countryexaminations_en.htm.

few and modest. This may indicate a slow-down in the willingness to reform, while there appear to be good reasons to speed up the liberalisation of network industries instead. Therefore, a co-ordinated and faster liberalisation process at the community level is necessary to achieve the objective of a European Single Market.

There have been few major reforms of network industries during 2001. This partly reflects that no deadlines for the implementation of EU directives expired in the past year. Thus, Member States have generally focused on catching up with transposition backlogs and measures to improve legislation and regulation enacted previously. Table 3.4-1 summarises the initiatives in key network industries during 2001. As few major reforms have taken place, most of the initiatives have a relatively limited scope in terms of liberalisation, which is one of the reservations that must be accounted for when interpreting the table. However, it clearly appears that most reforms have taken place in energy sectors and to a lesser extent in telecommunications. This reflects to a large degree that the liberalisation of telecommunications has been taking place in all Member States for some years, while the opening of energy markets is more recent. Yet it may be a cause for concern that only few initiatives are reported in other network industries. This is true for the three sectors – postal services, air transport and railways – included in the table, but also other sectors.

Table 3.4-1: Policy Measures in Network Industries in 2001

	Telecommunication	Energy	Postal Services	Air transport	Railways
Quantitative market opening	B, E, EL, IRL, L	A, EL, IRL, L	P		
Unbundling	F, UK	DK, EL, I, UK	F		
TPA regime	E	D, DK, L, P			
Establishment of TSO		BE			
Other legislation	F, UK	A, B, D, L, P	FIN, L, UK		B, NL
Reduce. incumb. Market share		B, E, F, I, IRL			DK
Other competitive measures	D, DK, FIN, P, S	FIN, UK		E, S	
Establishment of regulator		A, IRL		IRL	
Strengthening of regulator	FIN, EL	(D)			D
Restructuring state company		I, IRL	IRL	IRL	EL, I, IRL
Privatisation	A, EL	EL, I, NL	DK	A, E, EL	

Source: National Cardiff report, 2001.

Source: Economic Policy Committee (2002): Annual Report on Structural Reforms, Brussels 2002 (http://europa.eu.int/comm/economy_finance/epc/documents /ar02final_en.pdf), p. 18.

3.4.2 Telecommunications

Competition in telecommunications is well-established in most market segments, aided by new technologies that reduce the monopoly position of fixed networks. Competition is gradually becoming stronger and prices have decreased substantially in most Member States. While technological developments have contributed to the

reduction in prices, empirical analyses suggest that much of the improved performance can be attributed to the opening of markets. The fall in the costs of telecommunication between 1998 and 2000 was most pronounced in Member States where the costs in 1998 were relatively high, due partially to late introduction of competition. By contrast, costs were already low in 1998 in countries such as Finland and Sweden that were among the frontrunners and opened telecommunications markets in the early 1990s.

Besides the reduction in prices, other benefits have also been achieved. Thus telecommunication companies offer a wide range of products, suiting the needs of different population groups and businesses, and increases in the perceived quality of services has been reported in countries such as France, Italy, Spain and the UK. This has been achieved without compromising public service obligations (see box 3.4-1).

In January 2001, Greece became the last Member State to liberalise fixed-line telephony as EU directives have been transposed in a recently ratified law that provides for the full liberalisation of telecommunications markets. Portugal has also liberalised fixed-line telephony during the year 2000. Most of the other Member States have passed measures to strengthen competition in 2000. Pre-selection and number portability, which make switching phone company easier and thus increase competitive pressures, were for instance introduced in Belgium, Luxembourg and Spain.

Ireland has made and Austria is planning major revisions of the telecommunications law, while specific amendments to the existing framework have been made in 2000 by some Member States. Finland changed the regulation of tariffs for renting fixed lines. Spain is introducing tougher accounting standards for the dominant operator to make access charges reflect costs better, and a price cap has been implemented for teleservices and the leasing of fixed lines. Sweden is considering measures to enforce third-party access to fixed lines.

In mobile telecommunications, Spain has enforced accounting separation for interconnection charges for the two dominant operators, and Sweden has established that excess capacity in the mobile networks must be offered to competitors. The Netherlands has introduced a range of measures to counter the apparent lack of competition in cable networks, and Ireland has ensured easier access for domestic operators to satellite capacity.

Box 3.4-1: Maintaining Universal Service Obligations (USO)

What is USO?

When an economic reform is implemented it is important to take into consideration the provision of services of universal need such as transport, electricity, gas, telecommunication and postal services. These services are judged to be essential for the functioning of modern society and should be available to all citizens at reasonable prices to meet the objectives of universal access, despite differences in costs of supply. Historically, universal service obligations have been provided by public monopolies using cross-subsidies. For further information on USO, see annex 1.

Maintaining USO in telecommunications

When a market is opened to competition, services of public interest still need to be financed. The Commission permits cost-sharing arrangements to finance USO in competitive markets. However, nine Member States state that the costs of USO do not constitute an unfair burden on the dominant supplier and that the costs of establishing a fund are not justified. Therefore the costs of USO will be met by the incumbent in most Member States and the funds established in some countries are only temporary and will be phased out. Examples of USO requirements and funding mechanisms are provided in the table.

	Requirement	Funding mechanism
Denmark		If proven that a deficit exists in the provision of USO, the regulator will collect a contribution from fixed telephony service providers based on turnover
Finland	Dominant operator must serve all customers in their territory	The incumbent must meet all universal service costs
France	Obligation of overall geographic supply, phone books, public phones and lower prices for poor households	Two mechanisms were established in 1997: a mechanism of interconnection charges (suppressed at the end of 2000) and a national universal service fund to which is operator contributes on the basis of its traffic volume (this mechanism is still operating)
Spain	Obligation of overall geographic supply and phone books.	Telefonica has been designated the dominant operator and is required to provide universal services until the end of 2005
Sweden	Telia is obliged to provide telephone services between fixed points to all regardless of where they live at an affordable price	The incumbent must meet all universal service costs
United Kingdom	A connection to the fixed network able to support voice telephone and low speed data and fax transmission, the option of a more restricted service package at low cost and reasonable geographic access to public call boxes across the UK at affordable prices.	British Telecom is responsible for the provision of USO but the cost of the USO is not re-imbursed. Kingston Telecom is also responsible for the provision of universal service.

Source: OECD, *The implementation and effects of regulatory reform: Past experience and current issues*, 2000.

Source: Economic Policy Committee (2002): Annual Report on Structural Reforms, Brussels 2002 (http://europa.eu.int/comm/economy_finance/epc/documents /ar02final_en.pdf), p. 24.

Although the beneficial effects of competition are already clear, additional impetus to the process of price reductions and new services is expected to come from the next generations of mobile telecommunications. Probably the most notable development in telecommunications markets in 2000 was the auctions held over 3rd generation, UMTS, mobile licenses. Fixed Wireless Access (FWA) licenses have or

will also be awarded in most Member States, which will provide an alternative to high-speed fixed wire internet access.

It is important to ensure the effective allocation of a scarce resource such as radio spectrum. Although different countries have adopted different mechanisms – such as auctions and beauty contests – overall the aim is the same: to ensure the continuing development of a vibrant and innovative telecommunications sector, delivering choice, quality and value for money to the consumer.

Recently, much effort has been put into opening the local loop competition. Third-party access to the local loop was implemented in Belgium, France and Spain in January 2001, and has been prepared in Ireland during 2000. In France licenses for local loop access were granted to two national operators and two additional operators in each of the two regions in 2000. Italy is testing how to implement unbundling of the local loop in three major cities and based on experience unbundling will be introduced nation-wide, as it was done in Luxembourg and the UK during 2000, in Belgium in early 2001 and previously in other Member States. Yet several Member States report insufficient competition in the local loop and vis-à-vis smaller consumers. This market segment was only recently opened to competition in many Member States. Thus, in Belgium, Greece, Ireland, Luxembourg and Spain the fixed-line local loop was unbundled formally in 2001 in accordance with EU regulation, while new measures in relation to unbundling were introduced in France and the UK. Some countries still have to overcome technical obstacles to make competition firmly rooted. However, even countries which have made unbundled local loops for a number of years experience lack of competition. To address this, Denmark and Sweden introduced measures to promote number portability, while firmer regulation of the network owner's access charges was introduced in Germany. The telecomms regulator was reformed and strengthened in Finland and Greece, and reforms are underway in Belgium, Ireland and Portugal.

With the development of the telecommunication infrastructure, e-commerce can evolve. As e-commerce is still in its infancy in Europe, there is a trade-off that needs to be carefully balanced. On the one hand, consumers´ interests must be secured, but on the other hand, regulations must be flexible enough for businesses seeking new avenues for profitable trade. Much can thus be achieved in terms of transparency and consumer rights through self-regulation among companies offering products on the Internet. Alternative dispute resolution (ADR) mechanisms, aimed at easing the trade-off, are being introduced in several Member States. The UK government´s intention to enhance flexible co-regulation as well as to create a national "clearing house" that will give consumers access to ADR schemes across Europe is a promising avenue. Similarly, the French government is engaged in a dialogue with the private sector and interest groups on how to establish a system of co-regulation, where responsibilities are shared between government and the sector itself.

3.4.3 Energy – Electricity and Natural Gas

At the end of 2001, the current electricity and gas directives were transposed correctly into the national legislation of most Member States. During 2001, Belgium and Germany amended the gas legislation in response to infringement procedures, and Luxembourg transposed the gas directive. France has still not transposed the gas directive and the case was referred to the European Court of Justice in May 2001. However, temporary measures corresponding to the directive's requirements have been introduced until legislation is finalised. In 2001 the quantitative market opening was increased in several Member States, and some opted for new deadlines that should lead to faster full liberalisation. Austria's electricity market was fully liberalised. Greece officially initiated a gradual market opening, but the incumbent dominates and new entrants are not expected before 2004. Ireland enacted new legislation that provides for full market opening in 2005. Luxembourg increased market opening to 57 per cent. Wholesale electricity trade was fully liberalised in the Netherlands, and full market opening is aimed for in 2004. While Finland's geographical location prevents competition in the import of gas, new legislation allows for the establishment of a secondary market. Full opening of gas markets took place in 2002 in Austria and possibly Greece, while the Danish government has announced full market opening in 2004. Ireland has proposed to open the gas market more, but 50 per cent of transport capacity is already used by competitors to the incumbent. Most Member States have determined or at least announced targets for the complete opening of electricity and gas markets. The exceptions are France in gas and electricity and Greece, Italy and Portugal in electricity, while Finland, Greece and Portugal have derogations with respect to gas market opening. In some Member States, full liberalisation is moreover only expected in the medium term. As delays in market opening imply that the full benefits of a Single Market for energy services cannot be achieved, it would be preferable if an agreement could be reached on a co-ordinated and faster path towards competitive markets. The Commission's proposal for amendments to the electricity and gas directives from March 2001 provides an appropriate basis for obtaining political agreement in this respect. Similarly, the Commission's proposals for strengthening the qualitative aspects of market opening should be seriously considered. This includes the potential problems associated with the use of negotiated, as opposed to regulated, access as this may constitute as a barrier to entry. Also, stronger rules for unbundling network activities might be needed to avoid the risk of cross-subsidies and other non-competitive practices of vertically integrated utilities.

Regulated access to transmission and legal unbundling were introduced in 2001 into Denmark's revised gas legislation, and in Italy a new company was formed for the gas infrastructure, but it is still related to the incumbent. Greece amended the gas market legislation, implying unbundling and a proposal for a new tariff structure. In the UK, stronger unbundling was introduced in electricity. Thus, the same legal person can no longer hold licenses for both electricity supply and electricity distri-

bution. A new energy regulator was established in Austria in 2001 and is proposed in Ireland. Germany allocated more resources to the competition authorities dealing with discriminatory behaviour in the electricity sector. In Belgium and Spain a technical manager of the transport system (TSO) was appointed in 2001, although measures to achieve full compliance with the EU directive, e.g. independence of the TSO, have not yet been implemented. Austria awarded licences to two settlement agencies in charge of handling transactions and pricing of balancing energy.

Besides adapting the legal framework for energy markets, several countries implemented measures to make competition more effective. The UK established a new wholesale trading arrangement in electricity in 2001. The arrangement replaced the existing pool and is based on bilateral contracts, thereby introducing genuine competition. A review after three months showed that the new arrangement had led to lower prices and higher liquidity. Although somewhat delayed, Italy expects to establish a "Single Buyer" of electricity charged with acquiring electricity at the lowest costs for those customers without market access. To reduce the market share of the incumbent in electricity generation, the French incumbent had to sell 6 per cent of capacity for a merger transaction to be authorised by the European Commission. Ireland has carried out virtual independent power producer auctions, which function as a substitute until new power plants are coming on-stream. In Italy, three electricity generation companies that were demerged from the incumbent are planned to be sold. To strengthen cross-border trade, Belgium and France have established auctions over import/export electricity capacity. In Spain, an auction covering 25 per cent of Algerian gas imports was held in 2001.

In a majority of Member States measures have been taken or are under consideration to promote electricity production based on, e.g., renewable energy sources and small-scale CHP (combined heat and power). In several cases the establishment of these types of alternative generation capacity has been fully liberalised. Privatisations have been limited in the energy sector. Greece has made a public offering of the incumbent electricity company and is preparing the sale of the gas company. Bills governing privatisation or restructuring of state-owned, energy companies are under debate in Ireland and the Netherlands. Italy has privatised part of the electricity incumbent, but imposed certain restrictions on ownership and plans to make further privatisations in the energy sector.

Whereas the development of renewable energy production most frequently has been promoted through regulation, one effect of the opening of electricity markets has, in e.g. Finland, Germany and Sweden, been that some companies have offered "green" electricity to their customers, who now face differentiated electricity products. Another benefit for consumers and businesses of the opening of energy markets is that they can now in some Member States buy a range of energy products, including energy management services, from the same supplier.

While the liberalisation of energy markets has led to immediate gains, it remains to be seen if and how liberalised markets can supply sufficient investment in new capacity, be it generation capacity in electricity or networks in electricity and gas. The risk of capacity constraints is apparently largest in electricity generation. In California lack of capacity was one explanation for the extreme peak prices, but also in other liberalised markets such as the Nordic region extreme prices have been observed for brief periods. Similarly, there are examples that network companies – e.g. the British rail and gas infrastructure companies – seemingly have underinvested in new capacity and maintenance of existing networks. In the long term, high prices should lead to investment in new capacity, but capacity constraints may exist for prolonged time periods. This is partly due to the long time it takes for an investment project to come on-stream, which in some cases may span a decade. While the problem is easily identified, it is likely to be more difficult to solve. One obvious solution would be to introduce measures that could reduce the difference between peak and average demand. This requires that price variations are transmitted to end-users who can then act by reducing demand when prices are high. Today the available technology needed is gradually becoming more attractive also for smaller consumers. Meanwhile, Member States should monitor the development of capacity investment carefully, and situations might occur where direct public intervention is necessary for a successful outcome. Moreover, it should be noted that several Member States are expecting increased investment as a consequence of liberalisation. Belgium and France foresee investment in new electricity generation. In Italy new legislation has simplified the requirements for installation of electricity generation capacity.

3.4.4 Postal services

In December 2001, the Council adopted a common position on the future liberalisation of postal services. Today the reserved area is defined by weight and price limits. These are intended to be reduced in 2003 and further in 2006. While agreement on a path towards liberalisation is a step in the right direction, the speed is not impressive and it would have been preferable to have a deadline for the full opening of postal markets.

In Sweden and Finland postal services have been fully liberalised for a number of years and are functioning well. In both countries, the incumbent still dominates the market and effective competition is primarily taking place in certain niches, i.e. specific types of services and in densely populated areas around the larger cities. In Finland one operating license has been granted to a private operator, which has not yet started postal operations. In Spain, local mail, for instance inside the Madrid area, but not between cities, and direct advertising services have also been liberalised. Interestingly, the Swedish and Finnish incumbents have been able to meet all

public service obligations without requiring compensation from either state or competitors.

In general, there is evidence that increased competition has led to improved service quality and a wider range of products, while universal service obligations seem to have been maintained satisfactorily. A liberalised market for postal services is required to create an innovative and competitive industry.

While Member States generally report that competition in non-restricted areas is functioning, relatively little was done in the restricted area during 2001. At the end of 2000, Luxembourg transposed the existing postal directive, and a new access regime for mail operation came into effect in Portugal during 2001. The French government has submitted a bill that will require the minister to create conditions for effective competition. In the UK, as a first, albeit small, step in the direction of liberalisation the statutory monopoly of the Consignia was replaced by a licensing system, and five interim licenses for specific postal services were issued. Ireland published legislation in 2001 permitting private equity investment in the postal company, and the Danish government intends to privatise its postal company.

3.4.5 Air transport

The current downturn in the airline industry – worsened, but not caused by the terrorist attacks on 11 September 2001 – has clearly revealed significant structural weaknesses of the traditional European flag carriers. Having until now survived, partly due to direct or indirect state aid as well as a traditional system of regulation through bilateral air transport agreements, they are now under large pressure from low cost carriers to implement structural reforms and cost cutting. This is likely to benefit consumers in the medium term, but further policy measures are likely to be needed to achieve all potential benefits. For instance, concerns have been expressed that the current regulatory framework based on bilateral air transport agreements prevents an appropriate consolidation of the European airline industry. Few and seemingly minor changes in air transport regulation have taken place in 2001. Ireland established a new Commission for aviation regulation, and required reduction in airport charges. In many Member States competition is very limited on domestic flights. In Sweden this was addressed in 2001 by a ruling of the authorities, preventing points earned on the dominant airline's frequent flyer programme from being used on domestic routes subject to competition. A similar measure has been considered in Denmark, but does not appear to be implemented. Spain introduced new regulation of slot allocation rules supposed to increase competition in 2001. The Commission is considering a new proposal for market-based allocation of airport slots, which could provide new impetus to competition. Austria privatised Vienna Airport late in 2000, and Ireland is giving consideration to the involvement of the private sector in the ownership of the state-owned airport company. The Spanish

flag carrier was floated on the stock market in 2001, and Greece is considering re-organising Olympic Air as part of a privatisation plan.

3.4.6 Railways

Progress in the liberalisation of railways has been limited. Freight transport has been fully liberalised in several Member States, for instance in Italy in 2001. Moreover, Community regulation requires that international freight transport be opened for competition in 2003. Less is happening in passenger transport, although systems of licenses for local/regional railways have been in place in, e.g., Germany, the Netherlands, Portugal, Sweden and the UK for a number of years. In 2001, Denmark awarded the first license to a private operator, which will take over 15 per cent of passenger transport in 2003. Belgium is currently preparing a reform of railways, including a revision of the legal framework governing the relationship between the state and the railway company. In Germany, a draft law was presented in 2001 which if enacted will strengthen supervision of competition in railways and give the regulator a more proactive role. Moreover, a task force has recommended that a more transparent relationship be established between the operating and network division of the national railway company. However, it is also recommended that the network division should not be de-merged from the operating company. Correspondingly, an Irish report recommended, due to the scale of the country's railways, that the railway activities of the existing national transport company should not be placed in a separate railway company. By contrast, Italy established a separate infrastructure company in 2001. Based on the national reports it appears that Member States are pursuing different models for railway liberalisation. The key question is if networks should remain as part of the incumbent company – as in telecommunications – or unbundled into a separate company – the model chosen in energy markets in many Member States. Both models seem to be associated with problems, as illustrated by a general dissatisfaction with railway services, and the mixed experience with liberalisation in, e.g., the Netherlands, Sweden and the UK. One important topic is whether economies of scope are so strong that unbundling the network from service operations yields inherent unsatisfactory outcomes, at least with current paradigms for which services are allocated to the network company. Belgium, Germany and the UK have published plans for large-scale investment in rail infrastructure. Public-private-partnerships are expected to be a central vehicle to provide for investment in railway infrastructure in some Member States, including Portugal.

3.4.7 Summary

After reviewing the regulatory reforms in the Member States in the various network industries, we can summarise their impacts especially on innovation, but also on the market performance in general as follows:

- Telecommunications: new products and services
- Energy – electricity and natural gas: new products like "green electricity" and services
- Postal services: the incumbents still dominate the market and effective competition between new products and services is primarily taking place in certain niches
- Air transport: the traditional European flag carriers are now under large pressure from low cost carriers
- Railways: still a general dissatisfaction with railway services and the mixed experience with liberalisation

In general, we observe that the regulatory reforms respective to the liberalisation of the network industries allowed the access of new companies to the former mostly monopolised markets. In those sectors, where the market entry of a variety of powerful competitors has been successful, the following increased competition developed pressure on prices for the existing products and services, which lead to innovation activities both to reduce costs and to provide new and innovative products and services in order to remain competitive. However, if the market opening was not effective, then the entry of only a very limited number and often relatively weak competitors compared to the incumbent companies had only a restricted impact on the intensity of competition and possible innovation strategies. A first general lesson, that we learn from this overview is that the deregulation of formerly closed and monopolised markets is only successful in achieving competition and innovation if both the entry regulation and the regulatory framework after the liberalisation allow numerous and competitive companies to compete effectively with the incumbents.

3.5 Regulatory Reforms and their Impacts on Innovation in the United States, Canada and Japan

The literature on the impact of regulations does not focus generally on innovation. The analyses concentrate mostly on productivity gains, employment and wages (OECD 1997a,b) or on industry structure and competition, like in the United States (OECD 1999). The OECD approach (1997a,b) does not measure the impact of regulation in general, but the impact of regulatory reforms in the sense of OECD (1997a,b) defined as reforms to economic regulations which promote competition among firms. Concerning social regulations, it is defined as reforms which allow

firms to develop less expensive and more innovative approaches achieving compliance. Here performance based rather than design-based standards and economic instruments, like taxes, instead of command and control type instruments are meant. Administrative regulations can be reformed by streamlining government formalities for setting up a business or entering a new market.

Based on the OECD reports, the following Table 3.5-1 summarises the most important sectoral regulations of some selected sectors in the US, Canada and Japan, which may have an impact on innovation. The majority of the regulations concern the opening of markets by reducing or eliminating entry barriers and the deregulation of prices. This corresponds very well to the observations of the regulatory reforms of network industries in Europe. Furthermore, the comparison between the three countries, the USA, Canada and Japan makes obvious that the USA has reached a complete deregulation in some sectors, whereas Japan is only at the beginning of a comprehensive deregulation process.

The OECD studies cover the impact dimension innovation also, if it is feasible to define and measure it. However, the approach to quantify the impact of regulatory reforms on innovation and its results are not convincing, therefore we present only the concrete impacts of the reform of sectoral economic regulations in the United States, Canada and Japan in Table 3.5-2. The impacts on innovation illustrate that the increased competitive pressure by opening markets and liberalising prices forced the companies in the respective sectors to become both more productive and efficient and to introduce new products and services. The development in various sectors respective to innovation cannot exclusively be attributed to regulatory reform, since the development of the information and communication technologies is also a major driving force, not only for innovation in the telecommunication sector, but also in the transport sectors and for financial services. However, the increased competitive pressure caused by the regulatory reforms has accelerated the adoption and diffusion of new technologies in order to be more efficient and to provide innovative products and services in relation to the competitors. This is also an important finding: the increased competitive pressure has a positive impact on the adoption and diffusion of new technologies, whose development can be further fostered by their adoption and diffusion. Therefore, we have a virtuous cycle between competition and technology development. Deregulated markets can therefore have an indirect effect on the development of new technologies, which may then be the basis for new products and services.

Table 3.5-1: Most important sectoral economic regulation in the United States, Canada, and Japan

Industry	United States	Canada	Japan
Air transport	Complete deregulation of air fares Complete deregulation of entry	Deregulation and liberalisation for licensing, fares, entry and exit	Licensing of routes to more than one airline Liberalisation of air fares Entry and exit on individual routes based on supply and demand balance
Road transport	Complete price deregulation Elimination of entry restrictions		Elimination of demand-supply balancing and replaced tariff approval with prior notification Relaxed licensing for individual routes Relaxed entry regulations
Rail freight	Eliminated rate regulation except for maximum tariffs Contracts by shippers completely deregulated	Privatisation of Canadian National Railway	
Telecommunications	Deregulation of equipment and long-distance prices Open entry to long distance and business services and data transmission Legal barriers to entry into local markets removed Open interconnection to transmission network, unbundling of access to local loops, resale of any retail service	Reform for universal service funding Regulatory frameworks for competition in all segments Licensing of international and wireless service providers Open entry in all segments	Liberalisation of entry, especially foreign entry Elimination of price caps
Natural gas transmission and distribution	Open access to interconnected grid by brokers, distributors and end users		
Financial services	Permitted interstate bank branching	Reforms to enhance efficiency, increase domestic competition, increase consumer protection, and to improve the regulatory environment Possibility of foreign banks to establish branches Reduction in the minimum start-up capital requirement Possibility for financial institutions to organise under a holding company structure for greater opertational efficiency	Liberalisation of foreign exchange transactions Gradual liberalisation of interest rates Liberalisation of insurance rates Liberalisation of cross-entry of incumbent financial firms

Source: OECD (1999a): Regulatory Reform in Japan, Paris: OECD; OECD (1999b): Regulatory Reform in the United States, Paris: OECD; OECD (2002): OECD Reviews on Regulatory Reform: Canada Maintaining Leadership Through Innovation, Paris: OECD.

Table 3.5-2: Impacts of the reform of sectoral economic regulation on innovation in the United States, Canada and Japan

Industry	United States	Canada	Japan
Air transport	Innovation in pricing and computer reservation systems applied to maximising loads and revenues Innovation of peak-load pricing Discount fares now available on internet	Adoption of new information technology to improve service and performance, like e-ticketing, online reservations, and automated check-in	Increased flight frequency on major routes
Road transport	Innovation in application of information technology to maximise routing efficiency, track shipments, and analyse shipper distribution patterns Development of third party freight analysts and brokers	Majority of trucking firms are using some form of information technology in business operations, but most firms do not use the internet to its full potential	Introduction of several new transport services, including frozen delivery, guaranteed delivery times, and more rapid deliveries.
Rail freight	Same as road transport Innovation of intermodal, double stacked cars Pricing more closely based on distance, number of switching	Growth in short line industry RoadRailer/Expressway intermodal technology to attract new traffic Advanced Control traction Track monitoring technologies E-business Interline service groups Community/shipper/short line operator partnerships Longer unit trains and double stacked cars Co-operation between the two Class carriers to share infrastructure (track) GPS technology to manage congestion with commuter rail operations in urban corridors	
Telecommunications	More rapid introduction of fiber optic and digitalised networks Automation and computerisation of operator and directory services accelerated	Telecom services industry invested over CAD 32 billion between 1994 and 1999 in new technology	Improved service quality New (discount) services Completion of fixed network digitalisation
Natural gas transmission and distribution	Innovation in automation and information technology in meter-reading, billing, route planning and scheduling New technologies in boring and extension		
Financial services		Strong development and use of new technology High ABM use per capita 17% of Canadians banking online over the Internet	

Source: OECD (1999a): Regulatory Reform in Japan, Paris: OECD; OECD (1999b): Regulatory Reform in the United States, Paris: OECD; OECD (2002): OECD Reviews on Regulatory Reform: Canada Maintaining Leadership Through Innovation, Paris: OECD.

3.6 Concerns and Priorities of the Major European, USA and Japanese Regulatory Institutions

3.6.1 Introduction

The review of the body of regulations with possible impacts on new products and services has shown that only a small fraction of regulations deals explicitly with innovation. One reason for the underevaluation of this dimension within existing regulations may have its origin in the priorities of the bodies and institutions responsible for regulatory issues. Before we present the views of the stakeholders within the regulatory process, like companies and non-governmental organisations, regarding the relation between regulation and innovation in chapter 4, we screen the certain missions and goals, which regulatory bodies themselves try to achieve. The review and analysis of these missions has the objective to identify their priorities and concerns especially regarding innovation and to perform a comparative analysis. The result are a further input for the outlook of future regulatory policy.

In this chapter the concerns and priorities of major organisations relevant for the development of the regulatory framework in the EU, USA and Japan are analysed. For this purpose, the missions and philosophies of the most important institutions involved in regulation procedures (see Table 3.6-1) in the three regions are screened in order to identify relevant priorities and especially the role of innovation. This is performed by internet searches and screening of relevant literature. Within the case studies, the policies of some regulatory bodies are again subject of the analysis.

The remainder of the chapter is structured as follows. First, we present the priorities and missions of the most important regulatory bodies in Europe, the United States and Japan and the possible role of innovation in some important fields of regulation. The second part consists of a comparative analysis. Finally, we conclude with the main results and preliminary lessons to be learned.

Surveying the missions and objectives of the most important European, American and Japanese governmental bodies responsible for regulatory affairs made the variety of priorities and preferences obvious. However, the comparative analysis cannot simply be performed according to the regional dimension, because of the obvious differences between the objectives of regulatory bodies responsible for different areas within countries. Therefore, we differentiate the following regulatory areas according to those in which we perform a cross-country comparison:

- Competition
- Energy
- Transport
- Telecommunication

- Environment
- Health

Table 3.6-1: Overview of Bodies responsible for Regulation in Europe, the US and Japan

Field of Regulation	Regions		
	Europe	**United States**	**Japan**
Competition	DG Competition	FTC	METI, JFTC
Energy	DG Energy and Transport	FERC	METI
Transport		DOT	MLIT
Telecommunication	DG Information Society	FCC	MPMHAPT
Environment	DG Environment	EPA	MENV
Health (incl. food and drugs)	DG Health and Consumer Protection; EFSA; EMEA	FDA; CPSC	MHLW

Acronyms: EFSA: European Food Safety Agency; EMEA: European Agency for the Evaluation of Medicinal Products; FTC: Federal Trade Commission; FERC: Federal Energy Regulatory Commission; DOT: Department of Transport; FCC: Federal Communications Commission; EPA: Environmental Protection Agency; FDA: Food and Drug Administration; CPSC: Consumer Product Safety Commission; METI: Ministry of Economy, Trade and Industry; JFTC: Japan Fair Trade Commission; MLIT: Ministry of Land, Infrastructure and Transport; MPMHAPT: Ministry of Public Management, Home Affairs, Posts and Telecommunications: MENV: Ministry of Environment; MHLW: Ministry of Health, Labour and Welfare.

3.6.2 Competition

The regulation of competition is a cross-sectoral issue and aims to ensure the functioning of the market forces in order to avoid welfare loss especially for the consumers, caused by high prices and restricted supply. Regarding regulation of competition we compare the activities of DG Competition, with the Federal Trade Commission (FTC) in the United States and the Japanese Ministry of Economy, Trade and Industry (METI) and the Japan Fair Trade Commission (JFTC).

Europe

DG Competition´s main areas of activity are anti-trust issues, merger control, the liberalisation of sector and state intervention and state aid. DG Competition also

deals with the international dimension of competition policy, as partner of the industrially developed countries (i.e. USA, Japan, Canada, etc.) or as a counsellor to countries with transforming economies (i.e. countries of Eastern and Central Europe).

For DG Competition, competition in the marketplace is a simple and efficient means of guaranteeing consumers products and services of excellent quality at competitive prices. Suppliers (producers and traders) offer goods or services on the market to meet their customers' demands. Customers seek the best deal available in terms of quality and price for the products they require. The best deal for customers emerges as a result of a contest between suppliers. Its policy aims to ensure wider consumer choice, technological innovation and effective price competition, thus contributing to both consumer welfare and to the competitiveness of European industry. This is achieved by ensuring that companies compete rather than collude, that dominant companies do not abuse their market power and that efficiencies are passed on to final consumers.

USA

In the United States, the FTC is one of the central institutions responsible for functioning markets. The FTC acts to ensure that markets operate efficiently to benefit consumers. The FTC's twin missions of competition and consumer protection serve a common aim: to enhance consumer welfare.

The FTC´s competition mission promotes free and open competitive markets, bringing consumers lower prices, innovation, and choice among products and services. The Commission's consumer protection mission fosters the exchange of accurate, non-deceptive information, allowing consumers to make informed choices in their purchases. Thus, these missions complement each other – accurate information in the marketplace facilitates fair and robust competition – and maximise benefits for consumers.

Japan

In Japan, the Ministry of Economy, Trade and Industry (METI) is responsible for the improvement of the overall business environment while respecting market principles. Since the late 1970s, mounting demands have been made by foreign countries for a more competitive and open Japanese market. In response to these demands, the Japanese government has implemented various measures. In recent years, it has become vital to actively pursue competition policy in conjunction with "deregulation". The Antimonopoly Act has now entered a turning-point in meeting these demands. The Japan Fair Trade Commission JFTC is in charge of the implementation of the Antimonopoly Act. The JFTC implements, besides the Antimo-

nopoly Act, the Act Against Unjustifiable Premiums and Misleading Representations and the Act Against Delays in Payment of Subcontract Proceeds, etc. to Subcontractors, which are special laws complementing the Antimonopoly Act.

Private monopolisation by firms constitutes a violation of the Antimonopoly Act. Private monopolisation refers to the formation of market power or the exercise of existing market power by a firm by artificially excluding or controlling the business activities of other firms, either individually or by combination or conspiracy with other firms. As such, even if a firm that supplies high-quality, inexpensive products comes to monopolise the market after other firms leave the market as a result of competition, this would not constitute a violation of the Antimonopoly Act.

Comparison

Comparing the missions and objectives of the responsible institutions in the three regions, both the European and US institutions have, besides securing competition explicitly the promotion of innovation in their agenda. It should be noted that the US FTC emphasises the role of informed consumers for the functioning of competition. Japan´s institutions restrict themselves to the prevention of monopolies.

3.6.3 Energy

The energy sector is a highly regulated sector. In the past, both the production and the distribution of energy was a natural monopoly due to large investments and economies of scale. Only recently, have new technologies allowed to be introduced competition-related aspects in this sector.

Europe

The DG for Energy and Transport is responsible for developing and implementing European policies in the energy field. Its mission is to ensure that energy policies are designed for the benefit of all sectors of the society, businesses, cities, rural areas and above all of citizens. The energy sector is pivotal to the European way of life and to the functioning of its economy; as such operation has to be responsible in economic, environmental, safety and social terms.

The main goals of DG Energy and Transport (http://europa.eu.int/comm/dgs/ energy_transport/home/doc/leaflet_en.pdf) in the field of energy are

- the completion of the internal market in energy: the opening of the energy market needs to be accompanied by new forms of regulation to ensure the creation of a truly European market and to safeguard the quality and security of services

- ensuring sustainable development of energy: specific measures to control energy demand (energy efficiency, biofuels, etc.), to promote renewables and to step up research efforts, including in the nuclear field, have to be undertaken

- improving safety: technology and expertise at the service of security and safety throughout Europe have to be improved and non-proliferation of nuclear materials and their peaceful use has to be ensured

- accomplishing enlargement: the effective application of Community legislation on energy by the candidate countries has to be verified and an accent has to be put on safety, e. g. the safety of nuclear installations

- developing practical international co-operation and strengthening the European Union´s voice in the international arena: a dialogue and co-operation with the major international players in the energy field (e.g. Russia), has to be developed.

Among all these goals, innovation is not included. not even implicitly. Safety and sustainable development are of major concern. Only the completion of the Single Market and the liberalisation of the energy market will have impacts on innovation, but this impact dimension is not explicitly mentioned in the mission of the DG Energy and Transport.

United States

In the United States, the Department of Energy is responsible for energy related issues. The Federal Energy Regulatory Commission (FERC) is an independent regulatory agency within the Department of Energy that

- regulates the transmission and sale of natural gas, oil, electricity for resale in interstate commerce
- licenses and inspects private, municipal and state hydroelectric projects
- oversees environmental matters related to natural gas, oil, electricity and hydroelectric projects
- administers accounting and financial reporting regulations and conduct of jurisdictional companies, and
- approves site choices as well as abandonment of interstate pipeline facilities.

The main goals of FERC are to

- promote a secure, high-quality, environmentally responsible infrastructure through consistent policies
- foster nation-wide competitive energy markets as a substitute for traditional regulation

- protect customers and market participants through vigilant and fair oversight of the transitioning energy market.

Similar to the FTC, FERC aims both to foster competition, but also to assure security and the protection of customers. Increased competition has definitely a positive impact on the development of new products and services, especially if entry restrictions are abolished and new companies enter the market with new ideas. However, the deregulation of the energy market in the USA has endangered the secure and stable provision of the customers with energy due to insufficient investments in infrastructure. Consequently, the FERC has to find a new balance between secure energy provision and increased competition.

Japan

In Japan, the Ministry of Economy, Trade and Industry (METI) is also responsible for the energy sector. In contrast to its general competition policy, the regulatory policy in the energy market has the objective to secure the national energy supply and to improve its efficiency. If necessary, METI even allows structures which are not very competitive to reach these goals. Innovation is no explicit objective in the energy sector at all for the METI.

Comparison

Although all regulatory authorities claim to foster competition, the secure supply of energy is of the highest priority for the responsible bodies in all three regions. Since there is obviously a tension between competition and the security of energy supply, the inclination to increase significantly the competition in the sector with possible impacts on innovation is limited.

3.6.4 Transport

Like the energy sector, the transport sector provides an important infrastructure for modern economies. Although it also has features which may justify public monopolies, competition between different carriers is common within road transport and air transport, whereas competition between railway carriers is at the very beginning.

Europe

The DG for Energy and Transport is responsible for developing and implementing European policies also in the transport field. The objectives regarding future regu-

lation are defined in the White Paper of European Transport Policy (http://europa.eu.int/comm/energy_transport /library/lb_texte_complet_en.pdf)

- increasing the competition by opening of the sector not only for international services, but also for cabotage on the national markets and for international passenger services
- harmonisation in the fields interoperability and safety (i.e. maritime safety)
- improving quality in the road transport sector
- harmonisation of inspection procedures
- expansion of airport capacity subject to new regulations to reduce noise and pollution by aircraft
- turning intermodality into reality by technical harmonisation and interoperability
- improving road safety:
  - harmonisation of signs at particularly dangerous black spots
  - harmonisation of the rules governing checks and penalties for international commercial transport with regard to speeding and driving
- harmonisation of fuel taxation for commercial users, particularly in road transport
- alignment of the principle for charging for infrastructure use
- recognising the rights and obligations of users (rights to information)
- managing the effects of globalisation (facilitation of trade, taking into account environmental concerns)

This list of regulatory objectives shows three focal points. First, the opening of transport markets and more competition are central issues. Second, due to numerous accidents in all transport modes, transport safety was and will be of highest priority for policy-makers. The relevance of this issue has led to the foundation of two new agencies, the European Aviation Safety Agency (EASA) and the European Maritime Safety Agency. Third, the activities of the transport sector are accompanied by strong impacts on the environment via air, water pollution and noise.

However, only within the first priority do we find direct links especially to innovative services, which will emerge if the regulatory framework allows new companies to enter the market. Furthermore, increased competition will put more pressure on the transport companies to develop new services and implement new technologies. The negative side aspect of increased competition can be also a race to the bottom regarding expenditures for safety measures.

United States

In the United States, the Department of Transportation (DOT) is responsible for the transport sector. DOT consists of the Office of the Secretary and eleven individual

Operating Administrations responsible for aviation, the highways, the railroads, and different safety aspects.

The mission of DOT is to develop and co-ordinate policies that will provide an efficient and economical national transportation system, with due regard for need, the environment, and national defence. It is the primary agency in the federal government with the responsibility for shaping and administering policies and programmes to protect and enhance the safety, adequacy, and efficiency of the transportation system and services.

Although the efficiency of the transport system should be increased, there is no explicit link to the use of new technologies and the development of new products and services. Furthermore, the protection and enhancement of safety is an essential objective of DOT.

Japan

In Japan, the Ministry of Land, Infrastructure and Transport is among others responsible for the development of an integrated transport system while deregulating governmental controls over transportation business. Regarding transport, national safety is the main priority, which means that the Ministry seeks to minimise disasters, ensure traffic safety and maintain maritime order and safety. Furthermore, the road policy (http://www.mlit.go.jp/road/road_e/fy2001/index.html) seeks to

- improve expressways and regional expressways with emphasis on ring roads in city areas, a network of recycling regional blocks and access roads to airports and harbours
- establish multi-modal traffic systems and give priority to the improvement of roads that reinforce connections with airports and harbors
- reinforce bridges, reconstruct tunnels and improve roads in order to respond to large-sized vehicles
- take measures for the traffic demand management of distribution such as the efficient transmission of freight cars in cities under comprehensive projects for facilitating smooth traffic flows based on regional consent
- support such conditions of locations for logistics centres that allow transshipment along expressways or around interchanges
- aim at prompt, highly reliable road management by utilising information technology to facilitate realtime inspections and repairs on structures with advanced inspection technology
- proceed with engineering research and development related to roads efficiently and effectively by sharing responsibilities and co-operating with industrial and academic circles and governments for various advanced fields.

All these objectives are rather conservative in the sense of securing safety, but also maintaining the road and other traffic systems. However, among the policy objectives the improvement of the efficiency and the integration of the traffic system has a high priority, which may have also indirect effects on the development of new transport services. Finally, the progress in engineering research and development should be considered in the policy process, which may also have indirect impacts on innovation. However, the regulatory policy of the Japanese ministry responsible for transport does not explicitly consider the role of new products and services or innovation in general.

Comparison

Comparing the regulatory policies in the transport sector in Europe, the USA and Japan, we find only to a limited degree a link to innovation in the sense of new products and services. However, only on the European level the increase of competition and the opening of markets have been explicitly mentioned and will have positive impacts on the development of new transport services. Nevertheless, ensuring traffic safety and protecting the environment are common and important objectives in all three domains, which enjoy especially in the USA and Japan a higher importance than objectives with indirect links to innovation.

3.6.5 Telecommunication

Telecommunication is another network industry, which was dominated by publicly-owned monopolies for several decades. Since the 1990s, the telecommunication market has been continuously liberalised in Europe following the US example. However, due to the strong network effects, the sector needs still to be regulated in order to assure competition.

Europe

The DG Information Society of the European Commission is playing a key role in implementing the "vision" set by Europe's heads of state in Lisbon, 2000: to make Europe the world's most competitive and dynamic economy, characterised by sustainable growth, more and better jobs and greater social cohesion, by 2010. As set out in the Europe action plan, this will require advanced and easily accessible Information Society technologies to permeate throughout European business and society. This Directorate-General therefore

- stimulates research into Information Society technologies which can be integrated into the citizen’s everyday environment, business and administration

- has established and is maintaining a framework of regulation designed to generate competition and stimulate the development of applications and content
- supports initiatives that encourage and enable all European citizens to benefit from, and participate in the Information Society.

The respective national regulatory bodies (http://www.regtp.de/en/links/start/in_10-00-00-00-00_m/) have similar objectives, like Belgium, Denmark, Finland, and France. However, the innovation dimension is in most cases not explicitly mentioned as a strategic objective.

United States

In the United States, the Federal Communications Commission (FCC) is an independent government agency and is charged with regulating interstate and international communications by radio, television, wire, satellite and cable. Its mission is to ensure that the American people have available – at reasonable costs and without discrimination – rapid, efficient, nation- and world-wide communication services; whether by radio, television, wire, satellite, or cable.

The FCC is responsible for ensuring that an orderly framework exists within which communications products and services can be quickly and reasonably provided to consumers and businesses. Equally important, the FCC must also address the communications aspects of public health and safety, ensure the universal availability of basic telecommunications services, make communications services accessible to all people whether they live in a rural area or have a disability, and protect and inform consumers about their rights. In support of this mission, the FCC, in accordance with its statutory authority, has six general goals for the next years:

- establish regulatory policies that promote competition, innovation, and investment in broadband services and facilities while monitoring progress toward the deployment of broadband services in the United States and abroad
- support the Nation's economy by ensuring that there is a comprehensive and sound competitive framework for communications services. Such a framework should foster innovation and offer consumers meaningful choice in services. Such a pro-competitive framework should be promoted domestically and overseas
- encourage the highest and best use of spectrum domestically and internationally in order to encourage the growth and rapid deployment of innovative and efficient communications technologies and services
- revise media regulations so that media ownership rules promote competition and diversity in a comprehensive, legally sustainable manner and facilitate the mandated migration to digital modes of delivery
- provide leadership in evaluating and strengthening the national communications infrastructure, in ensuring rapid restoration of that infrastructure in the event of

disruption, and in ensuring that essential public health and safety personnel have effective communications services available to them in emergency situations
- emphasise performance and results through excellent management. Develop and retain independent mission-critical expertise and align the FCC with the dynamic communications markets.

In contrast to Europe with only an indirect link, the FCC has the objective to explicitly promote besides competition, innovation within the telecommunication sector.

Japan

In Japan, the Ministry of Public Management, Home Affairs, Posts and Telecommunications is responsible for the communications, and postal services. The Ministry focuses on the promotion of the sophistication of info-communications and post office networks.

The objectives of the Ministry in the field of posts and telecommunications are

- to build an advanced info-communications society and develop postal services for the 21st century
- aim at a society where everyone can live a convenient and secure life
- overall promotion of info-communications policies
- promotion of digitalised broadcasting
- environmental improvement for further development of telecommunications business
- securing and improvement of safe and efficient radio use
- planning and management of postal services
- planning and management of postal order and savings business
- planning and management of postal life insurance business.

Although not explicitly mentioned, the promotion of progress in the field of telecommunication is a major objective for the Ministry. However, innovations or new products and services are not mentioned. And it remains unclear how the Ministry is going to reach these objectives, especially "planning and management" suggest that the Ministry wants to interfere in the dynamics of the sector and has limited confidence in the capacities both of the technology and service providers and the customers.

Comparison

Comparing the missions of the regulatory bodies responsible for telecommunication, the promotion of a regulatory framework which fosters competition is common

for all three regions. However, the FCC mentions explicitly the promotion of innovation, whereas in Europe the development of applications points only indirectly to the innovation dimension in the regulatory framework which has to be shaped for the information society. The same is true for Japan´s regulatory authority which seeks to enhance competition, but does not refer explicitly to new products and services. Furthermore, the regulatory body is inclined to interfere and to plan and manage the telecommunication market, which may be a problem for innovation, especially in such a dynamic sector.

3.6.6 Environment

Since the late 1960s, environmental regulation has been a major political issue in all industrialised countries, because the increasing damage and depletion of the natural environment is going to threaten both the health and the foundation of the actual and future generation.

Europe

DG Environment is responsible for environmental policy and regulation. Its main role is to initiate and define new environmental legislation and to ensure that measures, which have been agreed, are actually put into practice in the Member States. Its mission is summarised in the following objectives (http://europa.eu.int/comm/dgs/environment/pdf/information_brochure_en.pdf)

- to maintain and improve the quality of life through a high level of protection of our natural resources, effective risk assessment and management and the timely implementation of Community legislation
- to foster resource-efficiency in production, consumption and waste-disposal measures
- to integrate environmental concerns into other EU policy areas
- to promote growth in the EU that takes account of the economic, social and environmental needs both of our citizens and of future generations
- to address the global challenges facing us, notably combating climate change and the international conservation of biodiversity
- to ensure that all policies and measures in the above areas are based on a multi-sectoral approach, involve all stakeholders in the process and are communicated in an effective way.

Within these objectives, we find no direct link to innovation or to new products and services. The promotion of resource-efficiency has certainly implications for process and product innovation and the integration of environmental issues in other policy areas certainly touches the innovation dimension. However, environmental

policy of DG Environment strives first to protect the environment, but does not explicitly consider using its instruments to foster innovation.

United States

The mission of the US Environmental Protection Agency (EPA) is to protect human health and to safeguard the natural environment - air, water, and land - upon which life depends.

EPA´s purpose is to ensure that

- all Americans are protected from significant risks to human health and the environment where they live, learn and work
- national efforts to reduce environmental risk are based on the best available scientific information
- federal laws protecting human health and the environment are enforced fairly and effectively
- environmental protection is an integral consideration in US policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade, and these factors are similarly considered in establishing environmental policy
- all parts of society – communities, individuals, business, state and local governments, tribal governments – have access to accurate information sufficient to effectively participate in managing human health and environmental risks
- environmental protection contributes to making our communities and ecosystems diverse, sustainable and economically productive
- the United States plays a leadership role in working with other nations to protect the global environment.

Obviously, the mission of the EPA shows a strong priority for the protection of the environment and it does not consider explicitly the role of new products and services. However, all environmental regulations have to be based on the best available scientific information, which guarantees the integration of latest research results. Furthermore, the concerns of economic growth have to be taken into account by shaping environmental policies, which implicitly includes innovative products and services as a source for economic growth. Nevertheless, innovation is no explicit dimension which is taken into account in the environmental policy of the USA.

Japan

In Japan, the basic law defines the policy goals of the Ministry for Environment. The purpose of this law is to comprehensively and systematically promote policies for environmental conservation to ensure healthy and cultured living for both the present and future generations of the nation, as well as to contribute to the welfare

of mankind, through articulating the basic principles, clarifying the responsibilities of the state, local governments, corporations and citizens, and prescribing the basic policy considerations for environmental conservation.

Environmental conservation shall be conducted appropriately to ensure that the present and future generations of human beings can enjoy the blessings of a healthy and productive environment and that the environment as the foundation of human survival can be preserved into the future, in consideration that preserving the healthy and productive environment is indispensable for healthy and cultured living for the people, and that the environment is maintained by a delicate balance of the ecosystem and forms the foundation of human survival, which is finite in its carrying capacity and presently at risk of being damaged by the environmental load generated by human activities.

Environmental conservation shall be promoted so that a society can be formulated where the healthy and productive environment is conserved and sustainable development is ensured by fostering sound economic development with reduced environmental load, through practices on environmental conservation such as reducing as much as possible the environmental load generated by socio-economic and other activities, which are voluntarily and positively pursued by all the people sharing fair burden; and so that interference with environmental conservation can be anticipatively prevented through enhancing scientific knowledge.

The priority of the Ministry for the Environment is environmental conservation especially also in order to guarantee a sustainable development allowing the survival of future generations. The reduction of environmental pollution is mentioned, but only the enhanced scientific knowledge builds an indirect bridge to new products and services which may be complementary with reaching environmental goals.

Comparison

Summarising the environmental regulatory policy in all three regions, the protection of the environment is consequently of highest priority, whereas the dimension of innovation or new products and processes is not considered at all. Only the progress in science is mentioned as a possible source for improvements for the environment. Environmental regulation has obviously not yet considered that the promotion of new products and services with less environmental damage or less usage of resources may be another instrument to reach ambitious environment-related objectives.

3.6.7 Health (incl. food and drugs)

The protection of consumers from dangerous products can be justified by their information deficits regarding product characteristics. For consumers to make rational choices, they must receive adequate information about products and services. In the absence of regulation, consumers would be restricted to information provided by producers who have incentives to withhold information that would negatively impact sales or liability. These asymmetries become more serious as products become increasingly complex.

Europe

In the European Commission, DG Health and Consumer Protection is responsible for issues that are relevant to the daily lives of each of Europe's citizens. The overall goal of the DG is to promote a better quality of life by ensuring a high level of protection of consumers' health, safety and economic interests as well as of public health.

This overall goal is addressed through legislative and non-legislative actions in three inter-related policy areas.

- Consumer policy:
  - to promote the safety and other interests of consumers in the internal market
  - to propose legislative and other initiatives for the benefit of consumers and to contribute to their proper enforcement across the European Union
  - to ensure that the interests of consumers are given due consideration in the development of other European Union policies
  - to enhance the capacity of consumers to make informed choices through more effective information and education initiatives, and to reinforce their representation in EU policy-making.

- Public health:
  - to assure a high level of human health protection in the development of all Community policies
  - to take actions to improve public health in the European Union, to prevent human illness and diseases and to obviate sources of danger to human health
  - to provide independent and transparent risk assessments.

- Food safety, animal health, animal welfare and plant health:
  - to assure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, whilst ensuring the effective functioning of the internal market

- to assure effective control systems and evaluate compliance with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU
- to manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health
- to manage relations with the European Food Safety Authority, and ensure a science-based risk managements.

In the following, we present the missions of two agencies which have been founded like the European Agency for the Evaluation of Medicinal Products, which is under the domain of DG Enterprise or are being currently founded, like the European Food Safety Agency.

The European Agency for the Evaluation of Medicinal Products (EMEA) is responsible for the regulation of the pharmaceutical sector in Europe. EMEA mission is to contribute to the protection and promotion of public and animal health by (http://www.emea.eu.int/aboutus.htm):

- mobilising scientific resources from throughout the European Union to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health professionals
- developing efficient and transparent procedures to allow timely access by users to innovative medicines through a single European marketing authorisation
- controlling the safety of medicines for humans and animals, in particular through pharmacovigilance network and the establishment of safe limits for residues in food-producing animals

Within this mission, we find explicitly the objective to allow timely access to innovative medicines. The regulatory body does not want to be an obstacle for the access to innovative medicines by implementing a slow approval process. It is aimed to try to reduce the time-to-market, but the regulatory practice does not explicitly aim to provide the framework for new medicinal products.

The EU legislation on foodstuffs (with some exceptions like novel foods and novel food ingredients) leaves food industry companies free to market their products without pre-market approval. Food manufacturers have to assure that their products are safe and do not mislead the consumer. These requirements must be met under the sole responsibility of the company and are subject to post-marketing controls by public authorities.

In April 1997 the European Commission published a Green Paper "The General Principles of Food Law in the European Union" which defines a regulatory framework which covers the entire food chain. The Green Paper had the following six objectives (European Commission 1997):

- to ensure a high level of protection of public health and safety and of consumer protection
- to ensure the free movement within the Single Market
- to base legislation on scientific evidence and risk assessment
- to ensure the competitiveness of European industry and enhance export prospects
- to place the primary responsibility for safe food with industry, producers and suppliers
- to ensure that legislation is consistent, rational and clear.

In order to achieve the targets of the Green Paper, the entire food chain "from stable to table" has to be included in the regulatory system. Important activities which are mentioned in the Green Paper are the simplification and harmonisation of EU food regulation, the scrutiny of existing regulations (e.g. with respect to transparency, adoption of the existing regulations to new scientific and technical developments, co-ordination of the different regulations, consistency in food labelling), ensuring an efficient implementation of the common EU rules in the Member States as well as consideration of international standards and recommendations. The European Food Safety Agency (EFSA) (http://www.efsa.eu.int/about_en.html) is responsible for the provision of independent scientific advice on all matters with a direct or indirect impact on food safety.

According to the Green Paper, the promotion of innovation is no explicit goal of the regulatory framework. However, innovation is relevant for ensuring competitiveness. Nevertheless, protection of public health and safety and of consumer protection have obviously a higher priority. In total, the concerns of the regulatory framework of the food sector are directed to protection, whereas innovation is not explicitly taken into account.

Summarising the various objectives of the consumer health and safety policies of the European Union, we find protection of the interest of the customers is the key priority of regulatory policy. Although the access to new products is also in the interest of the customers, only in the case of pharmaceuticals does the regulatory framework want to allow users a timely access to innovative medicines through a single European marketing authorisation. The benefits of those new products are obviously much higher than other "normal" products to be worth mentioning explicitly that they should be brought to the market in time. In this case, there is obviously a tension between allowing new products to enter the market and securing the safety of the consumers. Regarding food products, again the protection of the con-

sumers is of highest priority, whereas there is obviously no special need to seek for a fast marketing of new products, because of the missing market access restrictions.

United States

The Food and Drug Administration is one of the oldest and most respected US consumer protection agencies. Stated most simply, FDA's mission is to promote and protect public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use. The FDA Modernization Act of 1997 affirmed FDA's public health protection role and defined the Agency's mission:

- to promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner
- with respect to such products, protect public health by ensuring that foods are safe, wholesome, sanitary, and properly labelled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labelled, and public health and safety are protected from electronic product radiation
- participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonise regulatory requirements, and achieve appropriate reciprocal arrangements and
- carry out paragraphs all the tasks in consultation with experts in science, medicine, and public health, and in co-operation with consumers, users, manufacturers, importers, packers, distributors and retailers of regulated products.

The Consumer Product Safety Commission (CPSC) is an independent federal regulatory agency. CPSC works to save lives and keep families safe by reducing the risk of injuries and deaths associated with consumer products.

They do this by

- developing voluntary standards with industry
- issuing and enforcing mandatory standards or banning consumer products if no feasible standard would adequately protect the public
- obtaining the recall of products or arranging for their repair
- conducting research on potential product hazards
- informing and educating consumers through the media, state and local governments, private organisations, and by responding to consumer inquiries.

The FDA´s mission is at first the promotion and protection of public health. However, the reduction of the regulatory burden and timely procedures is mentioned

which indicates that an inefficient regulatory framework should not hinder the marketing of new medicinal products. In addition, strong links to experts should provide a sound base for regulatory decisions. Nevertheless, innovation is no central issue for the FDA. At the heart of all FDA's product evaluation decisions is a judgement about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgements are important. FDA allows a product to present more of a risk when its potential benefit is great - especially for products used to treat serious, life-threatening conditions. This approach allows companies to market products which may contain certain risks if the expected benefits are very high.

Again, in the mission of and the instruments used by CPSC, there is no explicit link to innovation and new products and services. The protection of the consumer is the main and most important priority and the CPSC tries to prohibit products from being marketed or to withdraw them from the market, if they present a risk for the consumers.

Japan

In Japan, the Ministry of Health, Labour and Welfare is expected to aim at "Securing and improving people's living" and "Prospering economic", and to propel the actions for "Improving and enhancing social welfare, social security and public health" and "Organising work environments, stabilising employment and developing human resources" in a comprehensive and unified fashion. In the following, we describe the policies of two major bureaus responsible for health regulation, the health policy bureau and the pharmaceutical and medical safety bureau.

The Health Policy Bureau plans and proposes policies for the realisation of a high-quality, effective system for offering medical services in the 21st century, in response to the ageing of society in recent years, changes in the disease structure and stronger people's demands for medical services of higher quality. It has the following main task, to

- establish a quality system to offer medical services that are at a level comparable to Japan's economic and living standards
- improve both "human resources" (doctors, nurses, etc.) and "facilities" (hospitals, etc.), which are the base for the promotion of medical policies
- secure quality human resources who are competent to take charge of people's health and lives, reviewing the training methods for medical professionals
- diffuse and spread the ideas of informed consent, or efforts to obtain understanding of patients through giving appropriate explanation in providing medical services
- realise a system for providing medical services based upon the trust between patients and medical professionals

- promote the disclosure of information necessary for patients' selection of medical institutions, through supporting the evaluation by third-party organisations of functions of hospitals
- prevent medical accidents that would affect the patients' lives, by giving directions to medical institutions
- support these new medical technologies and promote the development of the drug and medical equipment industries.

The Pharmaceutical and Medical Safety Bureau implements measures for securing the efficacy and safety of drugs/quasi-drugs, cosmetics and medical devices, safety measures for medical institutions, and measures against narcotics and stimulants, while handling blood business. Thus, the bureau addresses various issues directly related with people's life and health.

The advances in pharmaceuticals and medical devices resulted in the marked improvement of health and sanitary conditions. A lot of even more efficacious products were developed as a result of the rapid development of frontier technologies in the last few years. On the other hand, products that are difficult to take or that could cause severe adverse reactions also increased. In light of the above, the Pharmaceutical and Medical Safety Bureau aims to

- protect people's life and health through comprehensive efforts, covering clinical experiments, technical examinations for registration and after-sales follow-ups
- secure the safety, efficacy, etc. of pharmaceuticals
- implement clinical examinations, including the establishment of a system to invite positive participation of subjects in clinical examination and the improvement of a system of medical institutions conducting clinical examinations
- promote measures for securing safety in medical services, implementing, for example, various measures against hospital infection including the preparation of a guideline, so that people can receive medical services without anxiety
- promote blood donation, effective utilisation of donated blood, appropriate uses of blood products at medical institutions, the introduction of state-of-the-art scientific technology, etc.
- secure domestic self-sufficiency and safety in blood products.

In Japan, the Ministry and the two important bureaus responsible for health are seeking to protect the health and safety of the citizens, but also to secure the provision of the consumers with the necessary medical services and medicinal products, which should be of high quality. The increasing demand of the consumers to be better informed about medical services and pharmaceuticals has to be met by an extended and improved information policy. However, the development of new medicinal products is explicitly supported by simultaneously assuring high standards on the implementation of clinical trials on drugs.

Comparison

Comparing the priorities in the three regions in the field of health, we find for all the protection of health and safety as the top priority in order to serve the interests of the consumers. Furthermore, the responsible bodies try to react to the demand of the consumers for adequate information in order to make better informed decisions. In addition, the supply of health services has also to be guaranteed. Nevertheless, since new medicinal products are essential for the well-being of people, the fast marketing of new products is a major objective under all regimes. However, in the US there is an explicit risk-benefit balancing, which allows also to market products which may still contain some risks. This is at least not explicitly possible in Europe and Japan.

3.6.8 Conclusion

The review of the priorities of regulatory bodies in Europe, the United States and Japan in six highly regulated fields has produced a clear and consistent picture. First, the differences between the regulatory bodies responsible for the same field in different regions are rather small. The only one general observation, which can be derived from the analysis, is the tendency of the US institutions to promote a more liberal and competitive regulatory framework, whereas in Japan the confidence in the market forces is not well developed and the tendency to balance supply and demand by interventionist policies is still rather high. Europe represents often a compromise between the US and the Japanese situation. More interesting is the comparison between the objectives in the respective fields.

Table 3.6-2 makes obvious at the first glance, that the regulatory bodies responsible for the same field have rather similar objectives. The bodies responsible for competition have to secure at first that competition in the markets is not threatened by antitrust behaviour of companies. However, both the European and US bodies in charge of securing competition have also the explicit objective to promote innovation. In the energy sector, the regulatory bodies have to assure a stable supply, whereas in transport safety and environmental issues are of highest priority. Only in Europe, do the regulatory bodies want to promote competition within the different transport sectors in order to increase efficiency and, although not explicitly mentioned, to produce competitive pressure causing innovation. In the telecommunication sector, the transfer from monopolistic structures to full competition requires a regulatory framework. Although this sector is characterised by a high degree of innovation, only in the US is the promotion of innovation an explicit goal for the responsible regulatory body. Regarding the regulation of the environment, there are no differences between the three regions. The large field of health regulation including pharmaceuticals and food, which are analysed in-depth in two case studies, focuses first on the protection of health and safety. However, especially in the

regulation of pharmaceuticals the responsible bodies and agencies have taken into account that innovative medicinal products are crucial for securing the health of the citizens.

Table 3.6-2: Overview of Main Objectives to protect by Bodies responsible for Regulation in Europe, the USA and Japan

Field of Regulation	**Regions**		
	Europe	**United States**	**Japan**
Competition	Competition Innovation	Competition Innovation	Competition
Energy	Energy Supply	Energy Supply	Energy Supply
Transport	Safety Environment Competition	Safety Environment	Safety Environment
Telecommunication	Competition	Competition Innovation	Competition
Environment	Environment	Environment	Environment
Health (incl. food and drugs)	Health and safety (innovation in the case of medicinal products)	Health and safety (innovation in the case of medicinal products)	Health and safety (innovation in the case of medicinal products)

The overview in Table 3.6-2 shows clearly that innovation is an explicit priority for regulatory bodies in the three regions only in the context of competition. Whereas the regulatory bodies responsible for competition are aware that competition leads to innovation and innovation is necessary to have sustainable competition, regulatory bodies in other areas have not broadly recognised the potential of innovations for reaching their goals. However, in the regulatory policies of pharmaceuticals the necessity to stimulate innovation and to allow the fast marketing of new medicinal products in order to reach the own goals is already acknowledged. Since innovation can help regulatory bodies to reach their goals, it is also necessary to shape the regulatory framework in a way which is stimulative for innovations, because these innovations are again an instrument to achieve the own regulatory objectives. Most regulatory bodies take into account the new developments in science and technology to readjust their regulatory bodies, but this is only a defensive and passive attitude to deal with the potential of new developments in science and technology and new products and services.

3.7 Comparative Summary

Comparing and summarising the observations and results of chapter 3 on regulatory systems shaping new markets reveals a rather clear and consistent picture, although some particularities have to be mentioned. First, we provide a brief summary of the regulations shaping new market or relevant for the introduction of new products and services. Second, we reflect this result with the priorities of regulatory bodies in Europe, the USA and Japan, before we already present some preliminary conclusions for future regulatory policy.

Based on a new taxonomy of product market regulations, we produced an overview of European regulations relevant for the introduction of new products and services according to the categories developed above. The overview of regulations with an impact on innovation showed the variety of different types of regulation and the range of possible impacts on the introduction of new products and services. The main results are the following:

- very often the possible impact of product market regulations on innovation is ambivalent
- regulations, like labelling requirements, are soft framework requirements for the introduction of new products and services
- some regulations give companies strong incentives to develop and market new products and services, like:
  - direct financial support for the transfer of traditional to organic farming
  - indirect financial incentives like the guarantee to have restricted competition in the case of orphan drugs or the tax exemptions for renewable energies
- the liberalisation of several network industries alone allowed the market entry of new companies offering new and often better products and services, but further regulations had to be implemented in order to achieve sustainable competition accompanied by new products and services.

The review of recent national regulatory reforms revealed that within the so called network industries the most dramatic changes have taken place also due to the deregulation initiatives of the European Commission. We find the strongest impact on innovation in the telecommunication sectors by the entry of a large new companies into these markets offering – also supported by the development of new technologies – a broad range of new products and services. In the energy sector, the liberalisation of the markets is at the very beginning and requires large investments, therefore the entry of new companies and the supply of new products and services is still restricted. Within the postal services the incumbents still dominate the market and effective competition between new products and services is primarily taking place in certain niches. Air transporting the traditional European flag carriers under large pressure from low cost carriers which leads more to the introduction of cost saving procedures and less to new products and services. Finally, there is still a general

dissatisfaction with railway services and the experience with liberalisation is mixed due to more frequent accidents in completely liberalised markets.

The review of recent regulatory reforms in the USA, Canada and Japan revealed that especially the USA has reduced all regulatory burdens and restrictions in some service sectors, whereas Japan is still at the beginning of deregulation in these sectors. In general, regulatory changes leading to a stronger competitive pressure has also a positive impact on the prices and quality of products and services, but also on the introduction of innovative products and services.

In summary, there are almost no regulations which explicitly address the introduction of new products and services. However, we find numerous regulations which intend to increase or secure the competition in markets, which has certainly an indirect impact on the propensity of companies to introduce improved or new products and services. In addition, a small selection of regulations intend to provide supportive framework conditions for the suppliers of new goods and services by either offering financial incentives, like in the case of environmentally friendly products, or by increasing the acceptance of consumers, e.g. labelling regulations.

The screening of the objectives and missions of institutions and bodies responsible for regulatory policies in the European Union, the USA and Japan revealed that the promotion of innovation is only an explicit goal for the bodies which are responsible for competition issues, because of the direct and close link between competition and innovation. Furthermore, we find in regulatory bodies responsible for very dynamic sectors, like the telecommunication sector, either explicitly or implicitly fostering innovation as a further objective. Nevertheless, most regulatory bodies have conservative or protection-oriented mission, like those responsible for energy and certainly those in charge of the environment or the health and safety protection. In general, we find in the bodies of the USA a slightly higher propensity to have the promotion of innovation on their agenda compared to Europe, but definitely in relation to the Japanese regulatory bodies or responsible institutions.

The picture of objectives and missions of regulatory bodies corresponds very well with the lack of both regulations with the explicit objective to promote innovation and regulations considering innovation as an important aspect to take into account. We find only in the regulatory bodies responsible for securing competition also the explicit objective to foster innovation as another goal which is assumed to be achievable if competition is secured. Besides the implicit assumption that competition is a necessary condition to force companies to introduce new products and services, the authorities responsible for competition do not follow more explicit strategies within their regulatory policies to promote innovation, like approaches to restrict competition at least temporary in order to create strong incentives for companies to perform innovative activities or to introduce new products and services. However, sectoral regulatory bodies confronted with dynamic and radical technical

changes are keen to shape the regulatory framework in a way that not only competition is guaranteed but also the introduction of new products and services is promoted. Nevertheless, the broad majority of regulatory bodies miss both to take the impact of their regulations on innovation into account and to consider whether innovations in the field they are responsible for may be supportive for reaching their central objectives, like protecting the environment or securing energy supply.

4. European Survey on the Role of Regulation for Innovation among Different Stakeholders

4.1 Introduction

After reviewing the regulatory system in general, including the priorities of some regulatory bodies, the views and experiences of companies as the main driving forces for innovations and targets for regulatory policies have to be collected and presented. At first, this chapter presents and analyses the results of a survey among companies in selected sectors based on an Internet questionnaire. Furthermore, the experiences of research institutes were collected in the same way. In addition, telephone interviews and some personal interviews with key representatives of various interest groups, like consumer or environmental organisations, complete the picture about the relationship between innovation and regulation. This more qualitative information will complement the results of the survey, which also included some open questions in order to allow the respondents to mention and to explain specific examples.

The structure of the survey and the interview structure is guided by some central questions or hypotheses regarding the relationship between regulation and innovation. A first popular hypothesis is that regulations can stimulate innovation by setting ambitious targets, like the reduction of environmental pollution, which can only be achieved by the development of innovative technologies. In order to prove the relevance of this objective of innovation, we ask first for the general importance of various objectives to innovate. Second, it is important to get insights about the importance of regulations as barriers to innovations with reference to other obstacles. In contrast to existing studies, we have to distinguish between governmental and non-governmental regulations, since they might have different impacts on innovation. Furthermore, it is necessary to distinguish between the regulations themselves and their implementation. Third, regulations of product markets cover a broad variety of different types of regulations, which often do not directly address the issue of new products and services, like the regulations of prices and competitive behaviour. Since there is little knowledge about these indirect impacts of regulations on innovation, we ask for the importance of different types of regulations for the introduction of new products and services. Fourth, innovation is divided into different phases, various actors, inputs and outputs and other aspects. Consequently, regulations might have heterogeneous impacts on these innovation-related aspects. Fifth, industry is complaining about the current regulatory framework, especially the restrictions of their innovation activities. In order to identify specific options to improve the current regulatory framework, we have asked for the assessment of concrete regulatory issues covering the broad range from development to implementation. Finally, due to obvious dissatisfaction with the current regulatory framework,

possible changes in the direction of an innovation-stimulating framework should reflect the preferences of the involved stakeholders, the companies. Therefore, we have asked about the efficiency of a variety of currently discussed reforms of the regulatory system. So far we have neglected the international dimension, but it is also of interest whether the regulatory framework conditions are important for the initial introduction of new products and services world-wide and are different between countries. This question is directly linked to the concept of "lead markets" characterised by further features, which we are also taking into account.

Chapter 4.2, which refers to the answers of the companies, is structured according to these questions and issues. After the completion of the survey, we will also differentiate the answers by sectors and other characteristics of the companies, like their innovation activities. These working steps do not make sense based on only a sub-sample of the final sample, although the stability of the descriptive statistics is already confirmed by preceding analyses covering an even smaller number of observations. In Chapter 4.3, we present the results of the survey among research institutes, before we continue to present the views of stakeholders differentiated by sector. Finally, we complete this part with a comparative summary and some preliminary conclusions for the outlook.

4.2 Empirical Results of the Company Survey

The objectives of innovation activities, factors hampering innovation, the importance of regulations relevant for the introduction of new products and services, the impact of regulations on new products and services, the assessment of the current regulatory framework, and finally, the future of the regulation system, are the main elements for structuring the questionnaire of the on-line survey among companies in Europe. The results of the structured questionnaire help to answer the important question about the impact of regulation on innovation in general, but especially on shaping new markets for products and services.

Due to the increasing intensity of competition, the possible impacts of regulation on innovation and therefore on international competitiveness have to be assessed and possible changes of the regulatory framework and regulatory practice have to be considered. The results of this survey contribute to a more sophisticated discussion about the relevance and impacts of regulation for innovation, especially the introduction of new products and services, and provide both policy-makers, companies and regulatory bodies with insights for their decision processes.

4.2.1 The Methodology and Main Characteristics of the Sample

In agreement with the responsible services of DG Enterprise, the target group of the survey were the following six industry sectors:

- Environmental sector:
  - Water treatment (NACE 90 + 33; 45.2),
  - Wind energy (NACE 40.10 + 29.12);
- Food sector (NACE 15):
- Pharmaceutical sector (NACE 24.4);
- Mechanical engineering (NACE 29);
- Electro-technology (NACE 31);
- Transport and telecommunication services (NACE 64).

In the following presentation of the results, we differentiate only between sectors, if we observe significant differences otherwise, the differences are negligible.

Initially, we agreed to concentrate on the six large Member States France, Germany, Italy, Spain, Sweden, and the United Kingdom. However, we extended the survey to all Member States. In total, we received completed questionnaires from more than 260 companies (see annex). The companies were randomly selected by using the commercial database of Dun & Bradstreet. At first, the companies were approached via fax or via mail and asked to fill out the questionnaire either online or to download a pdf-file and return the questionnaire via mail or fax (see the annex for the questionnaire). Secondly, two thousand companies active in the six sector above in further Member States and one thousand companies in the USA and Canada were sent a paper version of the questionnaire.

The response rate was rather low compared to other non-mandatory business surveys in Europe, because of two reasons. First, the complex issue of regulation and innovation within companies is not yet broadly acknowledged and taken into account, consequently there is very often no one explicitly responsible for this issue. A survey in Germany on standardisation as a special type of regulation based on a paper questionnaire reached less than 5 % response.[9] Secondly, the response to Europe-wide surveys is significantly lower than to national surveys.[10]

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9 Cf. Mörschel and Schwengels (2002), p. 51.

10 Blind et al. (2003, p. 39) performed a Europe-wide survey among software companies about the issue of software patents and reached a similar response rate of 2.64 %. Recently, Blind (2003) surveyed European service companies on the issue of standards and realised a response rate of 2 %.

In more than one third of the answers, the chief executive officer answered the questionnaire. The other answers stem from members of the R&D or from the members of the marketing department. Members of the legal department are almost not included in answering the questionnaire.

The sample of the companies is characterised by a high degree of innovativeness (for the definition of innovation, see box below). Almost 80 % have introduced a product innovation, and almost 60 % a process innovation. These shares are higher than in the second Community Innovation Surveys (Eurostat 2000, p. 18). However, the share of turnover with new or significantly improved goods and services is almost 20 % and therefore lower than the reported 30 % in the second Community Innovation Survey (Eurostat 2000, p. 32). It has to be noted that the electrotechnology and the pharmaceutical sector report significantly higher shares, whereas the food sector is traditionally less innovative. The impact of process innovation is a cost reduction of about 7 %, which is similar to the third German Innovation Survey (Rammer et al. 2003, p. 5). Especially, the transport and telecommunication sector have experienced cost reductions of more than 10 %.

Definition:

For this survey product innovation covers both goods and services introduced to the market which are either new or significantly improved with respect to fundmental characteristics. The innovation should be based on the results of new technological developments, new combinations of existing technology or utilisation of other knowledge by your firm

Source: British version of the third Community Innovation Survey (http://www.dti.gov.uk/iese/cis_quest.pdf).

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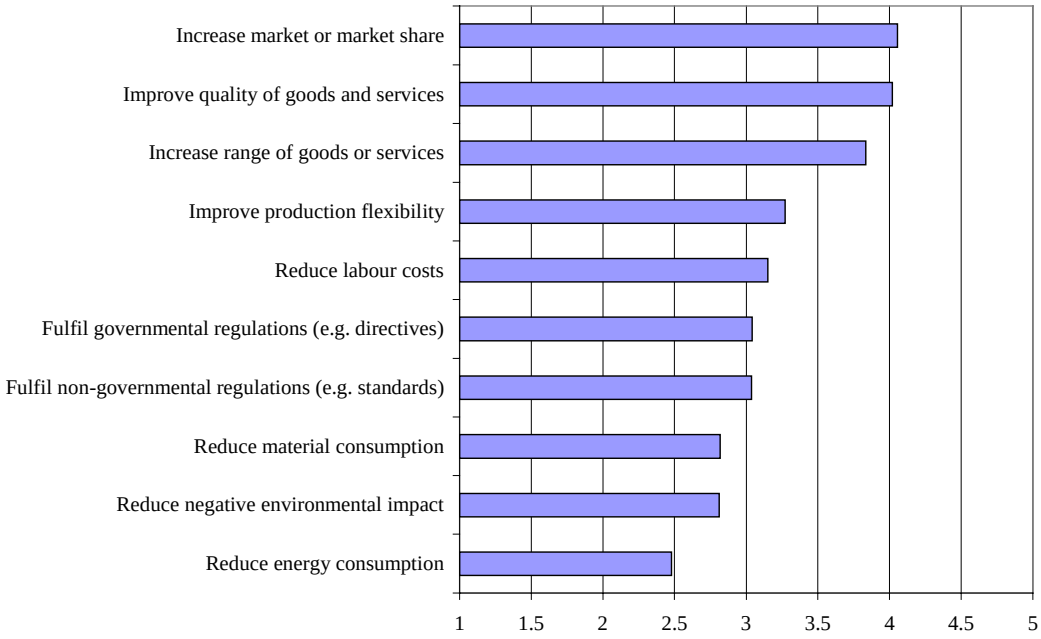
4.2.2 The Objectives of Innovation Activities

One central hypothesis about the relationship between regulation and innovation is based on the assumption that it is possible to trigger innovation and to stimulate the development and market introduction of new products and services by setting adequate incentive structures or by forcing sanctions on the involved actors. The most cited example regarding this innovation fostering stems from the area of environmental policy. Here, especially rigid obligations to reach significant reductions in polluting emissions serve as success stories for this paradigm. The system of intellectual property rights represents a more general kind of regulation, which also provides additional incentives for innovators.

In order to test this first hypothesis, we asked the companies for their objectives to innovate, including regulation-related issues (Figure 4.2-1). Of top priority for companies are innovative activities to increase their market and the market share and to improve the quality of their goods and services, which reflects very much the ranking of the second Community Innovation Survey (Eurostat 2000, p. 56). For the companies of the pharmaceutical sector, increasing market shares and extending the range of their products is more important compared to the other sector, whereas companies in electro-technology and the transport and telecommunication service put a high emphasis on improving the quality of their products and services. A second group of objectives to innovate aims to increase the range of goods and services, improve production flexibility and reduce labour costs. This relative position is also in accordance with the results of the second Community Innovation Survey. Innovations in order to reduce input factors, like material and energy, or to reduce environmental damage have the least importance for the companies. This result is also very close to the ranking in the second Community Innovation Survey.

Figure 4.2-1: Importance of objectives to innovate
(1 = very low importance to 5 = very high importance)

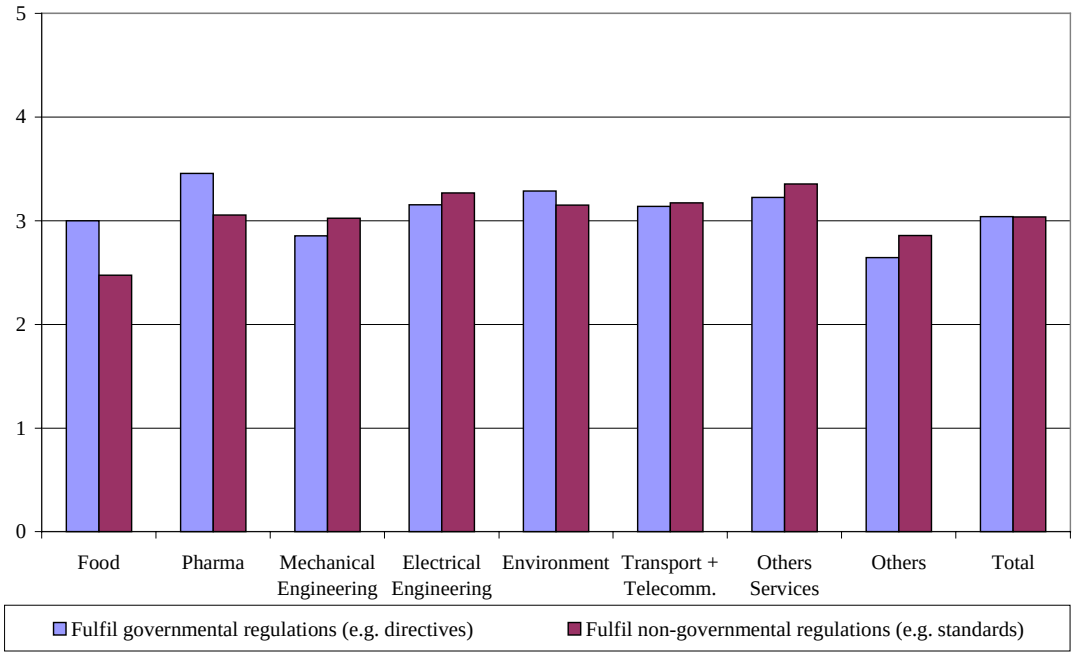


Source: own calculations.

Still just above medium is the importance of fulfilling governmental and non-governmental regulations. This assessment is higher than in the second Community Innovation Survey and reflects probably the sensitivity of the sample regarding the issue of regulation, but supports also the hypothesis that regulations represent an important incentive to innovate. Figure 4.2-2 presents the assessment of regulations as objective to innovate. We find significant differences between sectors, because in

the pharmaceutical sector, the food sector and the environmental sector the fulfilment of governmental regulations are much more important than of non-governmental regulations. For companies in mechanical engineering, electro-technology, but also the services other than transport and telecommunication, non-governmental regulations are more important than governmental regulations as objectives to innovate. These differences reflect two important dimensions. First, some sectors with strong impacts on health and the environment work certainly under a stronger regulatory regime than other "less risky" sectors. Second, the development and functioning of some sectors, like electro-technology, which have characteristics of network industries, rely strongly on formal and informal standards. Both aspects have to be taken into account when developing new regulatory frameworks conducive to the emergence of new products and services. Regarding the country differences for the companies in Southern Europe fulfilling regulations as an objective to innovate is more important than for companies in other regions.

Figure 4.2-2: Importance of regulations as objectives to innovate differentiated by sector (1 = very low importance to 5 = very high importance)

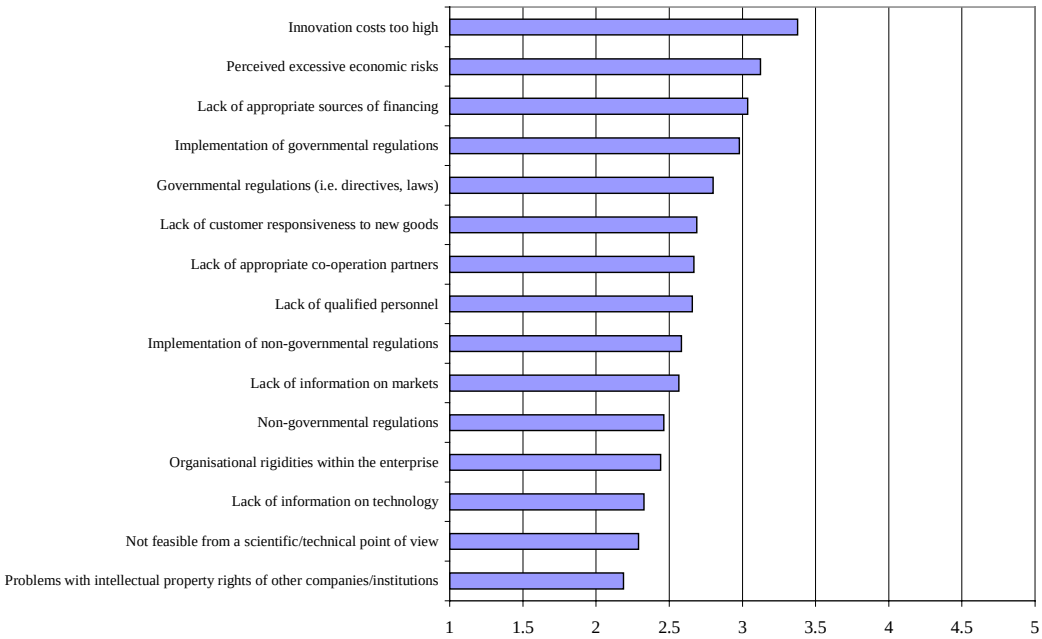


Source: own calculations.

4.2.3 Factors Hampering Innovation

Although regulations are the necessary "infrastructure" for the success of highly industrialised economies, since they provide the framework conditions for both the suppliers of goods and services and their consumers, like other infrastructures the regulatory framework is also characterised by a certain inertia, since well established rules, standards, and laws are difficult to change without any transaction costs, both on the side of the institutions responsible for the regulatory framework and the individuals and organisations affected by regulation. In addition, the increasing speed of technological change challenges the existing regulatory frameworks. On the one hand, existing regulations have to be adapted continuously to technological progress, even with the consequence of withdrawing outdated rules. Furthermore, the regulatory bodies have to construct new sets of regulations for upcoming technologies and products, respectively services, making use of these new technologies. Finally, the structure of the regulatory bodies and administrative responsibilities do not coincide with the needs of new technologies or newly emerging scientific paradigms. Concluding all these arguments, regulations can hamper innovation, because they may restrict companies in their research, developing and marketing activities.

Figure 4.2-3: Factors hampering innovations
(1 = very low importance to 5 = very high importance)



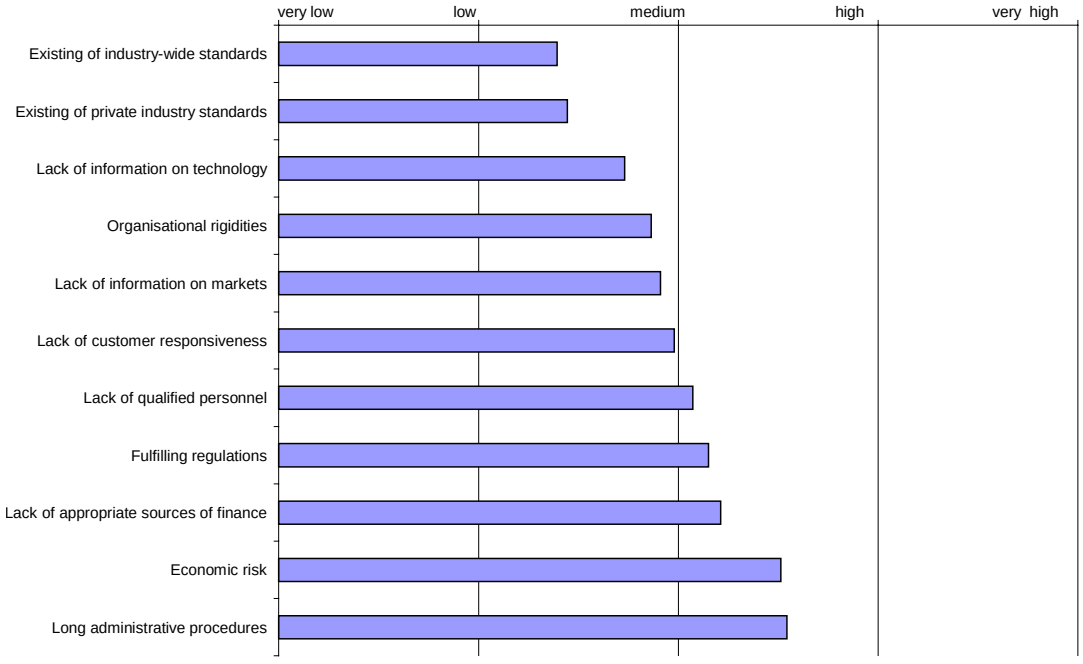
Source: own calculations.

Figure 4.2-3 presents the ranking of the most important factors hampering innovation activities. For the companies the economic factors, like the innovation costs,

the economic risks and the lack of financial resources, are most relevant for developing and introducing new products and services into the market. This result is consistent with the ranking of barriers to innovation in the second Community Innovation Survey (Eurostat 2000, pp. 83-89). It has to be noted, that for the pharmaceutical companies, the perceived excessive economic risks of innovation projects are significantly higher than for the rest of the sectors.

Before we discuss the role of regulations as obstacles to innovation activities, it is important to note that often the responsiveness of customers to new products and services is not satisfactory, which leads to a failure of the innovation activities. On the other hand, intellectual property rights of other companies and institutions do not present in general a problem for innovation activities. Finally, the current economic downturn is also reflected in the answers, because the lack of qualified personnel is no longer listed among the top priority obstacles for the companies.

Figure 4.2-4: Importance of factors hampering innovation in the German manufacturing sector

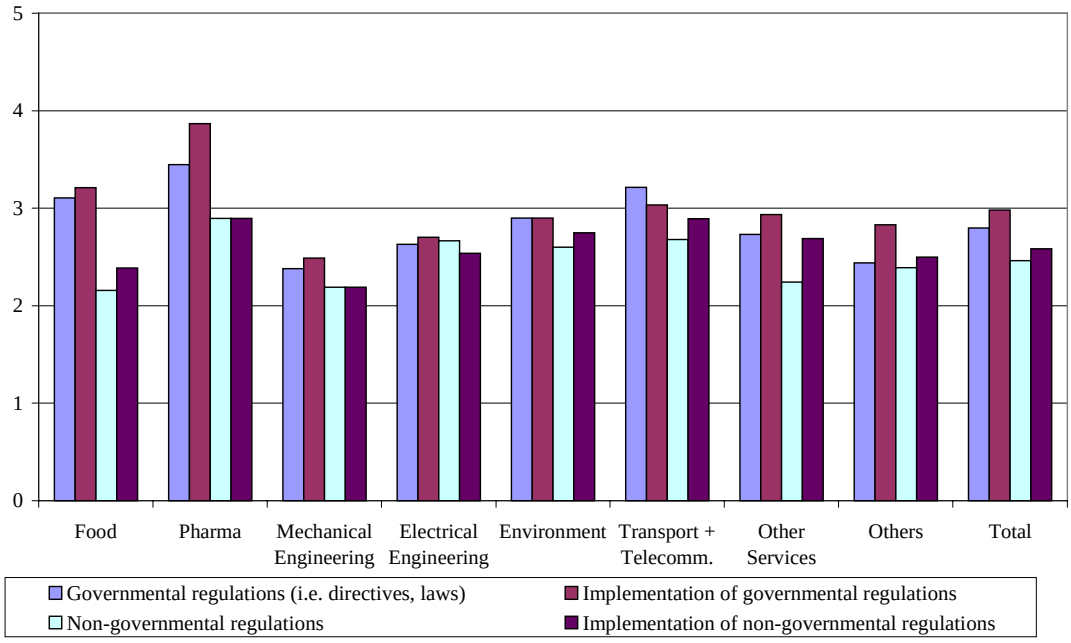


Source: Blind, K. and H. Grupp, H. (2000): Gesamtwirtschaftlicher Nutzen der Normung. Volkswirtschaftlicher Nutzen: Zusammenhang zwischen Normung und technischem Wandel, ihr Einfluss auf die Gesamtwirtschaft und den Außenhandel der Bundesrepublik Deutschland, edited by the Deutschen Institut für Normung, Berlin: Beuth Verlag.

The implementation of governmental regulations is fourth most important obstacle for developing and marketing new products and services. The governmental regula-

tions themselves are less important as barriers to innovation. In contrast to governmental regulations, like directives and laws, both the implementation of non-governmental regulations and the non-governmental regulations themselves are of significantly less importance respectively as barriers to innovation. As expected, this pattern is common for all Member States. In addition, this ranking confirms the results of a German survey conducted in 1999 about the impact of regulations on innovation, also differentiated according to different types of regulations (Figure 4.2-4). It turns out that long administrative procedures as a kind of administrative regulation are the most important hampering factor for innovation. On the other hand, both formal industry-wide standards, like CEN or BSI standards, and private industry standards, like the famous IBM standard, have only a low importance as innovation-hindering factors. This result confirms that for the analysis of the impact of regulation on innovation, it is necessary to distinguish between the different types of regulation.

Figure 4.2-5: Factors hampering innovations differentiated by sector (1 = very low importance to 5 = very high importance)



Source: own calculations.

The sector differences between governmental and non-governmental regulations already became obvious in the context of the objectives of innovation. Therefore, we present in Figure 4.2-5 a differentiation of the importance of regulations as hampering factors for innovation. Although governmental regulations are more severe obstacles for innovation than non-governmental regulations, we find in the pharmaceutical and the food sector the highest values and the largest discrepancies

to non-governmental regulations. Furthermore, the implementation of governmental regulation is in general a slightly more severe problem than the regulations themselves. This discrepancy is strongest in the pharmaceutical sector, but reversed in the transport and telecommunication sector, where the governmental regulations themselves are more a problem. In the transport and telecommunication sector, non-governmental regulations and their implementation have almost the same negative impact on innovation in general as in the pharmaceutical sector. However, in general this type of regulation is significantly less important as an obstacle for innovations.

These results allow us to derive two conclusions. First, the implementation of regulations, both governmental and non-governmental, is in general much more critical for the activities of companies regarding the development and the marketing of new products and services compared to the regulations themselves. This means that much more attention has to be focused on the implementation phase of regulations, whereas the regulations themselves do not present a major problem for innovation activities. Consequently, the institutions responsible for the implementation of regulations have to be made aware of this critical issue. In addition, the shaping of regulations should also consider possible problems connected with their implementation. We will discuss proposals for an improvement of the regulatory framework later, but a solution to this problem can be a better exchange of information between those authorities shaping regulations and those institutions implementing them. Furthermore, the approach to foresee an impact assessment for new regulations may also reduce problems connected with their implementation. Second, non-governmental regulations and their implementation are in general less a problem for innovation activities. Therefore, one has to check whether and under what circumstances this regulatory instrument is able to substitute governmental regulations which are obviously stronger obstacles for innovation activities.

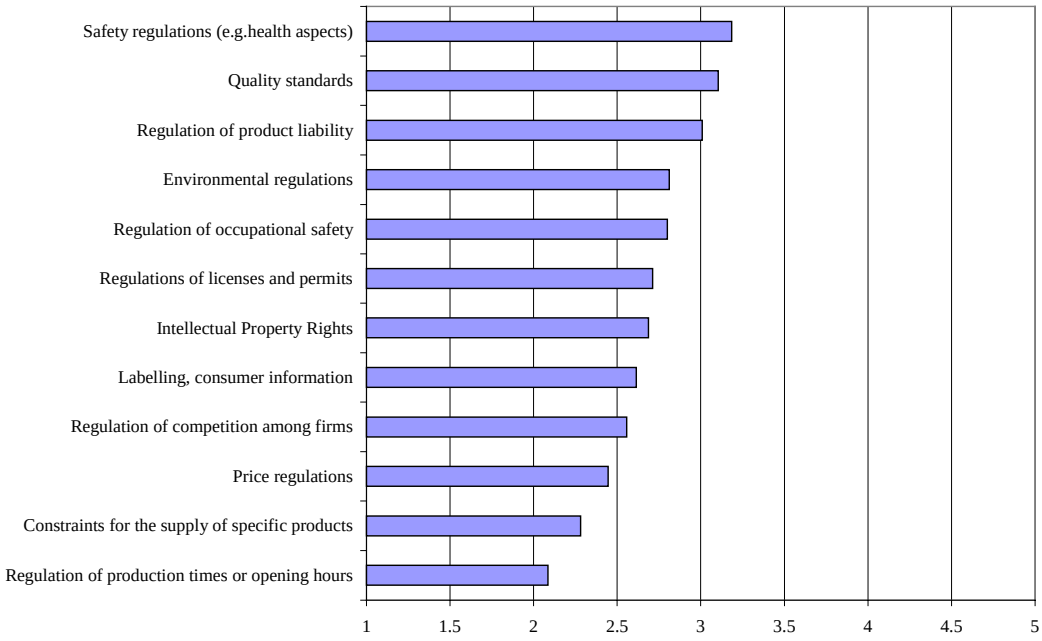
4.2.4 Importance of Regulations Relevant for New Products and Services

Starting from the rough classification of the OECD into economic, social and administrative regulation (see box in chapter 3.2) and the OECD taxonomy of product market regulations (see Figure 3.2-1) based on indicators derived from the evaluation of answers to qualitative questions about the public ownership, price regulations, administrative burdens and antitrust rules (Nicoletto et al. 2000), we have developed a taxonomy of product market regulations (see Figure 3.2-2). This allows us to differentiate more precisely between different types of regulations relevant for the development and introduction of new products and services. This classification served as background for the development of the questionnaire addressing those regulations which are directly relevant for the development and the introduction of new products and services.

The following Figure 4.2-6 presents the ranking of the importance of the different types of regulations for new products and services. The most important type are safety regulations, especially with respect to health issues. Quality standards, which have an intermediate character between voluntary self-regulation and obligatory regulation, reach also an above average importance. In third place, we find the regulation of product liability. Environmental regulation and occupational safety regulations follow in the ranking. Most of these regulations have in common that they aim to protect consumers from damages caused by the consumption of products and services. For the introduction of new products, the regulations concerning the interaction of companies on the supply side, like the regulation of competition, the regulation of licenses and permits, intellectual property rights and price regulations are of less importance.

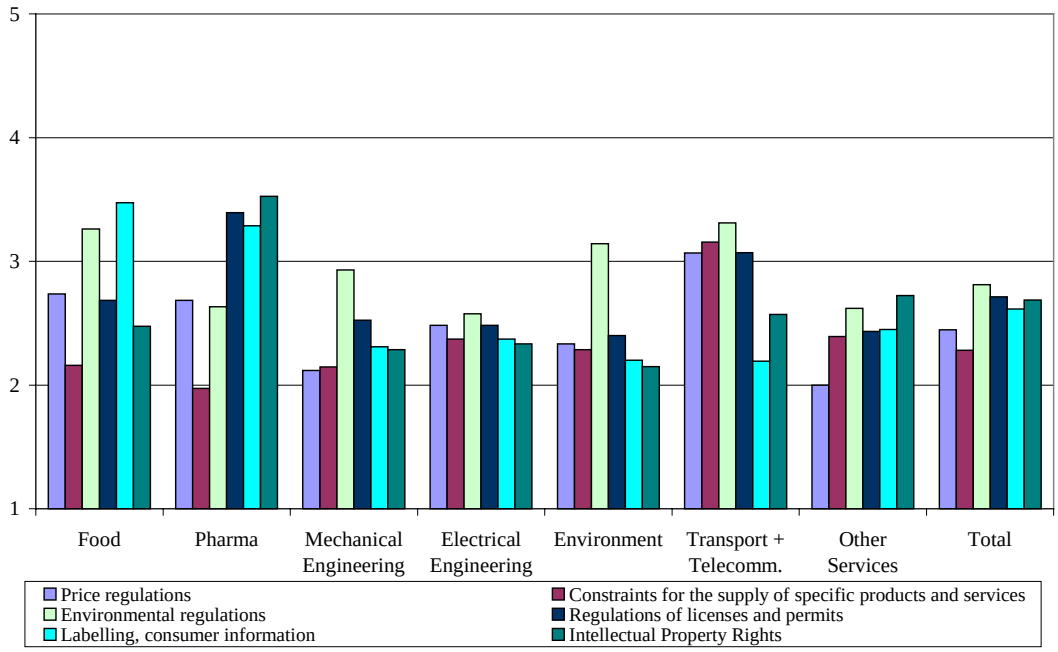
The results of the analysis based on answers to questions about the importance of different types of regulations for the development and introduction of new products and services confirm that the regulations managing and controlling the interactions between the actors of the supply side are less important, whereas it is more important to stabilise the link between the suppliers of new goods and services and the respective consumers by regulations concerning the health and safety aspects, the quality of new products and services, and the question of liability. Furthermore, the input factors labour and environment deserve special attention, especially in the production phase of new products and services, because they have to be protected from risks, which may be either unforeseen or difficult to calculate in advance.

Figure 4.2-6: Importance of regulations relevant for new products and services (1 = very low importance to 5 = very high importance)



Source: own calculations.

Figure 4.2-7: Importance of selected regulations relevant for new products and services differentiated by sector
(1 = very low importance to 5 = very high importance)



Source: own calculations

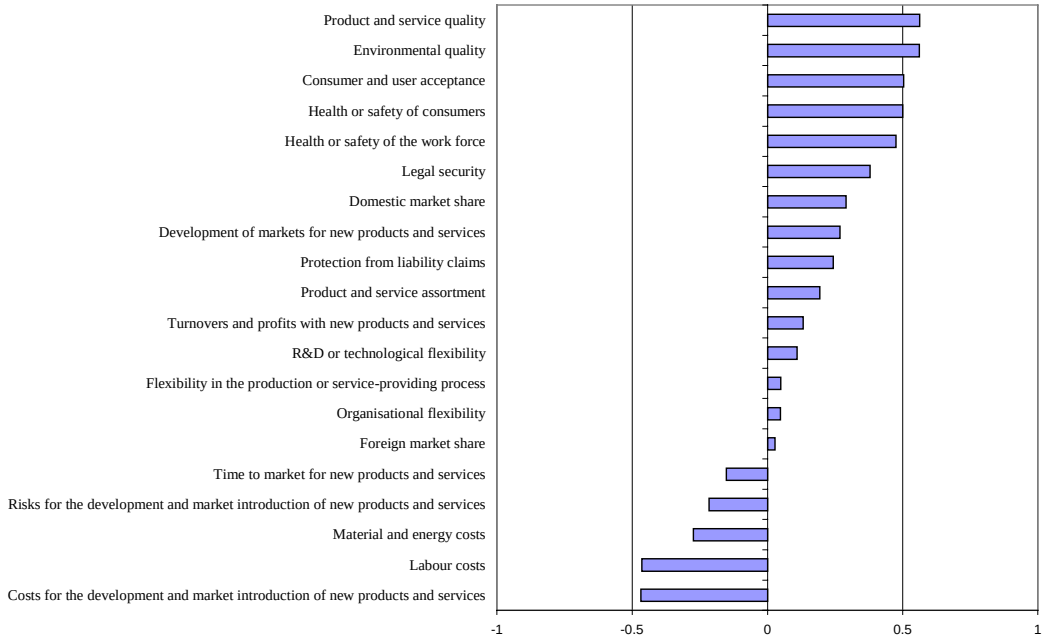
In the previous analyses, we observed sector differences. Therefore, we differentiate the results presented in Figure 4.2-6 by sector. First, it has to be noted that the average importance of all twelve regulation types for the introduction of new products and services is highest in the transport and telecommunication sector, but also in the food and pharmaceutical sector, which is consistent with the results in the previous sections. All other sectors are less affected by the various types of regulations. In order to focus on the most significant differences between sectors, we select in Figure 4.2-7 those regulations with the highest discrepancies between sectors. Regarding price regulation, companies from the transport and telecommunication sector experience the strongest impact, whereas this is no crucial regulation for the other sectors. Also for the transport and telecommunication sector, constraints for the supply of specific services have a strong importance for their activities in the context of new products and services. Environmental regulations are crucial for the companies in the food sector, mechanical engineering, the environmental sector itself and again the transport and telecommunication sector. Regulations of licenses and permits are crucial for the companies in the pharmaceutical sector and the transport and telecommunication sector. Labelling and consumer information requirements are relevant for the food and the pharmaceutical sector. Finally, intellectual property rights as an important regulation addressing the relationship between competitors is only very relevant for the companies in the pharmaceutical sector. All these results reflect very well the regulatory framework in the different

sectors and represent a basis for policy actions. Country differences are negligible, although companies in Benelux report a higher importance of environmental regulations and regulations of licenses and permits.

4.2.5 Impact of Regulations on New Products and Services

Regulation may be a hampering factor for the development and market introduction of new products and services. However, regulation may also have a positive influence on these activities, by forcing firms to search for new products and services. Furthermore, regulation may create new opportunities for new products and services by providing an adequate framework. Based on this background, we asked the companies to assess whether those regulations in the direct context of introducing new products and services into the market, which have been assessed as important (see Section 4.2.4), are more likely to have positive or negative impacts on these aspects.

Figure 4.2-8: Impacts of the regulatory framework relevant for the introduction of new products and services
(-1 = negative impact to +1 = positive impact)



Source: own calculations (n= 243).

The ranking of aspects related to the role of regulation in the introduction of new products and services in Figure 4.2-8 confirms the order of the importance of regulations relevant for the introduction of new products and services. The most positive impact of the regulatory framework is improved quality of products and services.

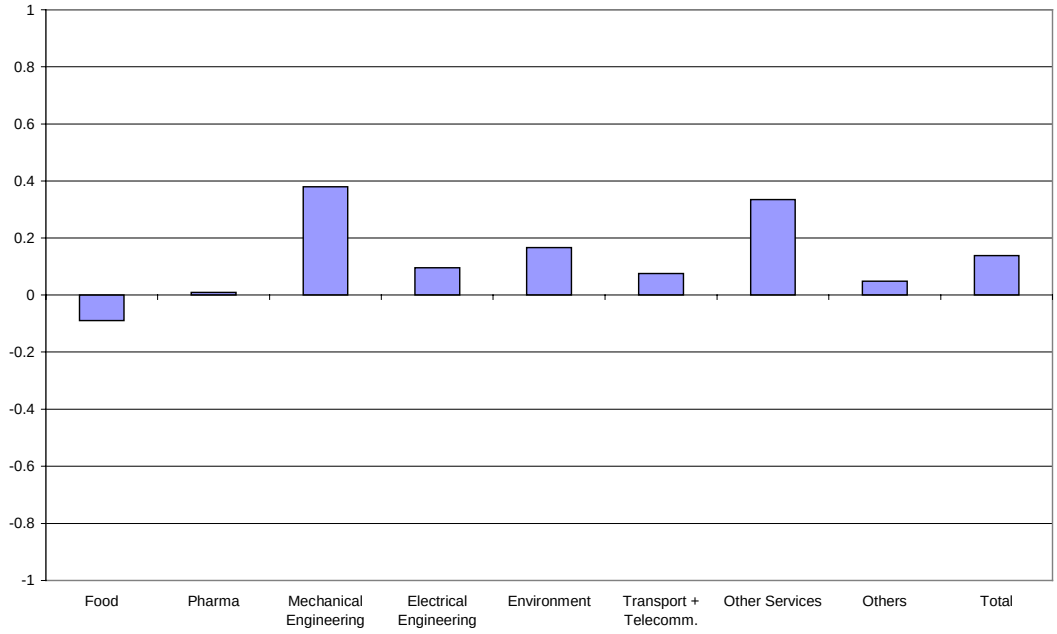
Second, regulation has a positive impact of the quality of the environment. Third, regulations increase the acceptance of new products and services by consumers and users. The health and safety of consumers, but also of the work force are positively influenced by regulations. Furthermore, regulations increase the legal security for the companies introducing new products and services. In this context, companies perceive regulations also as instruments, which improve the protection from liability claims. Whereas this result is not surprising, the companies assign to the regulatory framework also a positive impact on the general development of markets for new products and services and – to a less extent – on the turnover with new products and services. In addition, the market shares at home, but not abroad are positively influenced by regulations, which may be an indication for regulations as barriers to trade. And the product and service assortments themselves are not negatively, but positively affected by regulation. Finally, the flexibility both in R&D or choice of technology and in the production process itself is not hindered by regulation. The consistency of these answers support the hypothesis that an adequate regulatory framework is able to promote the development and marketing of new products and services.

In contrast to all these positive impacts, regulations have an especially strong negative impact on the costs for the development and market introduction of new products and services. The ambivalence of regulations for the development and the introduction of new products and services is confirmed by this assessment. Besides the input factor labour, energy and material costs are also negatively affected by regulation. The companies are slightly pessimistic regarding the impact of regulation on the time-to-market and on the risks connected with the introduction of new products and services.

Summarising the assessments about the possible impacts of regulation, the companies perceive definitely negative influences for the input factors labour, energy and other materials. On the other hand, regulations definitely foster the quality of products and services, protect the environment, health and safety of both consumers and the working force. And they provide framework conditions that reduce legal uncertainty. This last aspect has an important impact on the innovative activities of entrepreneurs. As a preliminary result it can be noted that companies have many more problems regarding regulations if inputs or production processes are concerned, whereas the output side, like products and services, experiences a positive support by the regulatory framework. This ambivalence has to be taken into account when policy implications have to be discussed.

The differentiation of the answers by sectors show significant differences. Figure 4.2-9 presents the average of all twenty impact dimensions. The regulatory framework has the most positive impact for the development of new products and services in mechanical engineering and other services, except transport and telecommunication. In contrast to this positive picture, we find ambivalent impacts in the

Figure 4.2-9: Total impact of the regulatory framework relevant for the introduction of new products and services
(-1 = negative impact to +1 = positive impact)



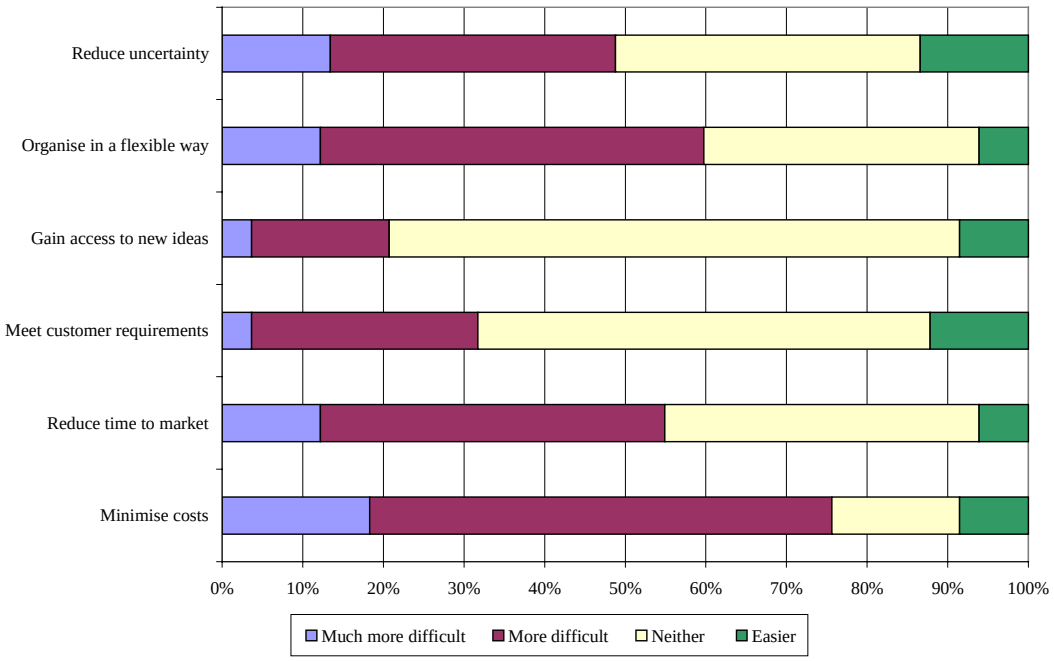
Source: own calculations (n= 243).

pharmaceutical sector and even a negative influence in the food sector. Looking at the most positive impact dimensions by sector, the environmental sector ranks consequently the role of the regulatory framework as most positive for the environmental quality of new products and services. The companies active in mechanical engineering, but also those active in the environmental sector, perceive a very positive impact of the regulatory framework for the quality of their products. For the former group of companies the regulatory framework is also favourable for the development of markets for new products and services, including consumer and user acceptance. Very negative is the regulatory framework for the costs generated by the development and market introduction of new products and services in the food and pharmaceutical sector. The negative influence of regulation on the labour costs is strongest for the companies in the transport and telecommunication sector, but also in the environmental sector. The risks accompanying the development and market introduction of new products and services are especially increased by the regulatory setting in the electro-technology and the food sector. Time-to-market rises in the pharmaceutical sector and in the transport and telecommunication sector due to the restrictions of the regulatory framework. Both the overall picture of the total impact of regulation on various dimensions of innovation and the selective discussion of specific impact dimensions impressively highlight the sector differences, which have to be taken into account also in reforming the regulatory framework. Surprisingly, the companies located in Southern Europe, but also in Benelux

perceive a more positive impact of regulations on the various dimensions of innovations than the other companies.

Although there is no survey which has addressed the same question, we can refer to the results of a survey performed by UNICE in 1994 (UNICE 1995), almost ten years ago. There, the influence of regulations on determinants of successful innovation was investigated (Figure 4.2-10). Regarding all dimensions, only a relatively small share of companies experienced that regulations make it easier to achieve the crucial factors of successful innovation. The majority of the firms report that regulation made it more difficult to minimise costs, to organise in a flexible way, reduce time to market and even to reduce uncertainty. These problems were found independent of size, sector and location of firms. In comparison with our results, the ranking of the determinants of innovations is similar, although the answers to the UNICE survey are much more critical than in our sample.

Figure 4.2-10: Do regulations make it easier or more difficult for companies to achieve determinants of successful innovation? (% of companies)

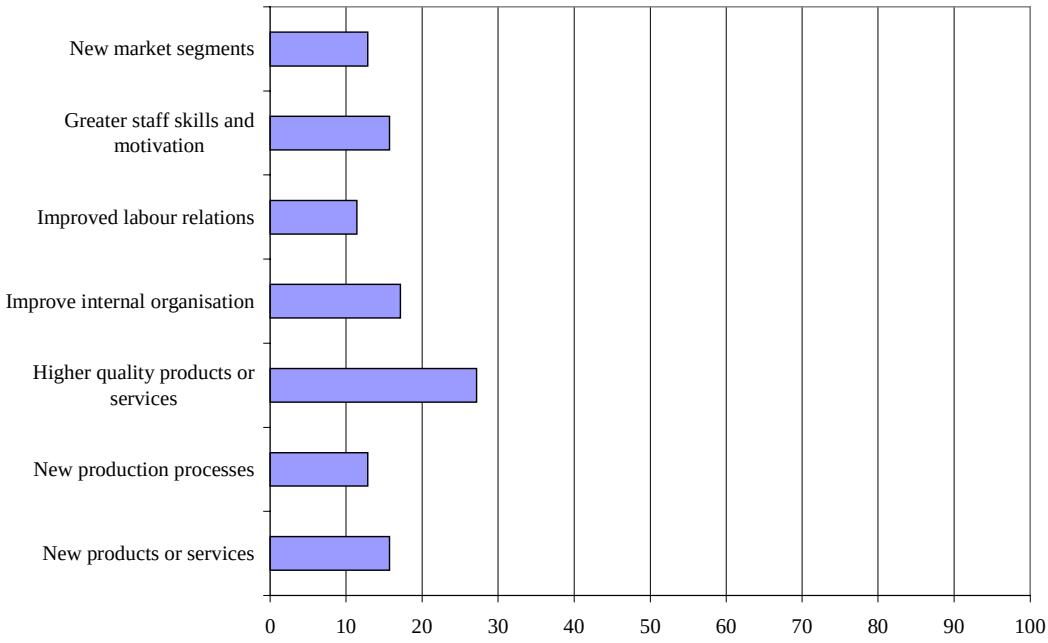


Source: UNICE (1995): Releasing Europe´s Potential Through Targeted Regulatory Reform: The UNICE Regulatory Report 1995, Bruxelles: UNICE, p. 18.

In the same context, the UNICE survey asked to which extent regulations triggered innovations in different dimensions. On average, about one fifth of the companies confirmed that regulation had triggered the development of new products and services, the introduction of new production processes, the improvement of the product and service quality, the promotion of the internal organisation, labour relations and

skills and motivation, and finally the opening of new market segments (Figure 4.2-11).

Figure 4.2-11: Companies agreeing that regulations have triggered innovations (% of companies)



Source: UNICE (1995): Releasing Europe´s Potential Through Targeted Regulatory Reform: The UNICE Regulatory Report 1995, Bruxelles: UNICE, p.18.

4.2.6 Assessment of the Current Regulatory Framework

In Section 4.2.5 we have seen that regulations can be positive for the development of new products and services. In order to find out how the companies assess specific aspects of the regulatory framework with respect to their impacts on innovation, we have differentiated the complex issue of regulation into institutional aspects, questions regarding their implementation and the achievement of their objectives. The assessment of these statements will provide us with more specific information as to where and how to improve the regulatory framework conducive to innovation. This supports the basis of evidence for formulating policy considerations.

Figure 4.2-12 ranks the different statements according to the degree of agreement by summing up total agreement and agreement. At the top, we find that SMEs have disadvantages in complying with regulations compared to larger companies. Although this result can be explained by the two thirds share of SMEs within the sample, it is an important aspect for policy-makers.

A large consensus (more than 70 % agreement) exists that approval procedures are both too costly and too long. Regarding the latter aspect, companies in the transport and telecommunication, the food and the pharmaceutical sector express a very high agreement to these statement. In addition, there is potential to decrease the administrative burden ("red tape") accompanying regulations especially in the pharmaceutical sector and electrical engineering. According to more than 60 % of the companies, the specifications of regulations are not transparent enough, this is especially the case in the food sector. The implementation of regulations is also a problem, because it is not flexible and transparent enough. This result confirms the answers in Figure 4.2-2, that the implementation of regulations is much more critical for the innovation activities of companies than the regulations themselves. On the other hand, the number of regulations is perceived to be definitely too high, especially by the pharmaceutical companies.[11] Therefore, there is obviously no lack of regulations regarding new technologies, the needs of the environment or of the consumers. The public support, e.g. by help-desks, regarding the fulfilment of regulations is not sufficient, according to the companies.

Finally, it is important to note that the companies perceive that regulations do not keep track of the development of technology. This assessment represents a further challenge for the regulatory bodies and calls for solutions to improve the up-to-dateness of regulations with respect to the dynamic developments in science and technology.[12]

Positively, it has to be noted that there is agreement about the existence of specific types of regulation, which create market opportunities for new products. However, especially the companies in the pharmaceutical and food sector complain that regulation hinders their development and market introduction of new products and services. All these assessments are in line with the opinions on the impact dimensions of regulation (see Figure 4.2-8). For all other statements, there is neither a majority of companies agreeing nor disagreeing, which underlines the ambivalence of regulation for innovation.

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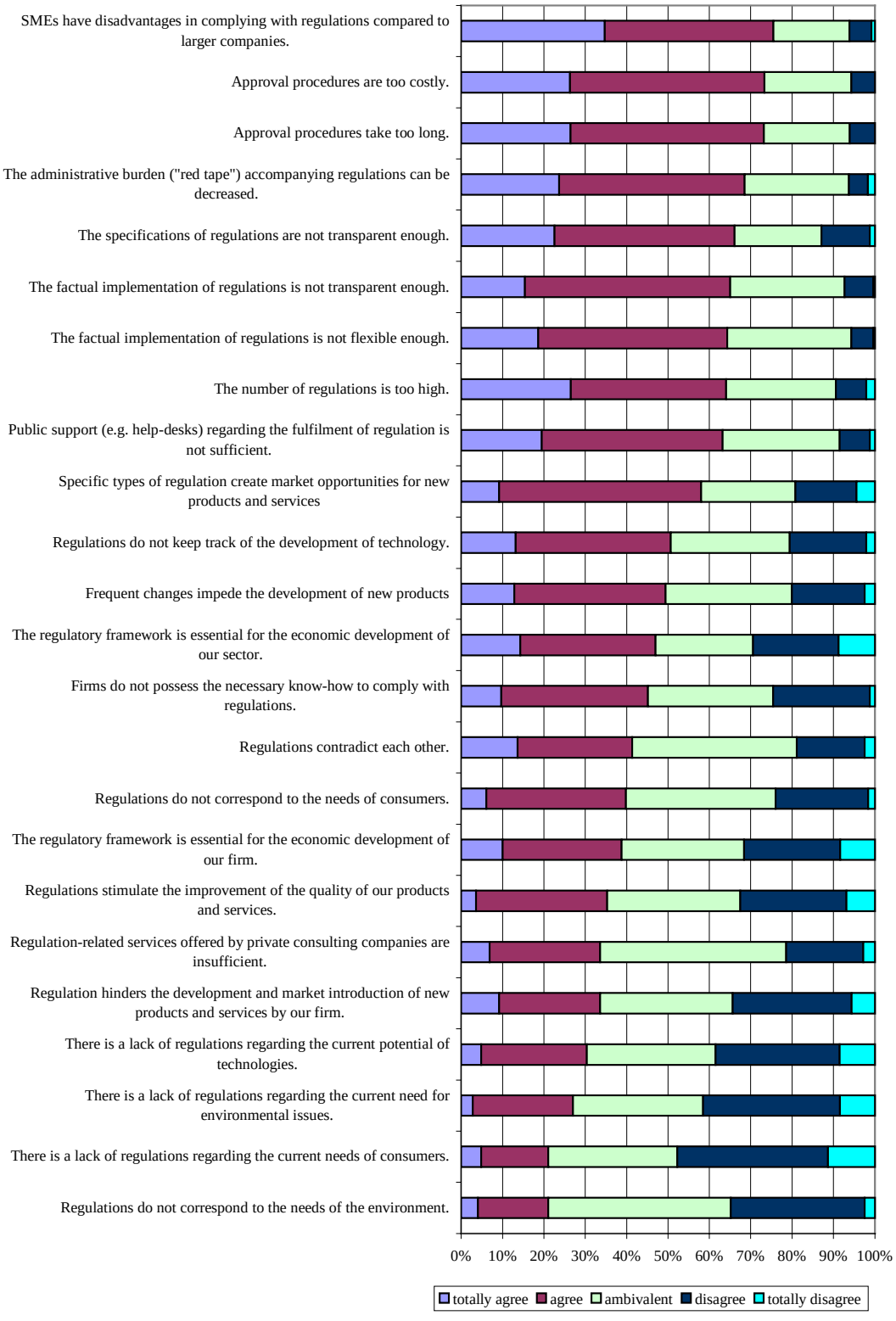
11 In a study for the German Institute for Standardization, a similar question was included regarding the stock of formal standards. The share of companies agreeing that the stock of standards is too large is significantly lower (cf. Blum et al. 2000, Vol. 2, p. 100) than the shares reported in Figure 2.2-7.

12 This requirement was already asked about respective to technical standards in Blind and Grupp (2000).

Figure 4.2-12: Assessment of the current regulatory framework (share of companies agreeing and disagreeing in %)



Source: own calculations (n= 259).

4.2.7 Future of the Regulation System

The preceding results have shown that significant shortcomings in the regulatory framework exist, especially regarding its impact on innovation and the development of new products and services. Several approaches are already currently being discussed or have even been already introduced in order to improve the present regulatory framework. We asked which approaches are suitable to make the regulatory framework more conducive to the development of new products and services as far as companies are concerned. The assessment of these proposals will provide the ground for development of possible changes in regulations and the respective institutional setting.

In Figure 4.2-13, the proposals are ranked according to their degree of effectiveness assessed by the companies surveyed. Most effective according to the companies are measures which simplify the regulatory framework by:

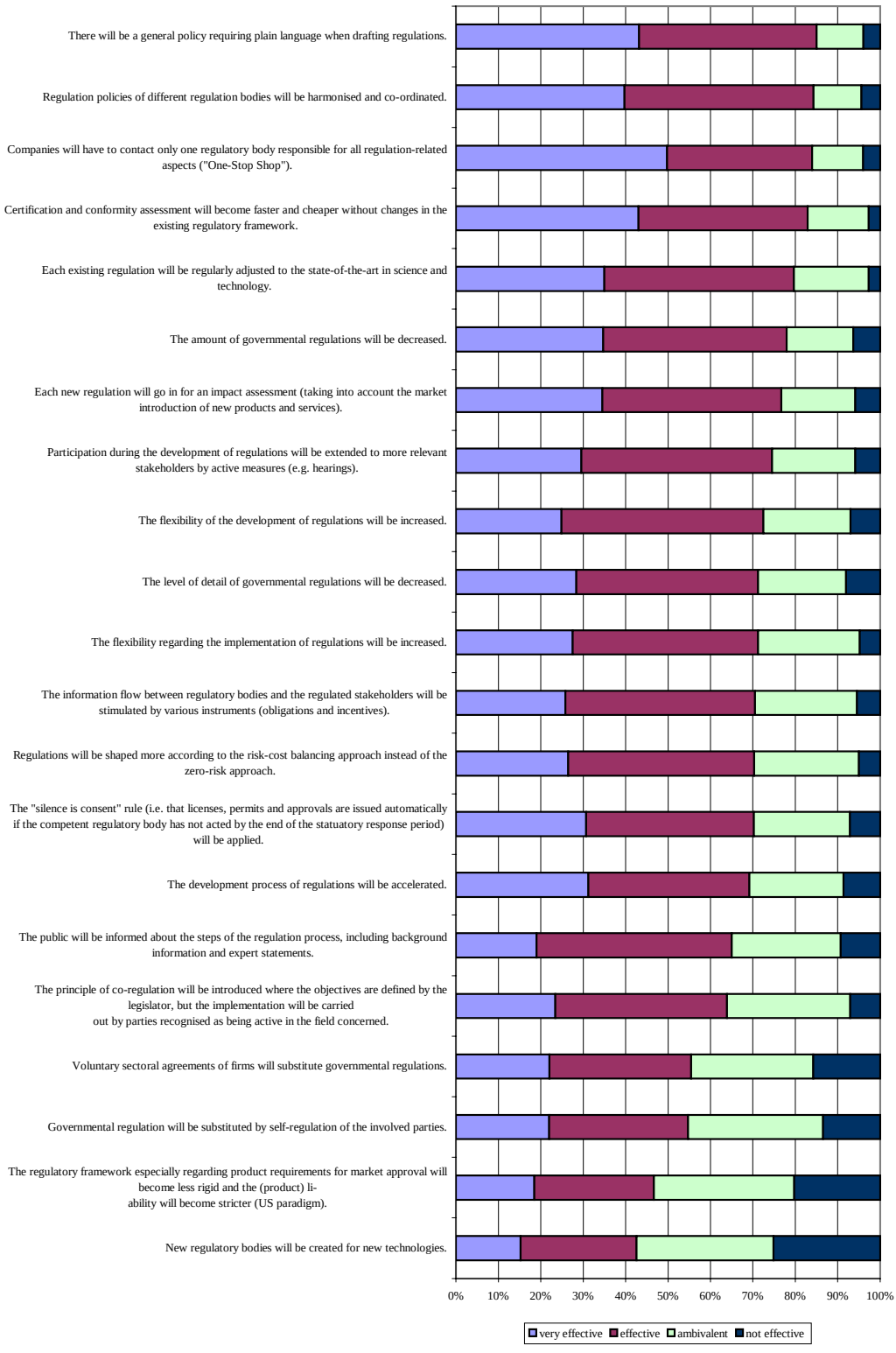
- requiring plain language when drafting regulations
- harmonising and co-ordinating the regulatory policies of different regulation bodies
- installing "One-Stop Shops" responsible for all regulation-related aspects
- accelerating and reducing costs of certification and conformity assessments
- decreasing the amount of governmental regulations.

Regarding the content of regulations, two approaches are evaluated to be effective. First, each existing regulation should be regularly adjusted to the state-of-the-art in science and technology. This measure responds directly to the assessment that regulations do not keep track of the development of technologies. In addition, each new regulation has to undergo an impact assessment, which also takes into account the market introduction of new products and services.

The development of regulation itself can be improved by extending the participation to more relevant stakeholders by active measures, like hearings, and by making it more flexible. Whereas this solution finds a broad support among the companies in the transport and telecommunication sector, a significant share of companies in the food sector is not convinced. Furthermore, the improvement of the information flow between regulatory bodies and the regulated stakeholders is evaluated as effective by the majority of the companies.

Coming to the ambivalent measures, we find that the majority of companies are not convinced that the creation of regulatory bodies for new technologies is effective and efficient for the promotion of new goods and services. Also, there is significant disagreement on whether the US paradigm of a less rigid regulatory framework, especially regarding product requirements and stronger product liabilities, should be adopted in Europe. Finally, it has to be noted that there is a significant share of

Figure 4.2-13: Assessment of the future regulation system (shares of companies assessing the measure as effective or not effective in %)



Source: own calculations.

companies which are not convinced that a substitution process which reduces governmental regulations either by self-regulation or co-regulation of the involved parties or by voluntary sectoral agreements is helpful. This ambivalence has to be taken into account when presenting and analysing the views of other stakeholders based on the sectoral level.

4.2.8 General Framework Conditions for Introducing New Products and Services World-wide

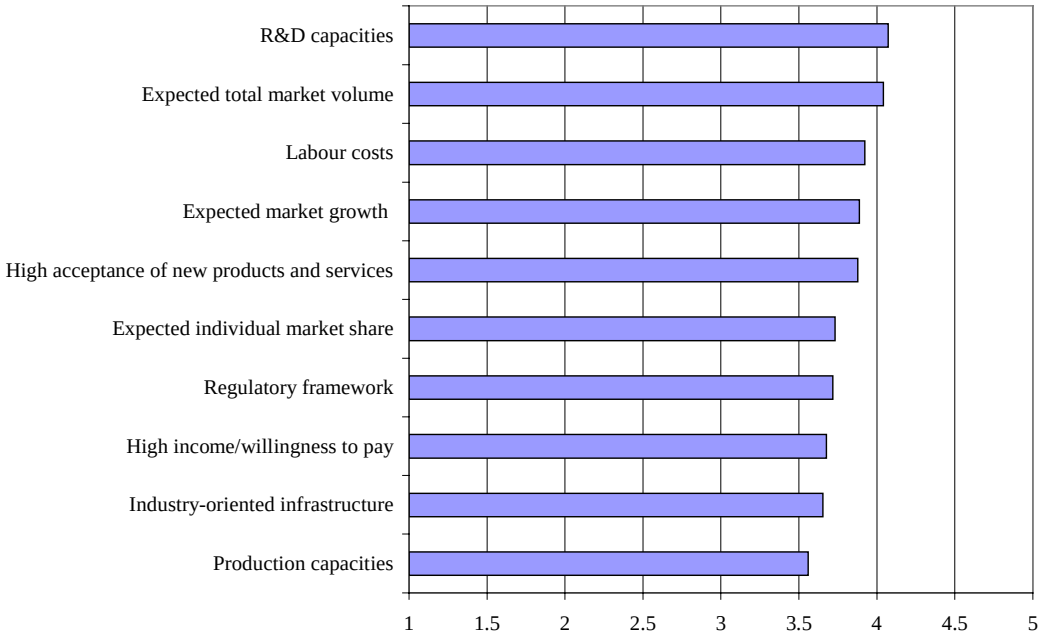
There is an increasing awareness that governments intensify their competition by trying to offer attractive packages of services and other framework conditions to attract physical capital, respectively companies, but also qualified labour. In the context of this study, regulatory framework conditions for the development and introduction of new products and services are important, both for the location of R&D centres and the initial introduction of products and services world-wide. This leads us to the concept of lead markets (Beise 2001). Lead markets are defined as national markets which have the characteristics that new products or services, which are designed to fit local demand preferences and local framework conditions, can subsequently be introduced successfully in other countries and regions. This aspect increases the importance of regulatory frameworks conducive to innovation, since the positive impacts of the domestic development and market introduction of new products and services are leveraged by the prospect of exporting these innovations world-wide.

First, we asked the companies about the importance of various conditions for the initial introduction of new products and services world-wide. One can divide the features characterising lead markets into peculiarities of the demand and of the supply side. For the supply side, R&D and production capacities, but also labour costs, industry-oriented infrastructures and last but not least, the regulatory framework are crucial for developing and introducing new products and services into the market. New products and services will be more successful if the demand side is both furnished with income and a high acceptance for new products and services, since these features attract companies providing new products and services.

Figure 4.2-14 ranks the importance of these various features of lead markets from the perspective of companies. At the top of the list, we find the existing R&D capacities and the expected total market volume. Then, labour costs, the expected market growth and the acceptance of new products and services by the consumers. Then the expected individual market share follows in the ranking before the regulatory framework and high income, respectively willingness to pay. At the bottom of the ranking are two further supply-side features, the production capacities and industry-oriented infrastructures. A brief evaluation of this picture of features relevant for the existence of lead markets should mention the above-average importance

of all factors and the medium relevance of the regulatory framework, whose importance is confirmed by the crucial role of consumer acceptance, which is in turn positively influenced by the regulatory framework (see Figure 4.2-8).

Figure 4.2-14: Importance of framework conditions for the initial introduction of new products and services world-wide
(1 = very low importance to 5 = very high importance)



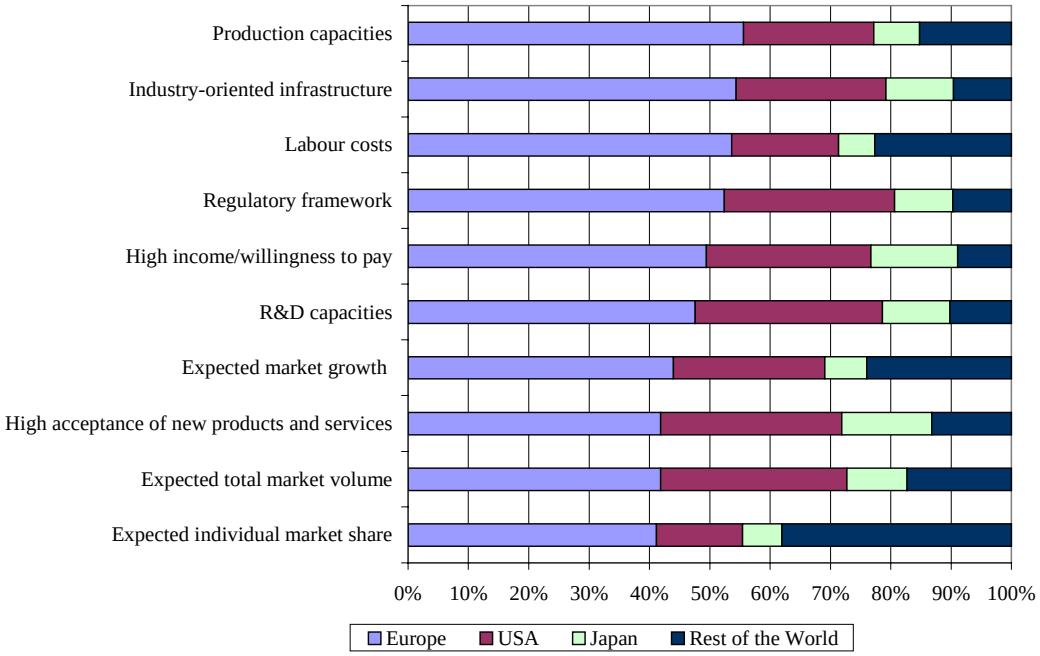
Source: own calculations.

In a second step, it is of interest what countries and regions are most favourable for the introduction of new products and services. Therefore we asked the companies to assess in which countries or regions the framework conditions relevant for lead markets are most attractive for the initial introduction of new products and services world-wide. Figure 4.2-15 ranks the different features of lead markets according to the selection of Europe as the most attractive location, which is caused by the strong European bias of the whole sample.

In general, the European companies prefer Europe as the region most attractive for the initial introduction of new products and services, because Europe is their home-base and most familiar to them. However, in relation to Figure 4.2-10, we observe a slightly reversed order, because Europe is most attractive due to its production capacities and its industry-oriented infrastructure, but much less interesting with respect to acceptance of new products and services by the consumers. This ambivalence represents a challenge for policy-makers. Regarding the role of the regulatory framework, we observe still a high degree of satisfaction among the responding

companies. Although the regulatory framework of the United States is most attractive for more than a quarter of the companies at least, which indicates to a certain degree the disadvantage of Europe with respect to regulations relevant for the development and market introduction of new products and services. Japan reaches only significant votes with respect to the two dimensions high income and a high acceptance of new products and services. Finally, the rest of the world is most attractive because of the low labour costs, the expectation of high market growth and individual market shares, which are difficult to realise in the more mature markets in Europe and the United States.

Figure 4.2-15: Countries or regions with the most attractive framework conditions for the initial introduction of new products and services world-wide (multiple answers possible) (shares in %)



Source: own calculations.

4.3 Empirical Results of the Survey Among Research Institutes

Regulations shaping new markets have the highest relevance for companies trying to introduce new products and services into the markets. However, very often significant efforts in research and development have to be undertaken in order to be able to produce a new innovative product or to provide a new service. If companies perform R&D intramurally, the survey among companies would be sufficient.

However, we experience a significant increase of outsourcing of R&D activities to private and public research institutes, because of an increasing complexity of research and development, which cannot be tackled just by the internal R&D department, because of securing flexibility and due to cost considerations. In Germany, R&D services generated a total turnover of €6 billion. Therefore, it is also important to collect the views and opinions of research institutes about the relationship between regulation and innovation, especially R&D.

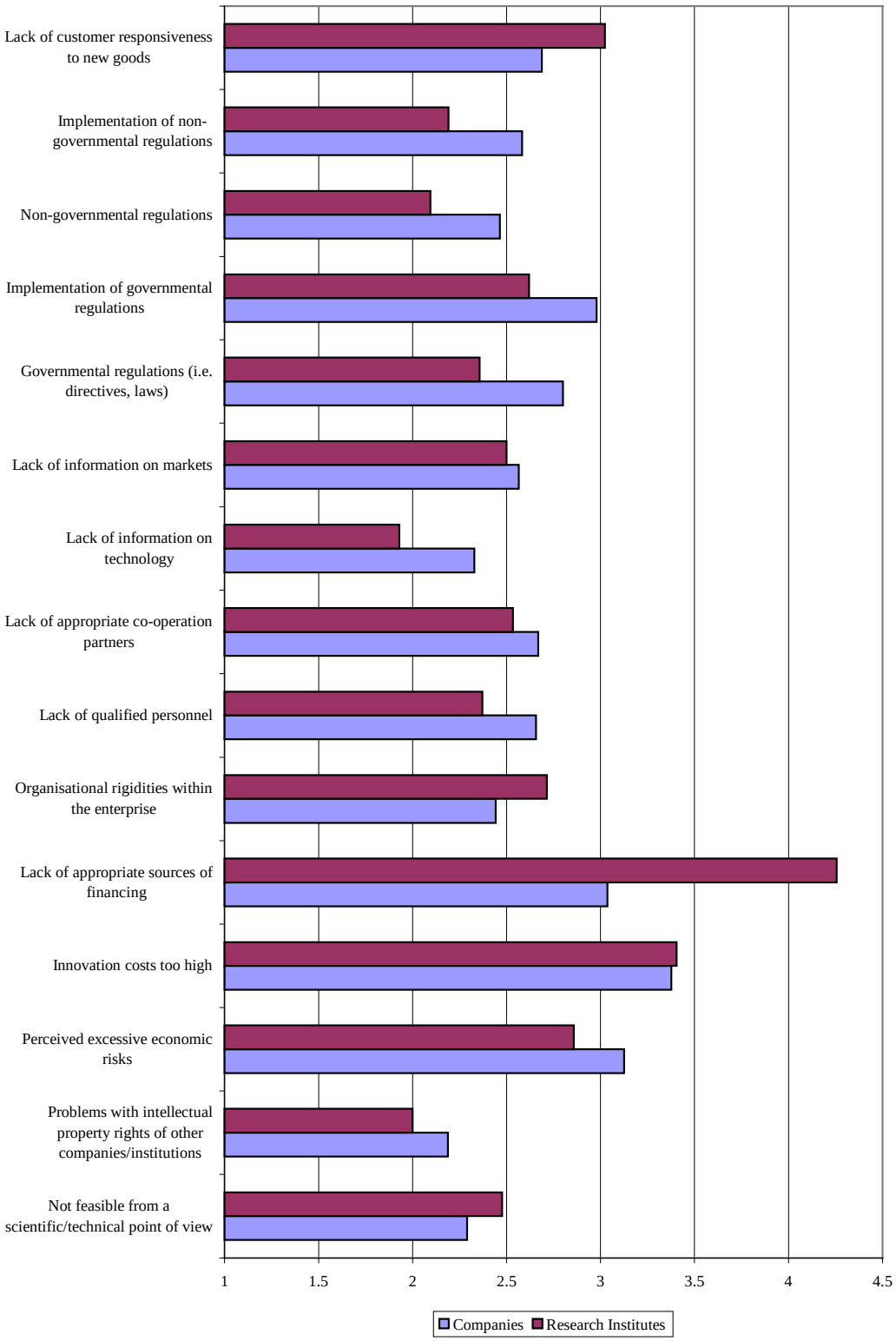
4.3.1 The Methodology and Main Characteristics of the Sample

We started to identify research institutes in the respective fields of the six company sectors by using information of the commercial database EUROMECUM, but also of the CORDIS database of participants of the 4th and 5th Framework Programmes. Research institutes active fields with relevance for the six industry sectors were approached. They answered a questionnaire exclusively addressing issues relevant for research institutes. We have collected the answers of more than 40 institutions in order to have a rough qualitative indication of major trends. Nevertheless, the number of observations allows us to present a picture of their experiences and opinions. Where appropriate, we compare their answers with the answers of the companies in order to point out first differences and similarities.

4.3.2 Factors Hampering R&D

As with innovation activities, the R&D activities can be hampered by various factors, which might prevent R&D projects to start, slow down or stop projects in progress, or even prevent planning of projects. Figure 4.3-1 presents the assessment of the importance of various factors hampering R&D activities by research institutes in the order of the evaluation by the companies. The top reason, the lack of adequate financial resources, is even more important for the research institutes than for companies. High innovation respectively R&D costs have the same relevance for companies and research institutes. It is surprising, but explainable by the strong representation of institutes active in biotechnology, that the lack of customer responsiveness to new products and services is more important for the research institutes than for the companies. Reason number four and of similar importance as for the companies is a perceived excessive economic risk.

Figure 4.3-1: Factors hampering R&D in research institutes and innovation in companies (1 = very low importance to 5 = very high importance)



Source: own calculations.

Focusing on the different aspects of regulations, we find in general the same pattern as for companies, but all these regulation-related aspects are less important for the research institutes, which confirms that their R&D activities are less regulated and that they are less affected by market-related regulations. Nevertheless, it is important to highlight that the implementation of both governmental and non-governmental regulations is more a problem than the regulations themselves. Furthermore, non-governmental regulations are of low importance and therefore significantly less important than governmental regulations.

Although the importance of the different types of regulations are less important for research institutes than for companies, their assessment confirms impressively the order of importance of various factors hampering innovation given by the companies.

4.3.3 Impact of Regulations on R&D and Innovation

As we have seen in Section 4.3.2, regulations have only a rather small importance as a hampering factor for R&D activities. In addition, regulation may also have a positive influence on innovation activities by forcing research institutes to search for new solutions, which may lead to innovations. In a second section we asked the research institutes to assess whether regulations are more likely to have positive or negative impacts on a range of specific R&D- and innovation-related aspects.

We have again included the answers of the companies to similar categories[13] for comparison. The most general result is that the research institutes perceive the impacts of regulation on a set of R&D-related assets as more positive and their negative impact on another set of R&D-related factors as less negative than the companies. The most positive impact dimensions of regulation for research institutes are those on the environmental quality, the health and safety of the consumers and of the work force. Only regarding R&D and labour costs does regulation have a negative impact. Besides these differences in scale on the one hand, there are on the other hand only a few impact dimensions, like on material and energy costs and on R&D risks, which the research institutes assess completely differently from the companies.

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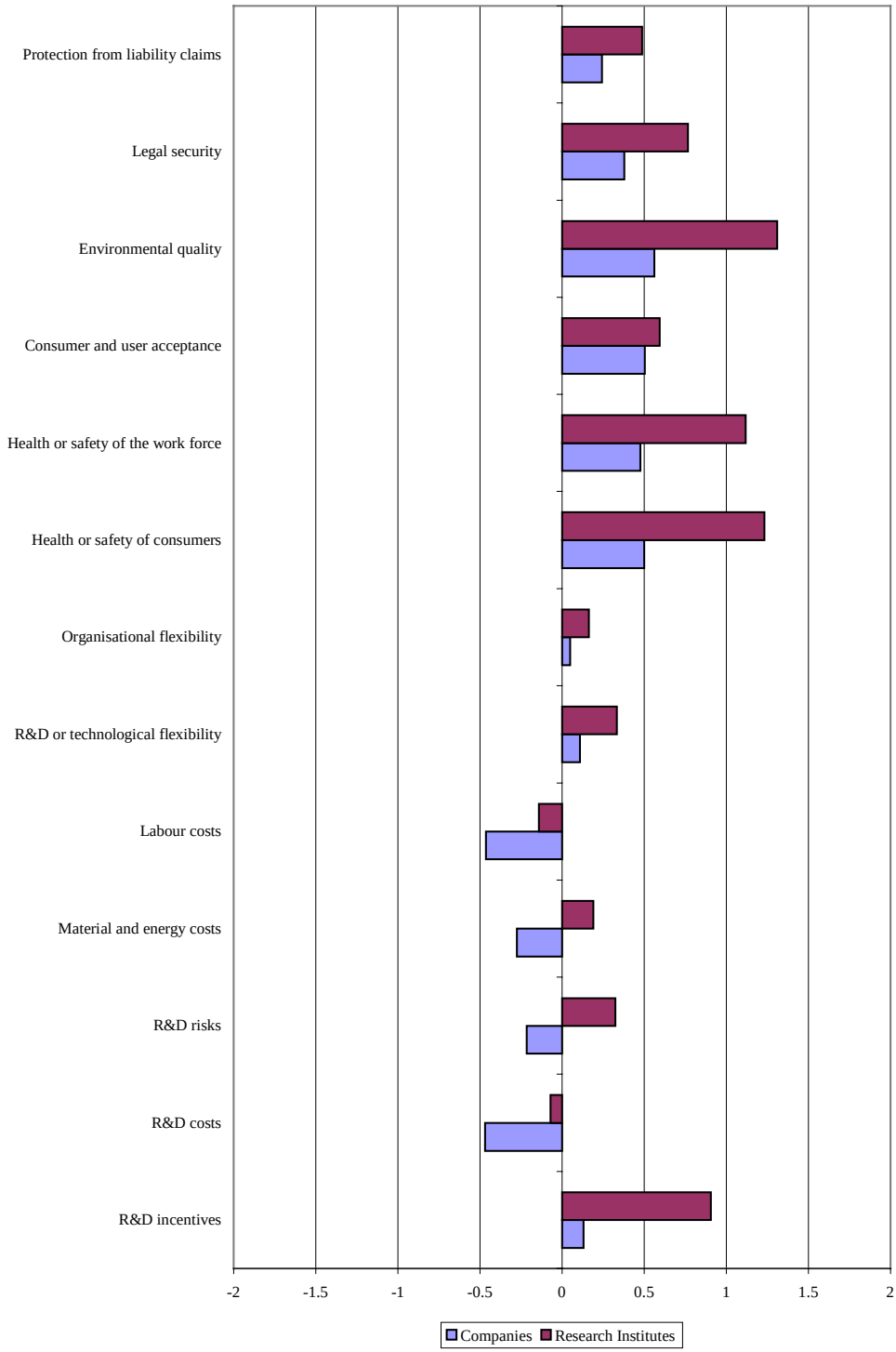
13 The categories for the companies address aspects covering both the research and development and the market introduction of new products and services, whereas for the research institutes only research and development in the narrower sense are relevant.

Figure 4.3-2: Impacts of the regulatory framework relevant for R&D in research institutes and the introduction of new products and services (-1 = negative impact to +1 = positive impact)



Source: own calculations.

In contrast to the companies which assess the impact of regulations most positively on their legal security, the research institutes see the most positive impacts on the quality of the environment, the health and safety of consumers and the work force. However, research institutes evaluate the impact on their legal security and the protection from liability claims more positively than the companies, the same is true for consumer and user acceptance. In contrast to the companies, research institutes still perceive a positive impact on R&D incentives and flexibility through regulations. Regulations even increase their organisational flexibility. Among the R&D-related aspects negatively affected by regulations, the research institutes attribute a negative impact only to the labour costs. All other aspects, like R&D risks and costs, are ambivalently affected by regulations.

What is the explanation for this more positive and less negative assessment of the regulatory framework on R&D by the research institutes? The assessed very positive impacts on environmental quality and health and safety aspects can be accounted for by the greater knowledge of the respondents about the scientific and technical details regarding the impacts of regulations due to their scientific and technical background. This agrees with the positive impacts they contribute to R&D incentives, since they might have a deeper understanding and interest in finding technical solutions complying with new and more challenging regulations. One demand factor for their business is a stronger regulatory framework in the sense of higher environmental, health and safety requirements, which can often only be fulfilled by developing new technologies and products.

Besides the more positive assessment of certain aspects, the research institutes feel only hampered by the fact that regulations increase their labour costs. Since all other input factors are of little importance for research institutes, the impact of regulation on these input factors is consequently also negligible.

4.3.4 Assessment of the Current Regulatory Framework

In addition to the opinions on whether different R&D-related aspects are positively or negatively affected by regulations, we have differentiated the complex issue of regulation into institutional aspects, questions regarding their implementation and the achievement of their objectives. The assessment of these statements will provide us with more specific information as to where and how to improve the regulatory framework fostering R&D and its efficiency. This supports the basis of evidence for formulating policy considerations addressing the activities of research institutes.

As in the case of companies, the agreement or disagreement with these statements are very consistent with the answers to the previous questions. The statement that specific types of regulations create opportunities to perform R&D in new fields in science and technology achieves the highest agreement of 75 %. This result sup-

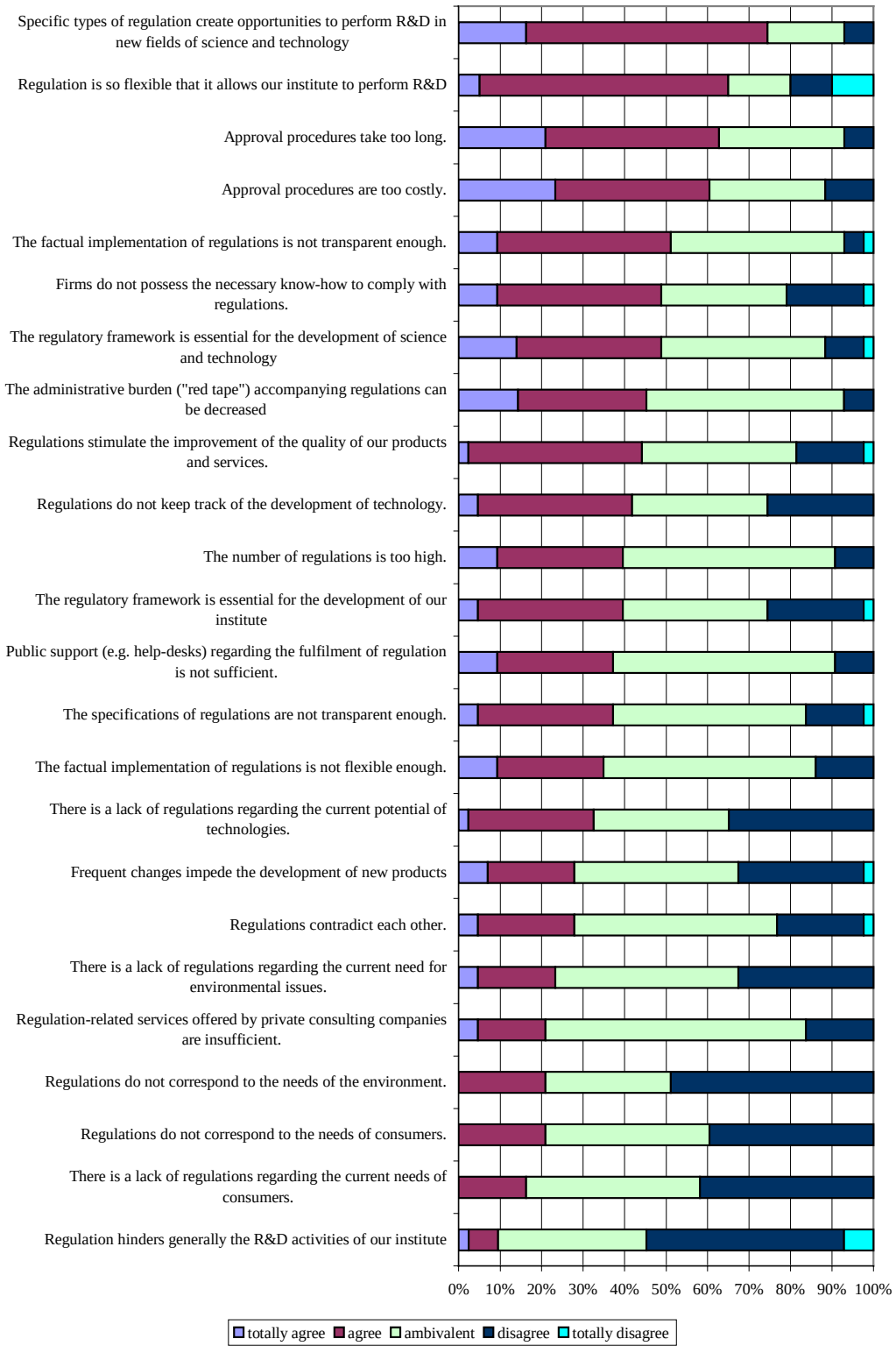
ports the interpretation made in Section 4.3.3 explaining the relative positive assessment of impact dimensions of regulations by research institutes. The share of companies agreeing to the similar company-specific statement is below 60 %. Complementary to the agreement to this statement is the strong confirmation that the regulation is flexible enough to allow the research institutes to perform their R&D.

In the same line with the companies, but not so strong, is the agreement among the research institutes that approval procedures are too costly and take too long. In contrast to the ambivalent assessment of the companies, for the majority of the research institutes the regulatory framework is essential for the development of science and technology in their area. However, there is also a majority of research institutes which feel they do not have enough know-how to comply with regulations and that the factual implementation of regulations is not transparent enough.

Parallel to the assessment of the companies, the statement that regulation hinders the R&D activities reaches the lowest agreement and the most disagreement. Surprisingly, the research institutes disagree also with the statements that regulations do not correspond with the needs of the environment and the customers. This confirms the rather large congruence of the assessments of the research institutes and the companies.

However, in general the companies are more critical regarding the current regulatory system and perceive that there are too many regulations, whereas the regulatory framework creates opportunities for research institutes to perform R&D in new fields of science and technology and is therefore essential for the development of science and technology. This reasoning is in line with the results of Section 4.3.2 and 4.3.3 above.

Figure 4.3-3: Assessment of the current regulatory framework (share of research institutes agreeing and disagreeing in %)



Source: own calculations.

4.3.5 Future of the Regulation System

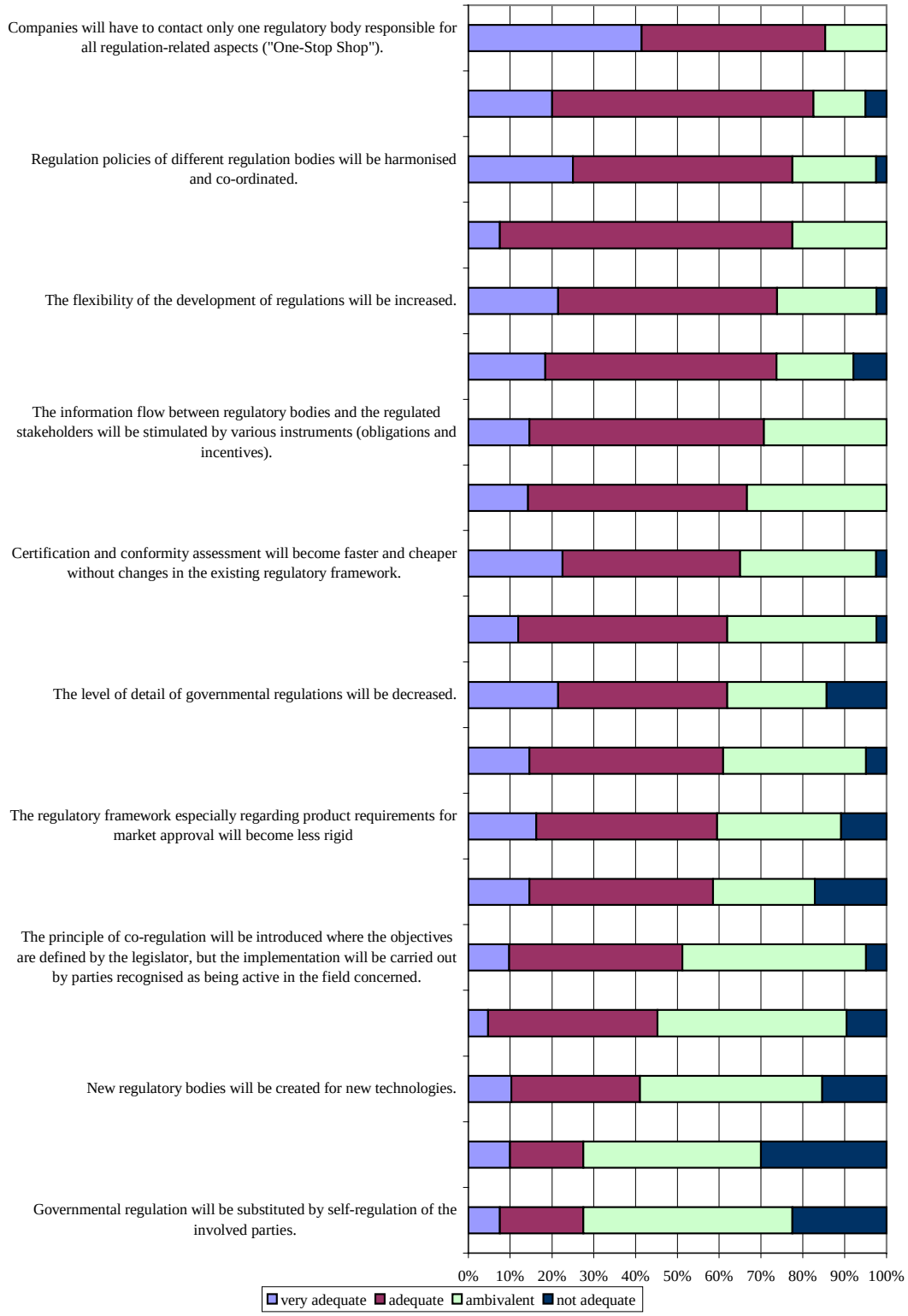
As in the case of the companies, the research institutes perceive some shortcomings in the regulatory framework, especially regarding its impact on R&D. Several approaches are already being currently discussed or have even been already introduced in order to improve the present regulatory framework. We asked which approaches are suitable to make the regulatory framework more conducive to the research and development of new products and services as far as research institutes are concerned. The assessment of these proposals by the research companies provide additional grounds for development of possible changes in regulations and the respective institutional setting.

Both research institutes and companies have a high preference for the introduction of "One-Stop Shops", which requires to contact only one regulatory body responsible for regulation-related aspects As the second most effective measure to improve the regulatory system it was assessed that each regulation will be regularly adjusted to the state-of-the-art in science and technology. This top position is similar to the high ranking by the companies. Furthermore, the research institutes are almost to the same degree as the companies in favour of harmonising the policies of different regulation bodies. However, it is slightly more important, because company activities cut across the requirements of more than one and often several regulatory bodies. The same similar positive assessment is given for the introduction of impact assessments for each new regulation, which takes also into account its influence on the introduction of new products and services.

In contrast to the companies, the research institutes evaluate an increased flexibility of the development of regulations and an impact assessment as more effective than companies do. A further, very interesting difference between companies and research institutes is that the latter group estimate a change towards the risk-cost balancing approach, away from the zero risk approach, as more effective than the companies. This difference might be explained by the fact that companies are more reluctant to undertake risks related to new products and services than research institutes.

Very impressive is the broad agreement among the research institutes and the companies about the least effective measures, like self-regulation in general or voluntary sectoral agreements instead of governmental regulations, but also the creation of new regulatory bodies for new technologies. Finally, a strengthened role of the public also does not convince either the companies or the research institutes.

Figure 4.3-4: Assessment of the future regulation system (shares of research institutes assessing the measure as effective or not effective in %)



Source: own calculations.

4.4 Views of other Stakeholders

4.4.1 Introduction

In the previous sections, we have presented the views and opinions of companies and research institutes regarding the role of regulation for innovation and the assessments of the current and possible future regulatory systems relevant for shaping new markets. Besides these two groups, several other stakeholders, like consumers, unions and environmental groups, are involved both in the regulatory process and targets of the regulatory framework. Since a systematic survey-based approach to collect the views and assessment of these groups is not very promising, we approached via telephone or personal interviews the representatives of important organisations in the six sectors selected for the company survey. Although we used a structural interview guideline, the information collected has a strong qualitative character which does not allow a quantitative analysis. Therefore, in the following sections we present the most important views of the selected stakeholders on regulation in general and the relationship between regulation and innovation. One has to highlight that these views presented in the following sections are not the views of the research team and are in general personal views which do not necessarily coincide with the opinion of the organisation they represent. In addition, the collection of views is not representative, not only because of the limited number of more than fifty interviews undertaken, but also due to a selection bias caused by the limited accessibility of some small organisations and the reluctance of other organisations to express their opinions. Some industry confederations represent different types of companies which do not agree on regulatory policies. Furthermore, in some sectors very large industry confederations dominate the regulatory policy, which leads to the fact that almost no other organisation has an independent opinion on regulatory issues. In very selected cases, we have also interviewed companies´ besides industry confederations in order to complete the companies views of the closed survey. Finally, some aspects in the interviews will be taken up again in the presentation of the case studies in the pharmaceutical, the food and environmental technologies sector. In addition to the six sector-related sections, we start with a general overview of the opinions of consumer representatives, because regulation is an important instrument to protect the interests of consumers, but also a strategy to increase the consumer acceptance for new products and services. In addition, consumers´ views are – if appropriate – also reported in the sectoral presentations. We close this chapter with a comparative summary of the views of companies, research institutes and other stakeholders on regulation and its relation to innovation, especially taking into account sectoral differences.

4.4.2 Views of Consumer Associations

Regulatory Issues

In the field of consumer protection, the issue of European-level regulation, standardisation and harmonisation is an important topic with European associations and national councils working in that field. According to the interviewees, the fact that consumer protection is an important issue that has to be considered within most regulatory activities which take place, is still not recognised adequately by all actors. Therefore, there is a need for more and comprehensive regulations, e.g. to assure high product safety and quality of products and services for consumers all over Europe. These European regulations are especially necessary because consumer protection needs to be established as an important objective in all EU countries alike. Already now, the awareness that consumer protection is an important topic increases in all European countries, especially against the background of child safety and product safety in general. Though the handling and level of consumer protection in EU countries still varies considerably, mainly due to different national traditions in that field. In Scandinavia, for example, consumer involvement and protection have a long and effective history. Therefore, consumers are involved and consumer concerns are taken into account within basically any public decision-making process. In contrast, in Southern Europe, overall consumer involvement is still rather low and consumer concerns are taken into account only to a small extent in decision-making processes. Finally, in the United States the involvement of consumers is rather difficult, due to the decentral structure of the US regulatory system.

Common Views and Conflicting Themes

Experts in the field of consumer protection recognise that considerable progress has already been made in enhancing consumer protection and consumer involvement in the European Union. But according to them, there is still much work to do to adequately involve and thus protect consumers. Especially the so called "New Approach" used widely within EU regulation is criticised and its application to new fields like environmental issues and services without thorough readjustment is objected to. Within the framework of the "New Approach", only general protection goals are defined by EU directives, all other specifications are set by means of co-regulation and self-regulation. This approach is criticised by the interviewees in consumer organisations because the process is mainly governed by industry lobbies. This being the case, consumer interests may be badly represented and the resulting regulations may thus have little effect regarding enhanced consumer protection. In contrast, according to the consumer representatives, formal, legally binding regulations better serve the public interest, because public authorities are the final regulatory authority and thus democratic control can better be ensured. Co-regulation

should only be used where it implies added value and serves the general interest. That also implies that a selection has to be made which regulations need to be handled in the political sphere and which ones can be left to the industrial sphere. In general, certain aspects of regulation can safely be dealt with by self- or co-regulation (e.g. regarding certain technical harmonisation measures), but certain regulatory competencies, e.g. regarding safety provisions for products, need to be relocated back into the political sphere in the near future.

Examples of consumer protection

Lighters

Serious safety deficiencies have been revealed in a test of disposable lighters carried out by the Austrian Consumer Council. Jet flames of a height of up to 30 cm, inadmissible flaring of the flame, formation of cracks during the drop test as well as gas loss and explosions during the temperature test have been observed. In addition, the ISO standard concerning safety of lighters, has provided evidence of clear shortcomings. The initiative of the Consumer Council in co-operation with other consumer organisations brought about a more stringent standard. Disposable gas lighters will have to be child-resistant in Europe in due course. After a long and difficult process the European standard was approved in April 2002. Actually it will enter into force after a transitional period of 3 years.

Noise limits for toys

Just one shot of a toy cap pistol can permanently damage hearing capacity. It has taken almost 10 years to set adequate limits for this type of noise within the European standardisation organisation CEN. The commercial interests of the relevant industry seem to have prevailed over the protection of the hearing capacities of children. The limit set by the responsible committee exceeded by far the admissible limit for a workplace in the EU. Warnings voiced by experts have been ignored. The national authorities of Germany and Austria had formally objected to the relevant clause of the toy standard following the so-called safeguard clause procedure. After a clear statement by the Commission which shared the strong concerns of consumer organisations, CEN´s toys committee eventually gave up its resistance in spring 2001.

Source: Interview with a representative of the Austrian Consumer Council

Impacts of Regulation on Innovation

Most consumer representatives recognise the high impact that regulation can have on innovation. On the one hand, they are aware that regulations have to be shaped so that they do not hinder innovation. But on the other hand, regulations have a considerable potential for innovation if they manage to move beyond pure self-regulation that only defines what is done by the industry anyway. If regulations are

set up in a way that demands certain efforts from industry to comply with them, there is potential for innovation and higher-quality products (e.g. in the fields of product safety, environmental protection, energy and research policy). Swedish industry for example is very competitive and innovative even if it is highly regulated. Companies need to comply with ample regulations (which also implies taking consumer issues into account) but if they do so, they can take advantage of the overall innovation-friendly business environment.

Possible Future Developments

According to the interviewees, much has been done to strengthen consumer policies on the European level during the last decades. But there is still need to set up additional binding regulations to further strengthen consumer protection and consumer involvement in the European Union. This can, in the view of consumer representatives, lead to innovation that in turn serves industry as well as consumer interest. The "New Approach" needs thus to be restricted to cases where it can reasonably be used. Instead, the consumer experts postulate that there need to be regulations which effectively establish adequate levels of safety, reliability of product information, interoperability and most importantly, accessibility for all consumers in all EU countries. This might lead to innovation especially in countries where consumer protection and involvement are rather low up till now. Furthermore, regulation and harmonisation of consumer policies needs to be done on a very high level (framework legislation) and all regulations need to be set up according to the current state-of-the-art in that field to be as effective as possible and to be able to safeguard consumers and their interests in the best possible way.

4.4.3 Views of Stakeholders in the Pharmaceutical Industry

Regulatory Issues

Innovation is an important topic for all stakeholders in the field of medicines. The most important aim of regulation from the consumers' and patients' view is the benefit of the patients. This is also a top level priority which is also accepted by the European Agency for the Evaluation of Medicinal Products (EMEA), not only within the aim of protection but also as a means for the promotion of public and individual health. A general interest of the European Society for Regulatory Affairs (ESRA) is that the system should be predictable for the applicants of a marketing authorisation.

It is controversially discussed what constitutes a real innovation as opposed to only marginally different products. According to the World Health Organisation (WHO),

an innovation has to show its advantages under day-to-day conditions in the market. From the regulatory standpoint, besides products new technologies can be innovative because they make new guidelines for their evaluation necessary.

Relevant issues for pharmaceutical innovation are – for the industry – the regulation of clinical research, marketing authorisation, pharmacovigilance and the marketing itself, including aspects of pricing, prescription and reimbursement, as well as environmental aspects. The representative of WHO agrees with the importance of the market and adds the funding of research as well as the protection of intellectual property rights (IPRs). Market factors are also stressed by the consumers and patients, who also have a special stake in questions of patient information on new products. Access to and safety of innovative medicines are stressed.

In the view of the industry, the regulation of the health systems including the pharmaceutical market have a strong influence on innovation. The systems are perceived as rigid and sticking to conventional therapies which often are less useful than innovative ones. Incentives for innovation are missing. These interventions in the market – which change very frequently and make the markets unpredictable – reduce the volume of the market as well as the prices. This results in medicines which are no longer available in the smaller markets and even stops the development of new products. On the other side, the market for pharmaceutical products is fragmented also in the USA because the important health maintenance organisations (HMOs) have different reimbursement schemes.

In general, the pharmaceutical regulatory system is seen as good or excellent by the consumers. The industry disagrees to some extent, in general regulations are seen more as slowing down processes.

Common Views and Conflicting Themes

The regulation of marketing authorisation is very strong, in the view of the WHO, societies and therefore also the authorities get more and more risk-averse. Heightening safety standards increases development costs and hinders access to new treatments for those in need. It is questioned how far this development can go without hampering a sustainable provision of drugs.

In Europe, the usefulness of the national marketing authorisation as opposed to the central marketing authorisation which is granted by the EMEA is being discussed. As the rules are broadly harmonised, the remaining differences are for example the duration of the approval process. The central procedure leads to a community-wide marketing authorisation, it takes 210 days (plus "clock-stops"). In the national authorisation with following mutual recognition procedure, 90 days have to be added to this. Despite their common wish to harmonise EU procedures, nearly all interviewees argued in favour of keeping both ways. The competition amongst na-

tional authorities increases the orientation of these authorities towards their clients and therefore supports the development of the authorisation procedures. ESRA stresses the positive aspects of the division of work between the different national authorities which have individual fields of special expertise. In some cases the marketing of a product is only intended in a few Member States. The opportunity for national authorisation including the mutual recognition procedure is seen as especially relevant for smaller companies as it is cheaper and easier to implement and more sensitive for different traditions. Even the centralised procedure is influenced by national interests to some extent via the national representatives in the Committee for Proprietary Medicinal Products (CPMP). Although the guidelines are similar in the Member States, national differences emerge from the application of these rules by different persons inside the authorities.

Related to marketing authorisation is the question of including pharmacoeconomic data as a "fourth hurdle". Although these data are not easy to obtain, value-for-money questions become inevitable in the view of WHO, whereas the industry is concerned about fair comparisons of cost-effectiveness ratios. In this respect (and in many others), the patients' and industry's interests meet as both consider new medicines as sometimes more costly but also as a chance to save money for less effective treatments.

WHO sees a trend to a stronger protection of IPRs as response to demands from the researching industry, but states that too a long protection is a barrier to innovation. According to WHO, no data show that more protection results in more innovation. This view is shared in part by the consumer organisation, who see generics as generally safer than new medicines and as cheaper for the consumers.

WHO sees therapeutic gaps in several fields, e.g. tropical diseases, for which special incentives in the market should be provided to make the development of new medicines more attractive. Instead, the consumers notice a concentration of the industry on "life-style drugs" and they also demand public support to foster innovation in those fields that are most important for public health.

Besides regulation, other factors which hamper innovation as perceived by the industry are

- an industry-adverse public climate, e.g. related to the necessary profit-orientation of the industry,
- low prestige of research in the EU, especially of research carried out by the industry,
- insufficient integration of new areas of research like bioinformatics and interdisciplinary work.

With respect to the competitiveness of the EU regulatory framework, according to the German regulatory authority, the framework conditions for innovation in the EU

are not worse than in other regions of the world. The consumers demand support for new medicines but argue for a strong regulation. In general, they see advantages of the European regulatory system as compared to the US system, which they say provides less benefits for the patients most in need whereas the industry considers the more liberal US system (e.g. related to prizes) to be more innovation-friendly.

The US Food and Drug Administration FDA has good means to support new medicines, and supports the developers throughout the whole developmental process. Although Europe has made significant advances in the field of scientific advice, this is not intended here to the extent that it is in the USA. In the USA, the necessary advice for the companies by the regulatory bodies is free of charge, whereas the latter bear a significant share of the regulatory costs by their proactive and preparatory work. Although the US FDA does not always have access to the best expertise, the FDA provides better advice to applicants. On the other hand, the European system with strong involvement of external experts is also seen as positive because very often the best experts for a specific field are only available in companies. The independence of industry experts is a bit questioned by the European Federation of Pharmaceutical Industries and Associations (EFPIA), because the external experts asked for advice receive the drug dossier which raises concerns about confidentiality of the included information.

Public research funding is a second difference, with the US National Institutes for Health spending much more money than the European administrations. Since the NIH are closer to the FDA, it is easier for the industry to get support in research issues. In addition, the EU system of research is more fragmented than the US research funding. For the patients, a stronger dialogue would help to redirect scientific research to the real needs of the society.

Clinical research is hampered by the fact that applications for trials have to be made in every Member State where patients shall be recruited. This is very demanding in time and rises the costs for trials. In the USA, with one trial authorisation the trial has potential access to 262 million people. In addition, clinical research in Europe is becoming more and more bureaucratic in the view of the industry so that even SMEs locate their trials to the USA.

Impacts of Regulation on Innovation

The field of pharmaceuticals is highly regulated, regulation is broadly harmonised between the EU Member states, the EU central authorisation procedure and even between the EU and the USA and Japan. Therefore, pure regulation does not make a large difference in differential development of new markets.

As mentioned above, besides regulation, other factors are important for innovation, e.g. the price for medicinal products which can be obtained on the market. The heterogeneous European market with different local languages makes the introduction of new products expensive. Differences between countries and regions exist in the practical application of the rules for marketing authorisation which have an impact, for example, on the decision of a company where to apply for an authorisation.

In the view of the German Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) as well as of the industry, the question where to locate their research is answered by the industry mostly on the basis of economic considerations, not on regulatory ones. It does not depend on the conditions for marketing approval, but rather on the conditions of the market itself, e.g. if national products are preferred in price negotiations, and the relevant aspects of national health policies.

An interesting perspective which stresses the tight relationship of regulation and innovation in this sector is the necessity to continuously adopt regulation to fast emerging new technologies like gene therapy or tissue engineering. This is supported by permanent working on guidelines and strong scientific input into regulation.

Possible Future Developments

Regulation is in general sufficient in the view of the German BfArM, but is also necessary because the most important issues have to be regulated by public authorities. A replacement of obligatory regulation by self-regulation would not be supported by the official regulatory bodies nor by the consumers who claim that medicines are not an ordinary product and therefore the market can never be accessible without authorisation. The consumers plead for a strict and harmonised regulation and good information for the citizens. On the other side, the industry advocates a more flexible implementation and self-control by the industry itself in some fields. An active strategy of regulation is advocated, including support for national and European production sites in the context of the EU enlargement.

Processes in the EU are still quite time-consuming because still many different national interests exist. The different cultures should be taken into account in the development of regulation, for example by more flexible implementation rules. The industry supports a stronger orientation of policy-making at the needs of the companies. Best use should be made of particular expertise in persons or countries as leaders of a development. In addition, the industry pleads for a reduction of over-regulation and generally more stability in regulation and more homogeneity throughout Europe. The industry would like to be accepted as a partner and not as a profiteer. The establishment of public trust could be supported by public debates on the role of the pharmaceutical industry for the public. Furthermore, the public as well as the prescribers (physicians) could be more strongly involved in the genera-

tion of regulation. Well organised patient organisations are ready to support the regulatory bodies in optimising the system with respect to the benefit of the societies. However, sometimes they feel that the usefulness of stronger patient involvement is not appreciated enough.

4.4.4 Views of Stakeholders in the Food Industry

Regulatory Issues

Generally, the food sector is highly regulated because of its relevance for human health, like the pharmaceutical sector. Regulations, for example, reach from plant breeding, product standards, trade with new varieties, treatment of animal diseases to packaging for food products.

The issue of innovation is becoming very relevant for the food industry, new or modified products are important means for marketing. Important aims of the industry are to allow the development and bringing onto the market of new products by a supportive regulatory framework. In this respect, from the industry's view, a positive example for regulation is the EU directive on ecological farming because quick harmonisation was achieved for a growing market. Regulatory uncertainties still persist, e.g. related to the co-existence of GM and traditional crops. Ecologists agree with the supportive aspect of regulation but would stress the need for ecologically sustainable innovations on the market. Measures could be a more sustainable tax system, tackling the extensive subsidy system in agriculture or a stronger application of the precautionary principle in regulation. The consumers are especially concerned by innovations in the field of novel and functional foods, aspects to be considered are health claims or labelling of the products.

Generally, especially for the farmers, innovations have to be economically advantageous to have a chance on the market. However, a specific feature of the agricultural sector is the relatively conservative attitudes of the farmers which prolong the time new products or methods need to come into place.
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Themes of special interest for the interviewees related to the impact of regulation on the shaping of new markets in the food sector are the application of new methods of biotechnology, claims and labelling, health and safety, product liability, and the protection of intellectual property rights (IPR).

Common Views and Conflicting Themes

The safety of products is a common concern of the industry and the consumers. Generally, the industry notices a tendency to create even tighter regulation for foods and to restrict the trade and market introduction especially of innovative foods. In the industry's view, consumer information and labelling are already over-regulated, foods are nearly treated as dangerous goods. But also among companies, the interests are heterogeneous. Large multinationals want to defend the return on their large investments whereas smaller firms prefer less restrictive regulations. Divergent opinions also exist concerning the hurdles for effectiveness studies and market approval of functional foods. Concerning the amount and strength of regulation, the consumer and ecological organisations tend to a more rigid approach than the industry. For the producers, economic aspects are in the foreground, whereas the consumers stress the safety of innovative products and processes.

This general difference becomes very obvious in the example of the use of genetically modified organisms (GMOs) in food production. The application of biotechnology in the food industry is one example where regulation greatly impacts on the generation of new markets. The food and seed industry welcomes the seed marketing directives, which allow to make better use of innovative potentials and are a good compromise between the industry's and the consumers' interests. However, regulatory uncertainties still persist. In addition, the use of these technologies is especially risky for SMEs due to missing risk diversification because the reaction of the market is not predictable. The agricultural associations have also to consider the interests of organic farmers who object to agrobiotech. The coexistence of genetically modified (GM) and traditional crops is also a concern to ecologists.

In the field of functional food, a major issue is the opportunity to market products with specific claims related to the effects of the food ingredients. The industry does not accept that "objectively" true claims cannot be made. Here the industry would plead for a liberalisation and a simple notification procedure. Although claims should only be allowed on the basis of scientific results, too high hurdles would impede the bringing-on-the-market of innovative products.

The labelling of food products is also an important issue for the ecologists, who join the consumer organisations in stressing health and safety aspects of new food products, as well as product liability. The latter is also important for the industry, as a clear legal framework is important for the companies to receive sufficient insurance and the necessary producer liability.

Different opinions exist concerning the competitiveness of the EU regulatory framework. In the view of the producers, the regulatory framework in the USA is more liberal than in the EU, which is counterbalanced in the USA by very strict liability laws. The different regulatory framework conditions in the Member States make processes of balancing consumers and industry difficult and time-consuming,

whereas in the USA regulation is based more on scientific evidence and less influenced by political institutions, which makes decisions faster and less complicated. From the consumers´ point of view, the EU system for regulation and marketing authorisation of GMOs is better than in the USA, where many products only need a notification and the safety of GM plants is less strictly controlled by the US FDA than by the European authorities. However, the liability obligations in the USA are called in part excessive even by the consumers.

Impacts of Regulation on Innovation

Related to innovation processes, the food industry sees a larger inertia of the EU regulatory system regarding new scientific developments than in the USA. Especially harmful is a climate of legal insecurity, as can be found in the area of biotechnology. This generates problems for the return on R&D investment because regulatory gaps lead to uncertainties concerning the marketing of new products, especially GMOs. On the other hand, the opportunity to apply for national as well as EU-wide protection of IPRs, especially patents, is seen as an advantage. Finally, the industry also needs fast procedures for marketing approval of new products. Examples here are the marketing authorisation according to the Novel Food Regulation or guidelines for health or other claims which are useful for the industry to support their new products on the market.

Besides regulation, other factors may play an even more important role, for example, the framework conditions related to the relevant markets (e.g. availability of planting areas). And, as already mentioned, farmers tend to be more conservative than the average population and therefore stick more to traditional methods and products. More public support and research funding would help especially such innovations for which the market is not promising enough for the industry, e.g. because they might be especially relevant for developing countries and therefore at the moment do not receive enough attention.

Possible Future Developments

As especially relevant for the food sector, measures to improve regulation to enable and make best use of new products and processes include harmonisation and simplification of regulation, filling regulatory gaps, and the acceleration of regulatory procedures.

As many issues cannot be treated any more on the national level in an efficient way, the tendency is to more regulatory harmonisation. The industry pleads to keep practicability in mind and keep a sufficient degree of flexibility. However, from the viewpoint of consumers, flexibility should not lead to a minimal harmonisation. The Bureau Européen des Unions des Consommateurs (BEUC) is sceptical concerning the usefulness of non-binding guidelines and prefers legally binding regulations and

the strict implementation of these in the Member States. Harmonisation can partly come via the installation of the European Food Safety Authority (EFSA), which could for example check and approve health claims. With respect to the co-existence of GM and traditional crops, the general regulatory framework could be provided by the EU whereas the concrete implementation of liability rules should be matched to national and regional conditions.

Simplification of mechanisms for decision and approval is a priority for the industry to foster the development of the Single Market. However, at the moment the industry is not able to detect real simplifications in the regulatory system. Co-decision procedures are seen to be complicated and susceptible to influence from different groups. National interests and red tape persist and it stays important for the industry to inform about the negative economic impacts of regulations. Simplification could also lead to an acceleration of approval procedures which would help the industry by shortening the time to market of new products.

Contrary to the industry, for the consumers it is a priority to fill regulatory gaps. The BEUC still sees gaps in the regulation of food ingredients, e.g. recombinant enzymes or oil from GM plants. The acceleration of regulatory procedures would be useful in the view of the consumers, but should not restrict democratic participation as e.g. in the form of the comitology principle.[14] A faster transformation of existing directives into national law is also a demand of the industry.

Other measures to improve the regulation concerning new products could be a higher degree of transparency in the published information. The industry suggests a stronger political commitment to the use of GMOs in the agrifood sector, to keep the status quo of IPR protection, and increase research funding related to life sciences and biotechnology in order to keep researchers in the EU.

4.4.5 Views of Stakeholders in the Environmental Technologies

Regulatory Issues

European regulation in the environmental sector is fairly diverse, reflecting numerous relevant environmental fields, such as the use of renewable energy sources, water treatment, nature conservation, and many others. Nevertheless, all the interviewees stemming from research, policy, industry, and NGOs agreed about the major importance of European-level regulation in the environmental sector. Most of

[14] Comitology means the delegation of power to committees in the phase of implementation of EU legislation, it aims at allowing a Community-wide co-ordination of policies without pre-empting special national considerations.

them are contributing to regulatory activities in a more or less institutionalised form.

European environmental regulation generally provides a certain range for its implementation by the Member States, hence according to the interviewees regulation is significantly heterogeneous within the European Union in most of the relevant fields. Furthermore, the environmental regulatory system is considered to be very complex, partly due to an extensive balancing of interests, which implicates difficulties for the actors concerned. On the other hand, the opinion is expressed that the European system is more stable and reliable compared to environmental regulation abroad, e.g. in the USA.

Common Views and Conflicting Themes

In the field of renewable energies, industry and consumers alike assess the European regulatory system to be exemplary compared to most other national regulations world-wide. Yet they criticise that the regulatory framework set by the EU is not sufficiently demanding, permitting Member States to implement national regulations unfavourable for the renewable energy sector. In the field of water treatment, the perceived differences between the EU Member States are less important and seem to be declining.

Heterogeneous regulation within the EU is criticised by the interviewed environmentalists as well. In the field of agriculture this heterogeneity may raise problems for farmers affected by stricter national environmental regulation than their colleagues abroad, for instance in the Danish-German borderland. Moreover, it is criticised that European subsidies are used to some degree for purposes undermining nature protection, notably in the fields of agriculture and energy policy. In spite of a general accordance between representatives of NGOs and industry in the environmental sector in respect of the need for a regulatory system that is more demanding, this postulation is more strongly highlighted by the environmentalists.

Impacts of Regulation on Innovation

The overall assessment of environmental regulation in the EU and its potential to foster innovation is rather positive. For some fields, the European Commission’s proactiveness combined with an ambitious target-setting is emphasised. Furthermore, European networks for scientists are regarded to be an important factor in the concerning innovation system. Though one aspect of European environmental regulation is strongly criticised: very often, general targets are ambitious, but clear timeframes and thresholds are lacking, reducing pressure on the affected industry to be innovative.

The renewable energy sector is considered to be a prominent example for successful environmental regulation. According to industry representatives, Europe is leading in the global wind energy market whose strong growth rates are in turn crucial for innovation. This is mainly due to favourable regulatory conditions in some Member States who implemented feed-in systems for renewables, such as the German Renewable Energy Sources Act. However, the fact that some Member States set less favourable conditions for the development of renewable energy sources within the European regulatory framework is criticised, leading to less innovation in that field.

In addition to that, most of the interviewees mentioned difficult application procedures for European funding as an important factor hindering innovation, especially compared to the situation in the USA. According to them, SMEs that generally do not have experts for those procedures are particularly concerned, although they provide a major part of the industry's innovation. Also, a lack of communication between the concerned European institutions and SMEs is addressed, resulting in enterprises being insufficiently informed about support programmes. Interviewees from politics expressed concerns about the fragmentation of the European environmental innovation system, which is considered to be strong compared to the Japanese system, for example. Finally, voluntary agreements are assessed negatively by nearly all the interviewees. They would have the potential to foster innovation if they were strict enough, but according to the interviewees they are mostly not.

Possible Future Developments

Regulation is perceived as a major issue in the work of all the different actors interviewed in the environmental sector, and its significance for innovation is undisputed. In many fields the European regulatory system is performing well compared to the situation abroad. However, a couple of aspects are criticised by the interviewees: predominantly, regulation often lacks concrete, binding provisions. Generally, environmental regulation with clearly defined ambitious targets combined with economic instruments is favoured compared to a detailed administrative regulation. In addition to that, harmonisation of environmental regulation between the European Member States is desirable, according to the interviewees. The amount of European regulation is perceived as appropriate or should even be increased, for instance in taxation of environmentally harmful substances, but wherever possible, it should be made easier to handle. A decreasing level of detail could be useful for innovation, but only on condition that precise and binding provisions are made. Also, voluntary agreements should play a minor role, the interviewees say. Finally, a better communication of support activities to SMEs is desired, as well as a better impact assessment of existing regulations.

4.4.6 Views of Stakeholders in the Mechanical Engineering Industry

Regulatory Issues

In the view of the mechanical engineering industry, the marketing authorisation, as well as health and safety and environmental issues are the most important fields of regulation. Health and safety are especially difficult to manage for the mechanical engineering sector compared to other economic sectors because mechanical engineering and metal working have to use heavy machinery and often dangerous substances, and produces problematic by-products. It is to some extent a "dirty" industry which cannot be made totally clean and safe.

As a reaction to the severe changes which the sector underwent in recent years (e.g. the strong automation), a task force on innovation was introduced by the unions. The European trade unions have been working for long on the issue of innovation in their sector. Their main aim in this respect is the sustainability of the sector's development not only in an environmental, but also in a social and democratic way. This includes aspects of the organisation of the companies and the participation of the workers in strategic planning, an increase of public and enterprise investment in R&D, a sectoral social dialogue with the employers about the industry's goals (including the definition of the most important areas for research), and decisions at the company level.

The aims of standardisation are transparent, fair conditions for market entry of products. Many regulations and agreements impact on standardisation, e.g. the WTO agreements on technical barriers to trade. A discussion exists if standardisation supports or hinders innovation. If standards are too tight, e.g. if they not only describe the goals (e.g. threshold values) but also the technical solutions to obtain these goals, they might impede innovative solutions.

Common Views and Conflicting Themes

In the industry's view, there are not many regulations which help the companies to innovate because regulation is not primarily made for this aim. A problem for innovation in the EU is the subdivision of the national markets with heterogeneous implementation of EU regulation in national legislation. In addition, the European regulation is more far-reaching than regulation in the USA. This is also emphasised by the representative of the unions who nevertheless acknowledges that efforts are being made in the EU and Member States to minimise regulation.

Other factors related to the regional features mentioned by the industry are the generally low investment in innovation combined with a short-term view of banks and

investors, skill shortage and the overseas competition. Advantages of the USA, on the other hand, are the larger and homogeneous market and a more liberal legislation, which makes it easier to bring products onto the market. In addition, research in the USA is closer to the needs of the industry in the view of the trade unions. The common networks are stronger, more research is funded publicly, but without the huge amount of bureaucracy that is found in Europe. From the view of standardisation, the USA also have rigid standards, the EU has the better approach here and many standards are later adopted internationally.

In general, there are not many conflicting views of the different stakeholders in the mechanical engineering sector, because the public interest is not so significant compared to the pharmaceutical or the food sector and consequently the introduction of new products into the market has not to overcome high regulatory barriers.

Impacts of Regulation on Innovation

Compared to other factors as e.g. the market or trade-related issues, regulation is not seen as critical for innovation by the industry because it forms the framework to develop and market new products. However, in most cases regulation has a hindering effect on innovation in the view of the industry because it raises costs. At the moment the machinery directive is under revision. In the view of the industry, the present draft would do nothing to foster innovation. Instead, it would increase the production costs. The costs of regulation are especially problematic for SMEs which cannot pass their R&D costs on to their clients.

Besides regulation, other factors have a strong impact on innovation. The unions mention in this context a lack of skills, of knowledge base and of research in the companies. Contacts with research institutes are too rare for several reasons, e.g. being afraid of sharing knowledge and poor dissemination of research results.

Possible Future Developments

According to the industry's aims, regulation should be restricted to those areas where it is urgently needed. This view is supported by the trade unions' representative as well as from the point of standardisation. More appropriate use should be made of regulation in the way it is implemented. Standards are seen as more flexible than directives which should not include technical specifications. To improve innovation, more attention should be paid to standardisation also by the companies. Better use should be made of the already existing instruments and bodies.

Innovation should be made a priority in regulation. Most interviewees would reinforce the involvement of the stakeholders in the process of developing regulation. The main challenge in the view of the unions is a socially responsible change. The

success depends on new products and cost-effective production, customer orientation, innovative logistics, networking and the stronger application of IT. Support should be given especially to those fields where market failure can be observed.

From the industry's point of view, aspects to improve regulation would be to decrease the amount and level of detail of regulation, to harmonise and co-ordinate regulation policies, make better use of the advice given by the industry, include financial institutions and the manufacturers as customers in the drafting of regulations, and include politicians from the Member States to assure due implementation of EU regulation in national legislation.

4.4.7 Views of Stakeholders in the Electrical Engineering Industry

Regulatory Issues

Most of the interviewed industry organisations take part in regulation activities within their fields, that means that they are actively involved in European as well as national regulatory issues and activities. On the European level, most regulations are shaped in a general way, giving no specific instructions on their implementation (following the Anglo-American regulatory system). The specification is realised by standards under the "New Approach". In some European countries though, e.g. in Germany, the industry is used to be given specific directions on the realisation and implementation of regulations which makes it more difficult for German industries to cope with European regulations than with national regulations.

Common Views and Conflicting Themes

In general, within the electrical engineering industry, there is according to the interviewees, a rather high level of regulation but there are differing opinions on how to assess European regulations within electrical engineering. Some organisations pointed out that there is no need for further European regulation apart from adapting to and regulating technical innovations. Already now, the EU tends to stretch its competencies regarding regulation and standardisation to areas traditionally ruled by other bodies, e.g. concerning technical self-regulation within the industry. Industry requests that the EU should instead keep to defining the framework for regulation and standardisation rather than engaging in the development of closely defined regulations itself. According to the interviewed industry organisations, especially within the fields of environment and consumer concerns, where many regulation activities are taking place at the moment, the current regulations are by far sufficient. If additional regulations will be set up, the high level of regulation will set pressure on the industry and it will, most probably, lead to distortions of

competition due to differences in the treatment of European and non-European companies.

Examples of regulations shaping new markets

- With entering into effect in 1974, Council Directive 73/23/EEC on Electrical Equipment designed for Use within certain Voltage Limits established the Common Market for electronic equipment.
- Directive 89/336/EEC on Electromagnetic Compatibility (EMV) sped up the market for services related to measuring electromagnetic disturbances.
- Directive 1999/5/EC on Radio Equipment and Telecommunications Terminal Equipment (R&TTE) simplified the movement of goods for telecommunication equipment and radio installations in Europe.
- Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) will stimulate the market for waste disposal and management, though at the expense of the producers of electronic equipment. The associated Directive 2002/95/EC on the Restriction of the Use of certain hazardous Substances in Electrical and Electronic Equipment (ROS) contains the ban of certain substances which will cause a complete technology transformation in certain manufacturing areas.
- Following the international Standard ISO 9000 on the Description of Quality Management Systems, the market for testing and inspection authorities/centres grew considerably, mainly at the costs of equipment producers. Therefore, the testing and inspection authorities/centres initiated the establishment of ever more management systems standards which were not the purpose of the industry.

Source: Interview with a representative of the Zentralverband Elektrotechnik und Elektroindustrie (ZVEI), Germany

On the other hand, regulations should not be seen as disadvantageous in themselves, another interviewee pointed out. The benefits of regulations depend highly on the content and scope of the very regulation and on the sector where it is applied. The EU initiative on the future regulation of chemicals for example can be seen as negative because it sets up very detailed standards whose utility is disputed, whereas the way the EU Directive on Machinery was shaped and its content can be seen as a positive example of regulation. In general, regulation is useful if it reduces distortions of competition within the EU, but at the same time, one has to take into consideration the different levels of regulation already present in the Member States. If European regulations set too high a benchmark, some countries will have serious difficulties to comply, but if the regulation level is set too low countries

which used to have high benchmarks will have to deal with stronger competition from abroad. Thus, European regulations need to have a high standard which lies considerably above the overall European level while taking care that all countries manage to comply with these regulations.

Impacts of Regulation on Innovation

At the moment, the innovation environment in Europe is perceived as rather negative by the interviewees. This is due to several factors: 1) The industry invests only small sums in R&D due to short-term profit maximising strategies which are pursued widely (trying to raise the shareholder value). 2) Innovations are low, due to a wide-ranging education problem. There is a lack of skilled labour and technically oriented students and engineers which already now hampers innovations or will do so in the near future. 3) Innovation activities are low, due to the reluctance of public actors to speed up necessary policy reforms. 4) Innovations are retarded due to high duties and taxes and due to an abundance of formal and informal regulations in nearly all Member States.

Nevertheless, regulations can be beneficial for innovation, according to the interviewed organisations. For this to be the case, regulations have to fulfil certain requirements: 1) As already mentioned above, regulations should only establish general requirements, the more detailed a regulation is formulated, the less it is suited for enhancing innovations within the affected industries. 2) Regulations encourage innovation if they integrate several existing regulations into one and thus reduce the overall amount of regulations. 3) And finally, European regulations encourage innovation if they replace national regulations and thus harmonise legislation in the Member States.

Possible Future Developments

In general, the level of regulation in Europe is perceived as being quite high and it should only be extended if the above listed criteria are met. In addition, there is a need for more efficient and flexible structures to support innovation on the national and on the European level. To achieve this structural transformation, European and national actors need to be willing to work on these issues and to actually transform the existing structures. To that end, the European Commission as one of the most important actors has to clarify its standpoint and the policies it pursues with regard to regulation and innovation. Up till now, the interviewees pointed out, there is a lack of consistency within European level regulation and thus considerable insecurity within industry about the overall EU policy directions in that field.

4.4.8 Views of Stakeholders in the Transport and Communication Sector

Regulatory Issues

Regulation is an important topic for the stakeholders within the transport and telecommunications sector, especially against the background of the liberalisation of former state-owned enterprises in this sector. The level of regulation within transport and telecommunications is highly diverse within the European Union. In the railroad sector for example some countries (e.g. in Southern Europe and Belgium) have undertaken barely any deregulation yet, whereas the British railroad system is fully liberalised. The effects of the British railroad liberalisation in terms of security and service is quite devastating though. This example shows that liberalisation as well as regulation of the European transport infrastructure is important, but it needs to be done in a proper way taking into consideration all relevant aspects (e.g. security, efficiency and competition aspects) and actors (industry, consumers, workforce, environment), even though these might be more divergent than in other areas.

Common Views and Conflicting Themes

Within the transport and communication sector, the opinions on European regulation are rather divergent. Formerly state-owned enterprises (postal services, railroad, telecommunications) had been protected against competition by state law and they usually still have an important position on the market. Thus liberalisation for them reduces their profit margins and may even threaten their survival. Small postal or (tele-) communication start-up companies on the other hand take advantage of the opening-up of the market and are thus much more interested in deregulation. It is thus the task of national postal and telecommunication authorities to adequately regulate the market and to prosecute market distortions. If European regulations are set up, these need to be applied instead of national ones, but conversion and enforcement of European regulations still vary within EU Member States. Within information technology, on the contrary, there has not been much regulation so far, which means that the ICT-Industry is (still) quite positive about regulations, e.g. regarding software patents or other intellectual property rights.

Consumer organisations point out that the European transport infrastructure needs to be further liberalised to reduce market distortions, at the same time raising transport efficiency and reducing transport costs. According to them, this needs to be done by additional European regulation, e.g. on the basis of the EU White Book on Infrastructure Pricing. Co- or self-regulation is not seen as an adequate means to do so as consumer organisations pointed out that this does not have positive effects on

regulation with regard to consumer interests. In general, a co-ordinated European transport management (equivalent to the European flight management system that already exists) will be necessary to offset the disadvantages that still exist for rail-road transport vis-à-vis road and air transport. These disadvantages are, besides others, incompatible national railway technologies (incomplete interoperability), intermodal and intramodal market distortions, reduced/difficult market access for prospective market entrants, unequal social conditions in rail vs. road transport and considerable pricing differences for the use of road vs. rail infrastructure.

European Trade Unions and Trade Union federations see an urgent need for re-regulation within the European transport sector. In their opinion, EU-level regulation is necessary because it gives a common background and equal conditions to everybody active in that field. These stable and uniform conditions are conducive to an efficient business environment. Even more importantly, by means of European regulation, equal social and working standards for all workers within the European transport industry have to be accomplished to reduce differences in pay, working conditions and social security provisions.

Impacts of Regulation on Innovation

As pointed out above, most interviewed organisations perceive European regulations as a necessary and adequate policy tool. Furthermore, there is potential for innovation within the transport and telecommunications sector that can be fostered by regulations. On the one hand, by shaping a stable business environment, regulations can foster innovation whereas unstable conditions provoke unsustainable, short-term decisions not conducive to innovation.

The impact of (de-)regulation on innovation

Positive Example:

Due to favourable framework conditions, improved planning and company organisation in collaboration with innovative ideas, the German-based BLG Logistics Group, Bremen, has evolved into an active and competitive company during the past years generating jobs and sustained growth.

Negative Examples:

(1) The British railroad system was fully liberalised in the 1990s. This led to the fragmentation and finally to the deteriorating of the whole system which in turn led to considerable expenses for the state and the individual customers.

(2) Deregulation in the area of road transport can be dangerous (e.g. lead to a rise in truck accidents) due to lacking or divergent security standards and insufficient enforcement mechanisms.

(3) Diverging national labour legislation can lead to the dumping of national social standards in the transport sector due to lower social security expenses in some EU member states than in others.

Source: Interview with a representative of the European Transport Worker's Federation, Brussels.

Furthermore, adapting social standards across Europe gives continuity to innovation processes and can lead to social innovation, especially in countries which used to have rather low social standards. In this respect, one trade unionist pointed out that the Common Market has already been established to a considerable extent whereas barely any adaptation of social standards has taken place in Europe so far (concerning working conditions, pay systems, safety regulations and social security) and jobs are created or transferred to where labour is rather cheap. Due to high flexibility and internationalisation, this can be done quite easily within transportation and communication. Thus, according to European trade unions, there is much to be done in that field concerning European-level regulation. At the same time, the EU has to take care that regulation and harmonisation is not done on a lower level than EU average, instead the overall regulation standard needs to be set above EU average to benefit all Member States and not to discourage countries which used to have higher regulation benchmarks.

Finally, there is still potential for innovation within information technology even though the sector has had considerable difficulties during previous years. Regulation in the area of communication security, intellectual property rights, software standards and workforce rights and organisation is thus supported by industry as well as trade unions.
Basic difficulties preventing innovation in Europe, which are still not tackled adequately, are inefficient and inflexible structures and framework conditions (e.g. slow and difficult administrative processes). They tend to prevent research initiatives and thus innovation to a considerable extent. According to industry as well as consumer representatives, more stable and at the same time more flexible structures and research conditions will thus lead to innovation in the transport and communications sector in the future.

Possible Future Developments

At first, one has to note that there is a huge diversity of actors involved in the field of transport and communication which results in a high complexity of the problems to be discussed. In general, the trend rather goes towards regulation or re-regulation than deregulation which has been the leading paradigm in the past. Especially the following topics have to be tackled in the future:

- Regulation has to be consistent on the European level and it should not be limited to the establishment of minimum standards.
- Within the transport sector, technical harmonisation is urgently needed. For example, up till now every Member State has its own railroad technology which prohibits fast and efficient cross-border transfer of goods and services and which in turn prevents innovations in that field.
- The same holds true for information technology, where improved intellectual property rights and software standards can foster innovation in the future. In addition, regulation in the field of information technology is needed to establish and/or harmonise the certification and organisation of IT professionals.

Finally, European regulation is needed to harmonise social standards and workforce rights in the field of communication and transport in all Member States. This is especially important because the high mobility and flexibility of transport and related businesses puts pressure on contractors and the workforce, e.g. with regard to payment levels, working standards, health care and retirement provisions, which can in the long run hamper stable growth and innovation in Europe.

4.5 Comparative Summary

This chapter was devoted to presenting the results of a European survey among companies and research institutes on the relationship between regulation and the R&D activities and the market introduction of new products and services. In addition, the more qualitative insights of interviews with other stakeholders were summarised.

The survey results confirm the ambivalent role of regulation for the innovation activities of companies. First, regulations hamper innovation and R&D activities, although there are several more important obstacles. Second, regulations provide companies and research institutes with framework conditions which increase their legal security and support therefore their activities relating both to R&D and the introduction of new products and services. In general, the answers from the companies and the research institutes are rather similar. However, the research institutes are less hampered in their R&D activities than companies are in their innovation activities which is closer to the more strictly regulated market. In addition, the changes in the regulatory framework towards higher environmental and safety requirements create new business opportunities for research institutes. Therefore, the research institutes assess the positive impacts of regulations in general higher and the negative impacts lower than the companies.

In contrast to the companies, the consumer organisations are in favour of regulations which secure the safety and quality of products. They argue that regulations are effective in providing incentives for companies to develop products of higher quality and safety. In common between consumer associations and companies, especially SMEs, is the critical attitude towards self-regulation, which is not a solution for all industries and certain dimensions to regulate like environmental issues. This leads to the finding that also within a group of stakeholders different opinions exist, for example between smaller and larger companies regarding the value of self-regulation or between consumer and patients' organisations regarding the value of generic medicines. Although trade unions favour in general a regulatory framework which protects the interests of the workforce, especially innovations reducing risks for health and safety, they are also very interested in framework conditions

which promote the innovative capacity of the respective industries often leading to a coalition with industry confederations.

Besides the different views of the stakeholders, significant differences between sectors can be observed. First, within those sectors, where we observe strong public interest regarding the protection of health, safety and the environment, the regulatory framework is more extensive and rigid. Consequently, the companies in the pharmaceutical or food industry bear higher regulatory costs. In addition, the conflicts between the representatives of the protected objects, like the consumer associations or environmental groups and companies, and industry are stronger, because more protection and less risk on the one side leads to more costs and less innovation on the other side. One exception is innovation within environmental technologies, which is promoted by more rigid regulations, because both the suppliers of such technologies and the environmental groups win in the form of increasing market shares and better quality of the environment.

In general, all stakeholders in all sectors complain about the incomplete harmonisation of the regulatory framework and even if the regulations are harmonised Europe-wide the implementation of regulations differs not only between countries, but within countries as well. This is a serious problem of regulations relevant for the introduction of new products and services, because it adds additional risk to an already rather risky process.

5. Selected Case Studies on the Impact of Regulations on Innovation

5.1 Introduction

In the previous chapters, we have presented both regulatory systems shaping new markets and the assessment of stakeholders, like companies or consumer organisations, of the regulatory system respectively its impact on innovation. Although we have already presented examples of regulations relevant for the introduction of new products and services, an in-depth analysis of specific areas of regulations is necessary in order to show its concrete impact on innovation. In this chapter, we present the main results of three case studies of the pharmaceutical sector, the food industry and environmental technologies.[15] As the previous analyses have already shown, the respective regulatory systems are very crucial for the development and market introduction of new products in these industries. Within the three sectors, we do not provide an overview of all regulatory issues, but focus on very specific regulations, which have a rather significant impact on innovation activities. In addition to the three case studies focusing in specific sectors, we present in section 5.5 the role of standards for the development of new products and services based on a selection of a few very successful standards. We conclude the chapter with a comparative summary of the case studies.

5.2 The Impact of Regulation on the Development of New Products in the Pharmaceutical Sector

5.2.1 Background and Objectives

The first case study discusses the impact of regulatory interventions on pharmaceutical innovations in the EU and compares these mechanisms to the situation in the USA and Canada.[16] First, a general overview of the regulatory regime in the pharmaceutical sector in the EU and USA/Canada is given. Then, special attention is paid to three regulatory fields which are of exceptional relevance for the questions to be considered here. These are the comparison of the general procedures for the

15 The full versions of the case studies are available as separate working documents prepared for the various interim reports.

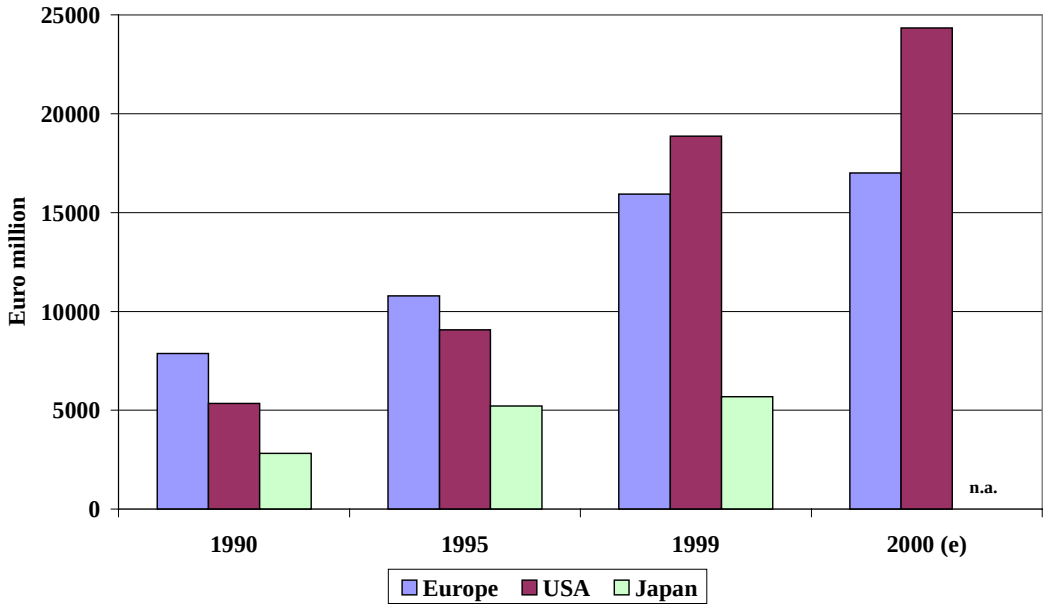
16 The complete case study prepared by Bührlen et al. (2003) can be found as working paper on the Cordis web site at http://www.cordis.lu/innovation-smes/src/studies.htm.

authorisation of medicines by the FDA (Food and Drug Administration) in the USA and by the EMEA (European Agency for the Evaluation of Medicinal Products) in the EU, the implementation of standards for clinical studies ('Good clinical practice'), and the regulation of medicines for rare diseases ('Orphan Medicinal Products'). In each chapter the problem or situation is characterised for the selected examples, the rationality of the regulation and the regulatory principles as well as their implementation are described, the results in terms of innovative performance are elaborated on and considerations and conclusions are presented. Concluding remarks complete this case study.

Over 560,000 persons work in the European pharmaceutical industry, which is more than two times the number of persons employed by US pharmaceutical companies. Industry and governments are concerned about the decreasing level of competitiveness of the European pharmaceutical industry. US pharmaceutical research and development (R&D) investment has risen fivefold, compared to just 2.4 times in Europe, reaching € 17 billion in 2000. In 1997, the US industry was able to overtake Europe in terms of total amount of R&D expenditure and reached € 24 billion in 2000. Also in terms of numbers of New Chemical Entities (NCEs) the US pharmaceutical industry has overtaken the EU industry in recent years. While in the 1960s European companies invented 65% of NCEs placed on the world market, by the end of the 1990s this share had fallen to 40%. The latest data for the period 1997-2000 show the predominance of the United States, which has now become the leading innovator of new molecules in the world.

Over the past ten years, Europe’s R&D basis has gradually eroded. Especially some new leading-edge technology research units have been transferred out of Europe, mainly to the United States. R&D expenditures have doubled over the last 10 years in Europe to reach €17 billion in 2000. In 1997, the US industry was able to overtake Europe in terms of total amount of R&D expenditure. As shown in Figure 5.2-1 , between 1990 and 2001, R&D investment in the USA rose fivefold, while in Europe it only grew 2.4 times and reached €24 billion in 2000. R&D expenditure in Europe represented 1.90 % of the GDP in 2000, the same figure as in 1990, whereas in 1999, the USA spent 2.64 % of their GDP on R&D and Japan 3.04 % (EFPIA 2001; 2002).

Figure 5.2-1: Pharmaceutical R&D expenditure in Europe, USA and Japan 1990-2000

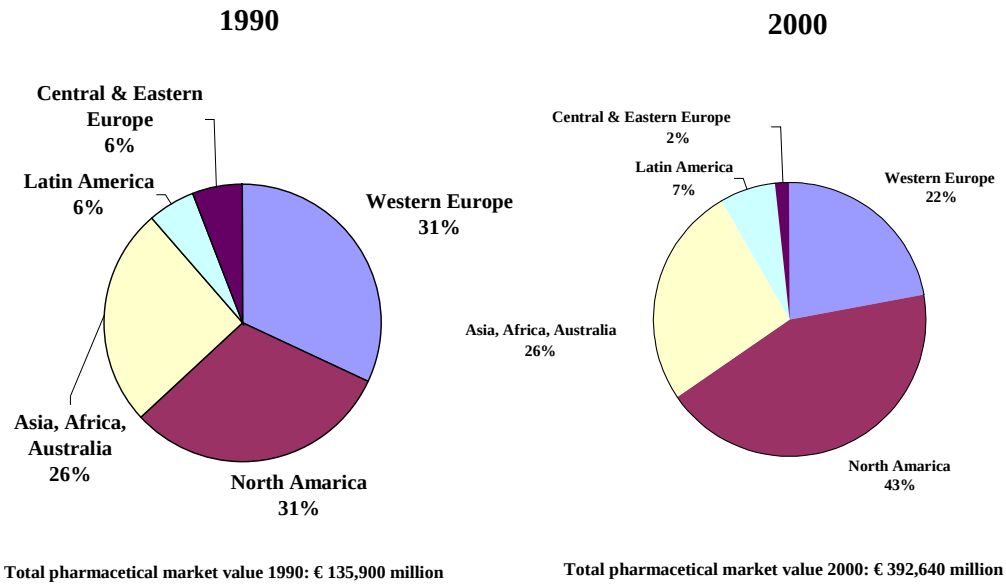


(e) estimate

Source: EFPIA (2001): G10 Medicines High Level Group on innovation and provision of medicines consultation paper - EFPIA comments (www.efpia.org/4_pos/ economic/g10.pdf; http://www.efpia.org/4_pos/economic/g10Annex.pdf).

Between 1990 and 1998, the US pharmaceutical market grew twice as fast as the European and Japanese markets in real terms (see Figure 5.2-2). In 2000, North America represented 43 % of the €392 billion global market of pharmaceuticals, compared to a 22 % market share of Western Europe. Ten years ago, the corresponding figures related to 31 % for both regions. As a kind of compensation for the less fast growing domestic market, export is of special relevance for the European pharmaceutical industry. It increased by 370 % since 1990 and reached a turnover value of € 89 billion in 2000.

Figure 5.2-2: Breakdown of the world pharmaceutical market 1990-2000



Source: EFPIA (2001): G10 Medicines High Level Group on innovation and provision of medicines consultation paper – EFPIA comments (www.efpia.org/4_pos/economic/g10.pdf; http://www.efpia.org/4_pos/economic/g10Annex.pdf).

5.2.2 General Overview of the Regulatory Regime in the Pharmaceutical Sector in the EU and the USA/Canada

In all of the EU Member States as well as in the USA and Canada and other industrialised countries, manufacturers need to submit adequate scientific evidence on safety and efficacy to their national (or EU) competent authority to obtain a product license. The national authorities evaluate and monitor the safety, efficacy, and quality of pharmaceutical drugs. This broad agreement on the general requirements for market authorisation can be largely attributed to shared general values and the implementation of guidelines, which have been developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) in recent years.

Parallel to these general attempts at harmonisation, the national and trans-national authorities make use of various regulatory means to support innovation and competitiveness of their respective pharmaceutical industry, and at the same time ensure satisfactory access of their citizens to medicinal products and ascertain containment of public health expenditures.

The first European pharmaceutical directive (Directive 65/65/EEC) was a reaction to the "thalidomide disaster" in the early 1960s. It aimed to establish and maintain a high level of protection for public health. A decade later, two directives (75/318/EEC and 75/319/EEC) introduced the mutual recognition, by Member States, of their respective national marketing authorisations. Since 1985, a number of directives have been adopted with the aim of achieving a single, EU-wide market for pharmaceuticals. A new European system for authorising medicinal products came into effect in January 1995 (Regulation 2309/93; Directive 93/41/EEC). It offered two routes for authorising medicinal products: "centralised" and "mutual recognition" procedure. In the same year, EMEA began its activities.

In 2001, the Commission ordered a detailed assessment of the regulatory framework for medicines. On the basis of this assessment as well as input from the High Level Group on Innovation and Provision of Medicines (the "G10 Medicines Group"), the Commission adopted a proposal for a comprehensive reform of the EU pharmaceutical legislation. With respect to innovation-related legislation, the review seeks to

- make better use of EMEA and increase the range of products approved under the centralised procedure
- increase access to and availability of new and innovative medicines e.g. by improving authorisation mechanisms and creating a "fast-track" registration procedure and making medicinal products available in advance of authorisation on a "compassionate use" basis
- support the European generics industry by harmonising the data protection period at ten years for all medicinal products and allowing tests on pharmaceuticals to be performed in advance of the expiry of the patent
- rationalise, simplify and enhance transparency, including replacement of the 5-year renewal procedure by reinforced pharmacovigilance monitoring.

Similar to Europe, in the USA in 1962 the "Kefauver-Harris" amendment was introduced into medicine regulation in response to the thalidomide tragedy. This amendment required extensive animal pharmacological and toxicological testing before a drug could be tested in humans. The data from these studies had to be submitted in the form of an investigational new drug application (IND) ("Notice of Claimed Investigational Exemption for a New Drug") and approved by the FDA before clinical studies could begin. The amendment also required that manufacturers submit to the FDA "substantial evidence" of the unapproved (investigational) drug's efficacy, as well as safety, in the form of an New Drug Application (NDA). In 1992, the Prescription Drug User Fee Act (PDUFA) introduced the collection of user fees from the pharmaceutical industry in order to increase the resources available for premarket reviews and obliged the FDA to reduce the premarket review times. In 1997, the Food and Drug Administration Modernization Act (FDAMA) introduced a fast-track review process decreasing the clinical study time for priority drugs.

Besides the regulation of the requirements for and the process of market approval, the protection of intellectual property rights exerts further impact on the development of new drugs. International patent law is harmonised to a great extent. However, national differences occur in the regulation of generic medicines. This has its impacts on the market share of generic products, and, because of its influence on the revenues which can be drawn from the original products, on the capital that is available for the development of new drugs.

Regulatory interventions can lead to changes in the innovative activity. This can be clearly demonstrated by reviewing historical examples of major legislative acts: effects of regulation can be found on indicators of innovation such as the number of clinical trials, R&D expenditures, the number of drug applications and authorisations, as well as on procedural indicators, especially the time needed for the review process. For example, it is estimated that the US regulations of the year 1962 reduced overall research spending by about 20 % to what would have been expected without them (Duetsch 1998).

The picture becomes less clear when more recent cases are considered. The later interventions are more restricted in scope because the general guidelines are already in place. Secondly, innovation activity and the development of the pharmaceutical markets are not only under the influence of regulation that is particularly directed to this issue, but also to other legislation and non-legislative factors. The system of pharmaceutical innovation has become more sophisticated and interlinked with other areas of regulation, especially the health care system, with in part contradictory goals, which reduces the possible impact of innovation regulation.

Important impacts on pharmaceutical innovation come especially from the reimbursement of pharmaceuticals. Cost containment policies reduce the yield from medicinal products and – from the view of the pharmaceutical industry – reduce the possibility to develop new products.

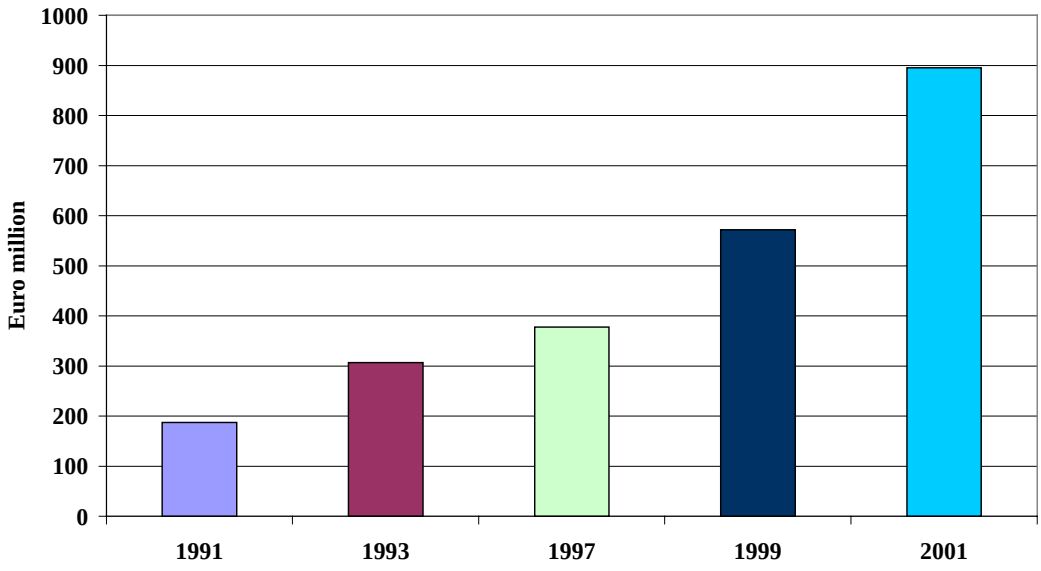
5.2.3 Procedures of EMEA and FDA for Reviewing New Drug Applications

In the historical perspective, the analysis shows that the European and the US regulatory system relevant for the pharmaceutical sector were triggered in their development mainly by the same stimuli and evolved in quite similar ways. In both systems, the challenges are mainly the same, namely to ensure the availability of high quality pharmaceutical products and to strengthen the competitiveness of the national or regional industry. A crucial point is the duration of the review process with the competent authority which was subject to several attempts at regulatory intervention. These amendments to existing regulation mostly had a significant, but very often also transient effect in the intended direction. For example, in the USA, the

Prescription Drug User Fee Act was effective in the reduction of the approval times which resulted in a significant increase in the number of drug approvals, but later on the approval times began to rise again, because of growing safety standards, among other factors.

A second factor affecting the innovative activity are the R&D costs, which in general rose due to the increased requirements for approval since the 1960s. According to a study of the Boston based Tuft University, the full costs of bringing a new compound to the market rose from around € 200 million at the beginning of the 1990s to more than € 800 million at the beginning of this decade (figure 5.2-3). No really effective measure was found to stop this trend for new active substances (NASs), whereas for generic and over the counter drugs the procedures were simplified (e.g. restriction on bioequivalency as criterion for approval) and therefore the research costs should have decreased.

Figure 5.2-3: Estimated full cost of bringing a new chemical or biological entity to market



Note: data have been expressed in million € at current exchange rates – original data in million $

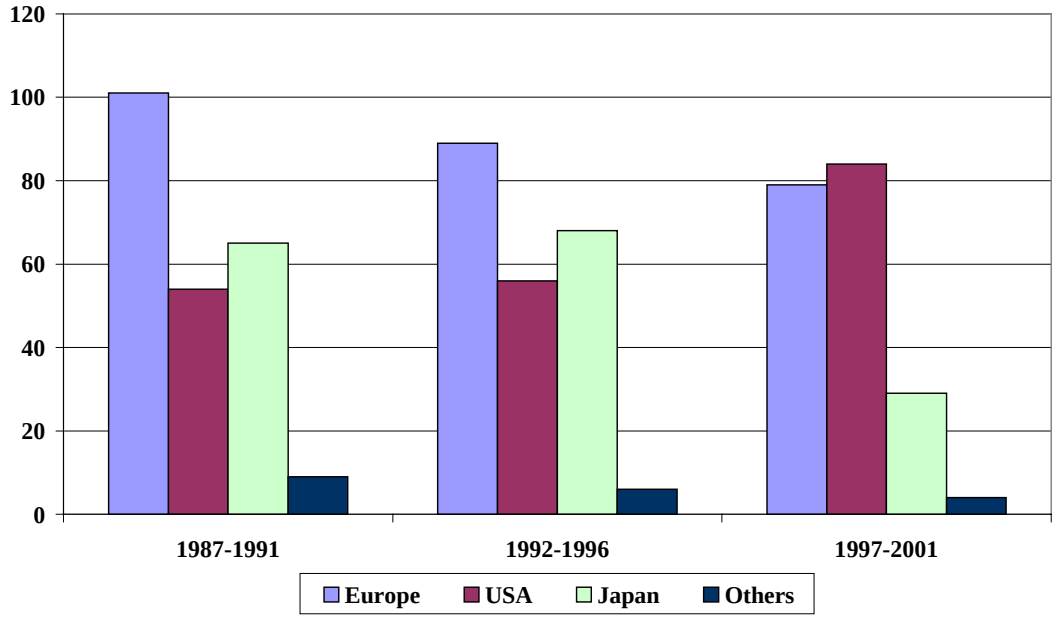
Source: EFPIA (2001): G10 Medicines High Level Group on innovation and provision of medicines consultation paper - EFPIA comments (www.efpia.org/4_pos/ economic/g10.pdf; http://www.efpia.org/4_pos/economic/g10Annex.pdf), p. 19.

In Europe, the creation of the EMEA and the centralised authorisation procedure were major steps to overcome hindrances from conflicting national approval policies. However, the European Commission values the decentralised authorisation

procedure because of its ability to maintain a decentralised evaluation capability, involve the national authorities in the system and help to build a consistent and efficient Community system. As the numbers of applications and approvals under the centralised procedure show, the industry in general accepts this step, although the companies also want the mutual recognition procedure to be maintained for flexibility reasons, whereas the European Parliament even supports a central authorisation procedure for all new medicines.

Data from EFPIA (2002) show that in the period 1960-65 European companies invented 65 % of NCEs placed on the world market, but by the end of the 1990s this share had fallen to 40 % (with direct effects to new drug applications). The latest data for the period 1997-2000 show the predominance of the United States which has now become the leading innovator of new molecules in the world (Figure 5.2-4).

Figure 5.2-4: Number of new chemical or biological entities (1987-2001)



Source: EFPIA (2001): G10 Medicines High Level Group on innovation and provision of medicines consultation paper - EFPIA comments (www.efpia.org/4_pos/ economic/g10.pdf; http://www.efpia.org/4_pos/economic/g10Annex.pdf).

In the centralised procedure of EMEA, from 1995 to 2000 inclusively, 97 list-A applications were filed and 182 list-B applications for a total of 279 applications. The mutual recognition procedure was used for medicinal products like generics, extensions of marketing authorisations already granted, medicinal products having followed the "concertation procedure" (which was in place before the entry into

force of the centralised procedure) as well as for medicinal products containing new active substances. From 1995 to 2000, 988 procedures have been finalised under this regime (European Commission DG Enterprise 2001).

In the last years, the ICH (International Conference on Harmonisation of Pharmaceuticals for Human Use) process promoted a far-reaching harmonisation of standards and procedures of the competent authorities in the approval of medicines, which led to a loss of nearly all degrees of freedom in the general authorisation procedure. Instruments left to influence the innovative behaviour of the national or regional actors in the pharmaceutical industry were exceptions to the general procedure like fast-track approvals, Treatment INDs (Investigational New Drug Applications), and special incentives for innovation in the form of research funding, orphan drug designation, intensified consultation and support for the applicants. Indirect measures such as the protection of patented against generic drugs complemented the bundle of measures to strengthen the market for original new drugs. However, generics are held to be a building block to contain the exploding health expenditures (and besides, the generics industry is a relevant factor for many countries, too) and this is why also the effect of protection against generic drugs to foster innovative activity is limited, like the other attempts to support innovation via the approval process.

5.2.4 Implementation of Standards for Clinical Trials: Good Clinical Practice

On the basis of the ICH process and the implementation of the respective guidelines in national and EU law, the standards for clinical trials are harmonised to a large extent between the EU, USA and Japan. Nevertheless, there are striking differences between these countries, for example, as far as the number of clinical trials is concerned (Table 5.2-1). This relates in particular to Denmark, where the number of clinical trials carried out per inhabitant are three times higher compared to Germany or France. In addition, European industry complains of an innovation-hindering climate in Europe, by far higher research funds for pharmacological research in the USA than in the EU and a shift of clinical research to the USA.

The differences in the number of clinical trials can in part be explained by differences in the market structure for pharmaceuticals, particularly in price control. However, the mentioned factors are not sufficient to explain the decisions of the researching companies on where to locate their clinical trials. Many other factors are discussed, but no empirical evidence can be found to decide which of these factors is really the most relevant one.

Table 5.2-1: Number of projects in clinical trial per 10 million inhabitants

Phase	I	II	III
Canada	13.0	28.5	27.9
Denmark	13.2	45.1	26.3
Australia	6.4	17.6	20.3
Netherlands	12.6	20.8	15.1
Ireland	8.2	21.3	14.7
United Kingdom	30.9	33.9	14.5
Sweden	12.3	22.4	13.4
USA	13.8	23.7	13.3
Germany	5.9	12.4	7.1
France	9.3	14.7	7.1

Source: Fink-Anthe, C. (2002): Aufwand für klinische Studien, Rahmenbedingungen und Wettbewerb, in: Die Pharmazeutische Industrie, Vol. 64, No. 10, pp. 182-184.

Many proposals are made to improve the framework conditions for clinical trials, many of them refer to the current update of the clinical trials regulation in the EU. Besides that, in a broader view on the evaluation of pharmaceuticals, based on a study in the Medicaid system, it is recommended to increase routine epidemiological surveillance, including service use, and clinical trials that include aspects of usual medical care early in the drug development process. Others highlight certification as a means of assessing competency and discuss investigator certification as a potentially accurate indicator of competence for conducting research and as a predictor of inherent quality at the research site.

5.2.5 Orphan Medicinal Products

In the 1980s and 1990s several countries took initiatives to develop a specific regulatory policy for medicinal products related to rare diseases (the so-called "orphans") for which the costs of R&D and marketing activities would not be recovered by the expected sales of such a product. Due to the low sales expectations, the pharmaceutical industry is rarely interested to develop medicinal products for orphan diseases under normal market conditions. In order to ensure patients suffering from such orphan diseases the same quality of treatment as other patients, specific regulations were established to stimulate R&D and market introduction of medicinal products targeted to such diseases. In the USA, EU and in other countries (such as Japan, Australia or Canada), the most important aim in regulation of orphan medicinal products is to promote the development of pharmaceuticals, diagnosing or treatment possibilities for serious rare diseases which affect only relatively low numbers of patients, or for diseases where without incentives it seems rather un-

likely that the market would generate sufficient turnover or profits to motivate pharmaceutical companies to invest in R&D in these areas.

In this context, the USA took the leadership by passing the Orphan Drug Act (ODA) in 1983. Based on the rules of this regulation, similar legislation was enacted in Japan in 1993. An Australian orphan drug programme based on the US model started in 1998. The EU Orphan Drug legislation was adopted in April 2000 by passing regulation EC 141/2000 on orphan medical products. The rationality for the US and the EU regulation are quite similar, but there are some differences concerning the detailed rules. While in the USA a prevalence of 75 persons per 100,000 inhabitants is used to define "orphan diseases", the corresponding figure in the EU relates to a prevalence of less than 50 per 100,000 inhabitants. Regarding the provided major incentive, a relatively strict market exclusivity of seven years is foreseen in the ODA, while market exclusivity shall be provided for ten years in the EU, but this time period can be reduced to six years, if the approved product is "sufficiently" profitable. The other incentives like fee waiver, specific grants for clinical studies or protocol assistance are almost similar between the EU and the USA.

Table 5.2-2: Development and status of orphan designation procedures in the EU (status: January 2003)

Year	Applications submitted	Applications withdrawn	Positive COMP opinions	Negative COMP opinions	Designations granted by European Commission
2000	72	3	26	-	14
2001	83	26	62	1	64
2002	79	37	49	3	48
Total sum	234	66	137	4	126

Sources: Baddack et al. 2002, Committee for Orphan Medicinal Products 2003.

Both in the USA and in the EU the introduction of the Orphan Drug regulation has had a strong impetus for R&D activities and applications for market approval for such products. Due to the much longer running period of the ODA, the number of US orphan medicinal product designations and market approvals by far exceed the corresponding figures of the EU. In the USA, around 1,200 products have received orphan designation since 1983 and a total of 232 have been approved by the end of 2002 (Table 5.2-2). From 200 to 2003, 126 orphan designations have been granted by the EU authorities and seven orphan medicinal products have been introduced in the market so far. The incentives provided by Orphan Drug regulation both in the USA and the EU are specifically attractive for specialised biotechnology companies and the development of "biological" compounds. It is expected that the relevance of

this group might further rise in future due to the high scientific progress in pharmacogenomic activities.

While market exclusivity has been discussed and criticised in the context of "blockbuster" drugs, there is an absence of analysis concerning whether or not the ODA's seven-year period strikes an appropriate balance between the need to give incentives for innovation in orphan medicinal products, and the public benefit associated with a competitive market. Such an analysis would provide a sound basis for adjusting the market exclusivity term to better balance the grant of a monopoly with the needs of society. In addition, the pricing of orphan medicinal products has been questioned in the past. Critics argue that orphan drugs are often overpriced, which can limit patients' access to affordable treatment, especially for those patients who do not have health insurance coverage. Accurate data on the prices, sales and profit margins for orphan products are very limited and vary by source. Because of lack of available data, it is not possible to provide a sound analysis on total sales, price ranges or profit margins of orphan products. Some reports claim that orphan medicinal products are among the biggest money-makers of the pharmaceutical industry. As shown in the case on treatment costs of MS (multiple sclerosis) exceeding € 20,000 and global sales of more than € 2.2 billion, there are some hints in this respect. However, other reports claim that most orphan drugs have relatively low revenues (as shown in the case study on Fabry's disease), while only a very few produce extremely high revenues. This pattern is very similar to the distribution of the values of patents.

As shown in the case on treatment of PAH (pulmonary arterial hypertension) and Fabry's disease, the time requirements for market approval seem to be one of the key factors, both for commercial success of an orphan medicinal product as well as to the human and social dimension related to the treatment of severe diseases which often are life-threatening and may lead to death. In particular the "approval race" of two almost similar products – as demonstrated in the Fabry case in the USA – has a rather negative feedback to the affected patients in the USA since there are potential treatment possibilities available (which are already used e. g. in the EU), but cannot be used for regulatory and legal reasons. In the same sense, it was argued at the joint meeting with all interested parties carried out by EMEA in December 2002, where "it was stressed that the real availability of orphan medicinal products and access to patients remain as one of the most important challenges for the success of the European Policy on orphan medicinal products" (EMEA 2002). In this respect a commitment from the European authorities responsible for pricing and reimbursement was regarded as necessary to ensure a complete success.

With respect to the EU the integration of patient organisations in the evaluation for designation of orphan medicinal products is regarded as a "remarkable achievement after the Regulation implementation" (EMEA 2002). Since most future projects and developments related to orphan medicinal products are limited by the available

funding for research, a "substantial budgetary effort at a European level" (EMEA 2002) was seen as necessary by patient organisations and industry at a joint meeting with EMEA in December 2002. In addition, there should be adequate information on current clinical trials – maybe by means of a public database – since this often represents a specific form of access to medicinal products related to rare diseases which have not been approved for marketing by the relevant authorities.

5.2.6 Concluding Remarks

The analysis of the impact of the regulatory framework on shaping (new) markets in the pharmaceutical sector could not provide an unambiguous picture of the relations and causalities between the regulatory framework and innovative activities, like the performance of research and development and the marketing of new products.

The comparison of the general regulatory framework relevant for the pharmaceutical sector in the EU and the USA/Canada shows that the significant differences of the past have been reduced to some minor discrepancies in detailed regulations. We observe a general convergence of the regulatory systems, which is especially caused by the activities of the ICH. The companies in the pharmaceutical sector are interested in getting developed drugs to the market as soon as possible and developing new or improved drugs for new indication fields or diseases, which cannot be treated so far. In contrast, the rationality of the approval authorities in the pharmaceutical sector is to maximise safety in the extreme case by blocking beneficial products even with minimal risks. Due to differences in the objectives, conflicts between industry and regulatory bodies will persist in the future.

Although significant progress has been made towards more efficient and faster approval procedures, the pharmaceutical industry both in Europe and in the USA still complain about the costly, uncertain and long procedures from first research to the marketing of new pharmaceutical products. Scientists argue that regulatory controls directly reduced the number of new product introductions by means of stringent testing and might have indirectly reduced introductions by discouraging research expenditures, since for pharmaceutical companies, the time-to-market is of highest relevance, because of its major impact on the revenue streams.

Since we observe differences between the USA and the EU in the development of indicators of innovative activities, like the increase in R&D expenditure or the expansion of the market for pharmaceuticals, which cannot be explained just by the small discrepancies of the regulatory system of the pharmaceutical sector in the narrower sense, other aspects like the demand from the health system, general liability rules, IPR regulation for generic drugs, user acceptance but also the environment for performing R&D have to be taken into account. Obviously, in the

United States the sum of these framework conditions are currently more favourable than in the EU.

5.3 The Impact of Regulation on the Development of New Products in the Food Industry

5.3.1 Background and Objectives

The question of regulation, innovation and their impact on competitiveness in global markets has a high relevance for the food industry.[17] However, little has been done to understand the effect of regulation on the capacity of such a traditional industry like the food industry to innovate and to introduce new products and services in the market. The case study about the food industry aims to bridge the gap between the challenge to shape a regulatory framework, which allows the emergence of new markets, and even to use regulation as an instrument to foster innovation and the lack of adequate, reliable and systematic knowledge on their interrelationship.

Table 5.3-1: Key figures of the EU food industry

	1998	1999	2000
Production (billion €)	545	572	593
Added value (billion €)	123	127	133
Employees (million)	2.6	2.6	2.7
Number of companies[1]	24,823	25,746	26,095
1: Companies with more than 20 employees			

Source: Confederation of the Food and Drink Industries of the EU (CIAA) (2003): The food and drink industry in the EU – Key figures (http://www.ciaa.be/navigation/frames_uk/frameset1.htm).

The food and drink industry is of high relevance to the economy of the European Union. The total production value of the food industry amounted to € 593 billion in 2000 which equals more than 13 % of the total production value in the EU manufacturing sector (see Table 5.3-1). In total, more than 2.7 million people were em-

17 The complete case study prepared by Menrad (2003) can be found as working paper on the Cordis web site at http://www.cordis.lu/innovation-smes/src/studies.htm.

ployed by the EU food industry, which represents almost 11 % of the employees in the EU manufacturing industry.

However, in terms of share of production in total manufacturing and share of value added in total manufacturing, the EU food industry lost relative importance since 1993. The production value in the USA was just above € 500 billion in 2000. The Japanese food industry produced foodstuffs worth around € 259 billion, while in Canada food and beverages were produced valued at € 36 billion. The almost 29,500 companies of the US food industry employed more than 1.6 million people in 1999, representing around 9.6 % of all employees in the US manufacturing sector (Table 5.3.2).

Table 5.3-2: Key figures of the US, Canadian and Japanese food industry in 1999

	Value added (billion US$)	% of total manufac-turing	Number of companies	% of total manufac-turing	Number of employees (1,000)	% of total manu-facturing
EU	136.0	10.7	25,746	-	2,548	11.8
Can-ada*	13.8	10.9	3,206	9.8	218	12.7
Japan	101.4	10.2	65,212	10.9	1,294	13.1
USA	205.8	12.1	29,405	8.2	1,606	9.6
* 1997						

Source: Confederation of the Food and Drink Industries of the EU (CIAA) (2003): The food and drink industry in the EU – Key figures (http://www.ciaa.be/navigation/frames_uk/frameset1.htm).

Germany, France and the United Kingdom are the most important countries for producing food and drinks in the EU. In the year 2000 the companies in France produced food and drinks worth around € 121 billion, slightly ahead of Germany with a production value of € 119 billion (Table 5.3-3). In terms of number of employees the German food industry (584,000 employees) was ahead of UK (534,000 employees) and France (400,000 employees). The relative importance of the food and drink industry for EU national economies can be illustrated by the fact that in nine Member States this sector is among the top three manufacturing industries in terms of value added. Concerning this indicator it is ranked first in the United Kingdom, Denmark, Greece, Spain, the Netherlands and Portugal within the EU (CIAA 2003). In the Netherlands and Spain 26 % and 20 % respectively of the total value of the manufacturing production was generated by the food industry in 2000. In several EU Member States almost a quarter of the employees of the manufacturing industries works in the food and drink sector, notably in Ireland, Denmark and Spain (CIAA 2003).

Not only in terms of company size and ownership, but also in relation to the processed products, the food and drink industry represents a rather heterogeneous industrial sector. The production of different branches of the EU food industry is shown in Table 5.3-4 for the years 1997 to 2000. The heterogeneity of the food and drink industry is illustrated by the fact that other food products represent the biggest "branch" with a production value of € 156 billion in 2000 (table 5.3-4). This group includes bakery, pastry, chocolate, confectionery products as main categories, but also a large number of other food products which are not mentioned in detail in Table 5.3-4. Other important segments of the food industry are slaughter houses and meat-processing plants, which achieved a production value of € 113 billion in 2000, followed by the production of beverages (€ 98 billion) and dairy products (€ 95 billion).

Table 5.3-3: Structure of the food industry by Member States in 2000

	Production (billion €)	Value added (billion €)	Employees (1,000)	No. of companies
Austria	11[1]	3	77[1]	664
Belgium	23[1]	5	62	754
Denmark	16[1]	4	83[1]	275
Finland	8[1]	2	43[1]	1,785[1]
France	121[2]	21	400	3,645
Germany	119	27	548	6,035
Greece	5	1	43	1,036[1]
Ireland	15	4	47	687[1]
Italy	63	12	197	2,844
Portugal	11[1]	2	112[3]	1,916[3]
Spain	60[1]	13	363[1]	3,040
Sweden	15[1]	3	54	338
The Netherlands	35	6	103	876
United Kingdom	91[1]	30[1]	534[1]	2,200
EU-15	**593**	**133**	**2,666**	**26,095**

Companies with more than 20 employees except:
1 more than 1 employee; 2 more than 3 employees; 3 more than 9 employees

Source: Confederation of the Food and Drink Industries of the EU (CIAA) (2003): The food and drink industry in the EU – Key figures (http://www.ciaa.be/navigation/frames_uk/frameset1.htm).

Table 5.3-4: Production of different branches of the EU food industry (billion €)

	1997	1998	1999	2000
Processed meat	109	102	109	113
Fish products	11	12	14	14
Processed fruit and vegetables	30	32	35	36
Oils and fats	35	29	26	23
Dairy products	88	88	93	95
Grain mill products and starch products	20	20	21	21
Animal feeds	34	35	38	37
Other food products	122	134	143	156
Beverages	86	93	93	98
Food and beverages total	**535**	**545**	**572**	**593**

Source: Confederation of the Food and Drink Industries of the EU (CIAA) (2003): The food and drink industry in the EU – Key figures (http://www.ciaa.be/navigation/frames_uk/frameset1.htm).

5.3.2 General Overview of the Regulatory Regime in the Food Industry

Due to the increasing internationalisation of food and commodity markets, political and regulatory factors gain increasing relevance for the food industry. By speeding up the integration of international markets and increasing numbers of international joint ventures, the food industry is more and more influenced by international legislation. Against this background, single national states are no longer able to have an independent food legislation for their own country.

The standards of the so-called *Codex Alimentarius* have specific relevance for food production and food processing. The *Codex Alimentarius* encloses all standards, voluntary agreements and recommendations of the so-called *Codex Alimentarius* Commission which is the highest international committee for defining world-wide accepted standards for foods. In 2000 the membership of the *Codex Alimentarius Commission* comprised 165 countries representing 98 % of the world's population. Currently, the *Codex Alimentarius* contains more than 230 standards, more than 3,000 upper levels of pesticide residues and more than 1,000 assessments of food additives. The Codex develops standards or gives recommendations on labelling issues, food additives, dietary food products, harmful substances in food, analytical methods, aspects of general food hygiene, the control of food imports and exports

as well as levels of residues of veterinary pharmaceuticals and pesticides in foods. The increasing relevance of this type of standards is underlined by the fact that an increasing number of countries are transforming the Codex's standards into national law.

The EU legislation on foodstuffs (with some exceptions like novel foods and novel food ingredients) leaves food industry companies free to market their products without pre-market approval. They have only to assure that their products are safe and do not mislead the consumer. These requirements must be met under the sole responsibility of the company and are subject to post-marketing controls by public authorities. In April 1997 the European Commission published a Green Paper "The general principles of Food Law in the European Union" which defines a regulatory framework which covers the entire food chain. The Green Paper had the objectives to ensure a high level of protection of public health and safety and of consumer protection, to ensure the free movement within the single market, to base legislation on scientific evidence and risk assessment, to ensure the competitiveness of the European industry and enhance export prospects, to place the primary responsibility for safe food with industry, producers and suppliers and to ensure that legislation is consistent, rational and clear. Following a series of food scandals in the 1990s, the European Commission proposed the establishment of an independent European Food Safety Authority in 2000 which should be responsible for independent scientific advice on all aspects related to food safety, operation of rapid alert systems and communication of risks. In addition, suggestions for a new legal framework concerning food safety, control activities, consumer information and international arrangements related to food safety were given.

In the USA foods are regulated under the Federal Food, Drug and Cosmetics Act (FFDCA). This Act was the first and most comprehensive law in the world covering production, distribution and trade of foods, drugs, medical devices and cosmetics. The FFDCA defines foods and standards for food, adulteration of food as well as regulations for misbranding. Under FFDCA the Food and Drug Administration (FDA) oversees safety and labelling of food products with the exception of those containing meat or poultry which are controlled by the United States Department of Agriculture, Food Safety and Inspection Service (FSIS). In the USA there are no federal requirements that food manufacturing companies have to be registered or get pre-market approval of food as it is the case for manufacturers of pharmaceuticals and medical devices. However, for some categories of food, such as seafood and low-acid canned foods, complex quality control programmes for manufacturing are mandatory. The US food safety system is based on strong but flexible science-based legislation and industry's leader responsibility to produce safe foods. In addition, mandatory labelling of food ingredients was introduced in US legislation in 1990.

5.3.3 GMOs and Novel foods

Since the mid 1990s genetically modified (GM) plants are being marketed and cultivated which can enter the food chain. In addition, genetic engineering approaches are regarded by their protagonists as major tools to increase productivity and efficiency in food processing in future. On the other hand, an intensive public debate is carried out globally concerning the safety of these approaches and derived novel foods, their health and environmental effects as well as their wider socio-economic impacts.

Since genetically modified organisms (GMOs) and derived novel food products represent new developments in the area of food production and food processing, there have been relatively restricted experiences with this type of products. Therefore, state authorities took specific activities to deal with potential risks of GMOs. The general targets of the respective legislations are to ensure human health when consuming GMOs or derived novel foods, to prevent or minimise potential harm of GMOs to the environment as well as to provide the necessary information in order to ensure the freedom of choice of consumers or users of such products. In particular, the EU policy related to GMOs was intensively influenced by the emergence of several food crises during the 1990s, public criticism and undermined trust in public authorities to adequately manage such, as well as low consumer acceptance of agro-food biotechnology.

The fundamental question which arises concerning regulation of GMOs is whether GM crops or other GMOs have to be acknowledged like conventional crops or organisms, and therefore it is sufficient to use the general legislation valid for such crops or organisms or whether it is necessary to adopt different and specific regulations for GMOs. In the USA, GM crops are considered specific and different in terms of intellectual property rights since a patent can be granted to them but not to conventional crops. On the other hand, the introduction of GM crops in the environment and into the market follows the principle of "substantial equivalence" and therefore the same steps are required like for conventional crops.

In comparison to the USA, the EU takes the opposite approach concerning regulation of GMOs since patents cannot be granted to GM crops, but they are protected by the same breeders rights acknowledged to conventional crops. In contrast to the US procedure, the EU approach for environmental release and market approval of GMOs follows a rather strict interpretation of the "precautionary principle". For this purpose specific regulations have been put into force dealing with GMOs which require different and often more complex procedures than for conventional products.

GMOs have been regulated by the EU since the beginning of the 1990s. The EU Directives 90/219/EEC and 90/220/EEC were the first regulations which tried to

establish a system for controlling R&D and commercialisation of GMOs in the EU. These regulations were designed to protect citizens' health and the environment, and addressed authorisation, labelling and traceability issues relevant for GMOs. Since its enactment in the year 1990 Directive 90/220/EEC was criticised by different stakeholder groups and all notifications for market approval of agricultural GMOs raised concerns of one or several EU Member States during the 1990s. Therefore, in June 1999 a de facto moratorium on commercialisation of GMOs was agreed by the Community's Council of Environmental Ministers to suspend all approval applications for GMOs until implementation of the revised Directive 90/220/EEC. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms was passed in 2001. This Directive modified the rules for environmental release and market approval of GMOs significantly by restricting market approval to ten years and the requirement of post-market monitoring of each GMO. In further regulations a tolerance level of 0.9 % is foreseen for adventitious admixture of GM material and the European Commission has suggested labelling rules for GM derived novel foods, irrespective of whether DNA or protein of GM origin can be found in the final product.

In contrast to the EU the US FDA outlined a policy that did not require the market approval for GM crops in 1992 and placed the responsibility for investigating and reporting potential problems associated with GM foods with the companies. During this phase FDA recommended voluntary labelling of specific GM foods but opposed mandatory labelling of GM foods. In 2001 FDA introduced a pre-market notification procedure for GMOs.

Table 5.3-5: Cancelling of R&D projects related to GMOs in the last four years

Institution	**Number of respondents**	**GMO projects cancelled**	
		Yes	**No**
SME	33	54.5 %	45.5 %
Large company	28	67.5 %	32.5 %
University institutes	44	25.0 %	75.0 %
Public research institutes	37[1)]	21.6 %	75.1 %
Total	165[2)]	38.8 %	60.6 %

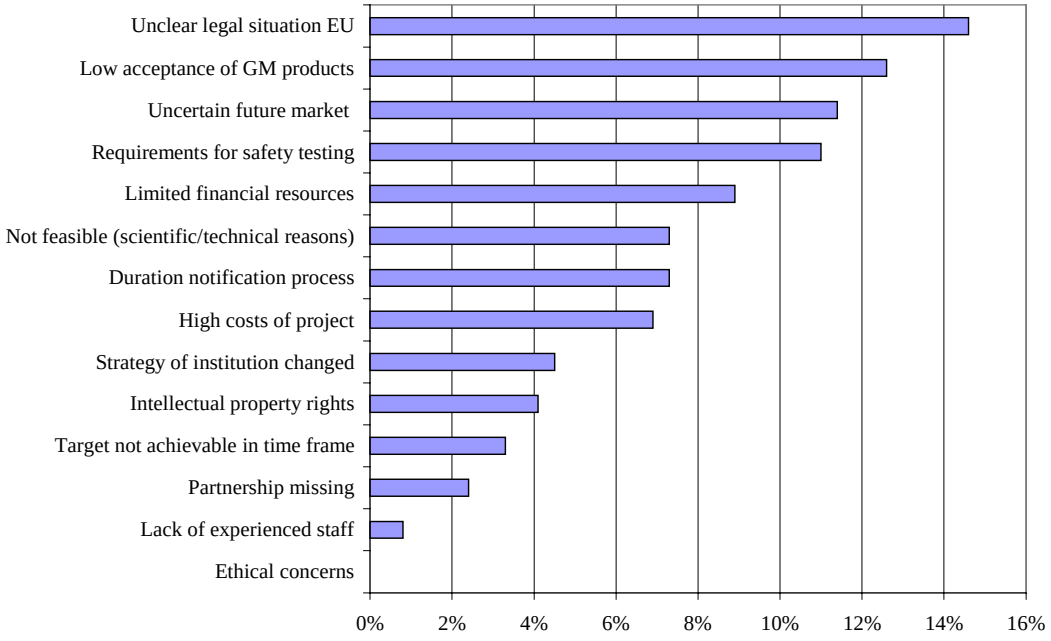
[1)] One respondent answered "Don't know"

[2)] Other institutions are included, 3 questionnaires without an answer to this question.

Source: Lheureux, K.; Libeau-Dulos, M.; Nilsagard, H.; Rodriguez Cerezo E.; Menrad, K.; Menrad, M.; Vorgrimler, D. (2003): Review of GMOs under research and development and in the pipeline in Europe. Seville: Institute for Prospective Technological Studies; Karlsruhe: Fraunhofer Institute for Systems and Innovation Research (http://www.jrc.es/home/publications/ publication.cfm?pub=1091).

In the EU there is still a broad pipeline of R&D activities related to agricultural and food GMOs which is fuelled by large multinational companies, SMEs, universities and research institutes. However, field trials with GMOs have dropped by 76 % since the introduction of the de facto moratorium due to the unclear legal situation in the EU, high costs and time requirements for safety testing, low consumer and user acceptance of GM products as well as uncertain future market perspectives (see Figure 5.3-1).

Figure 5.3-1: Reasons for cancelling R&D projects related to GMOs (multiple answers)



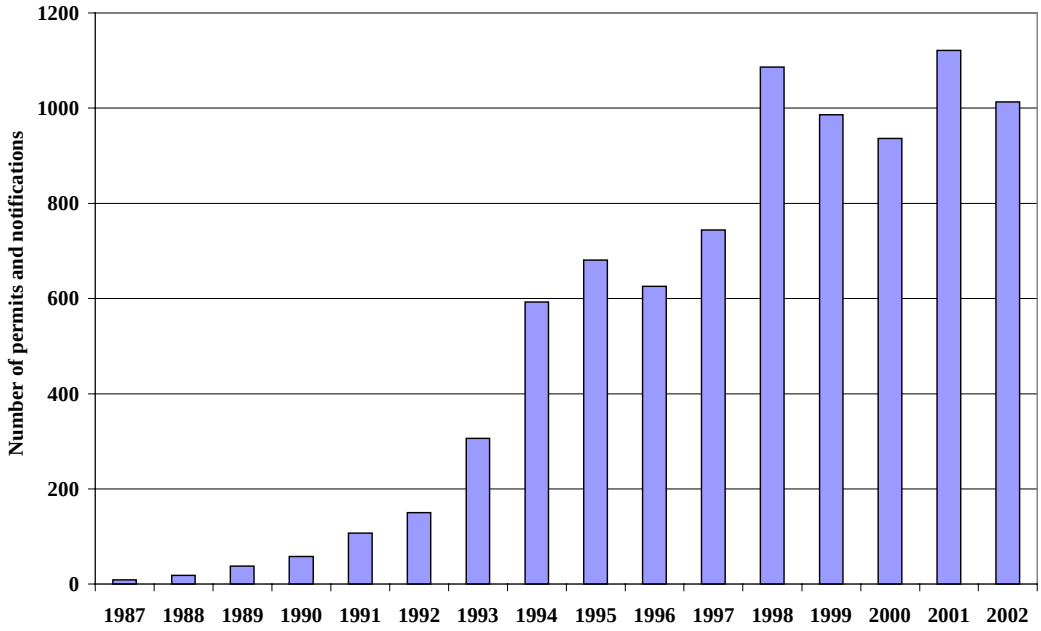
Source: Lheureux, K.; Libeau-Dulos, M.; Nilsagard, H.; Rodriguez Cerezo E.; Menrad, K.; Menrad, M.; Vorgrimler, D. (2003): Review of GMOs under research and development and in the pipeline in Europe. Seville: Institute for Prospective Technological Studies; Karlsruhe: Fraunhofer Institute for Systems and Innovation Research (http://www.jrc.es/home/publications/ publication.cfm?pub=1091).

Combining the findings of Lheureux et al. (2003) with the analysis of the performance of scientific publications in different subfields of biotechnology (Reiss and Dominguez Lacasa 2003) provides evidence that the unclear legal situation with respect to the commercialisation of GMOs which emerged in the second half of the 1990s led to the cutting down of research activities in plant biotechnology which can be measured as decreasing scientific output. In more general terms, the unclear legal situation related to GMO on the commercial side seems to have a negative feedback on the science base. This could give reason for concern that once the legal environment would become more stable and more favourable for commercialisation

of GMOs, the EU knowledge base would be less prepared to provide the required know-how.

In contrast to the situation in the EU, field trials with GMOs did not fall significantly in the USA in the last five years and several GMOs have been approved and cultivated to a high extent. There are several indications that in particular SMEs have given up innovation activities related to GMOs since the introduction of the de facto moratorium in the EU.

Figure 5.3-2: Total number of field trials with GM plants in USA



Source: Animal and Plant Health Inspection Service (APHIS) (2002): Test conducted under USDA regulations (http://www.nbiap.vt.edu/biomon/datacat.html).

The "proof of principle" of the differing GMO-related regulatory approaches of the USA and EU cannot be provided so far, since no consumer or user reactions which are based on purchasing behaviour can be measured in the EU. In this sense the case study on GMOs represents a field in which political decisions impede the functioning of the market mechanism, i. e. other areas of political intervention are regarded as being more relevant than innovation aspects. In addition, the GMO case represents a good example of the differing acceptance levels of risk and the handling of uncertainty which a society is willing to accept –which results in differing regulatory regimes and differing priorities of political actors.

5.3.4 Functional Food

With Functional Food a new generation of food products is moving into the supermarket shelves. These foods are not intended only to satisfy hunger and provide humans with the necessary nutrients, but also to prevent nutrition-related diseases and increase the physical and mental well-being of consumers. Functional Food contains specific ingredients to which particular effects on human health and well-being are attributed.

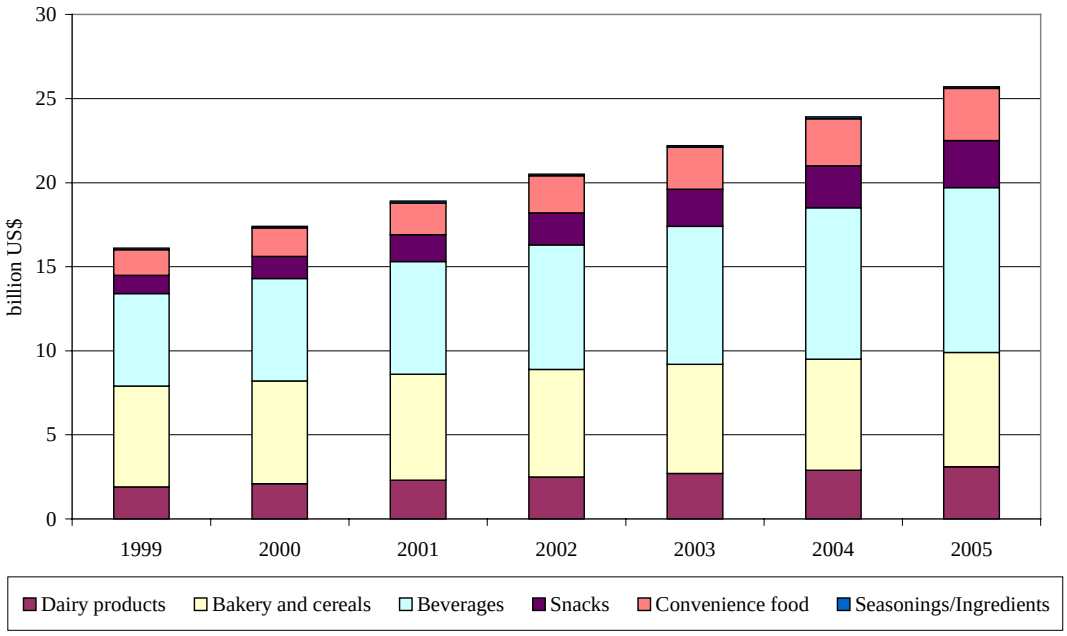
From a legal point of view, Functional Food is positioned in a transitional zone between food and pharmaceuticals. In the EU, its Member States and USA food and pharmaceutical products are subject to different regulation regimes and are – at least in the EU – regulated by separate relevant authorities. Another fundamental difference between these two product fields is the aspect that pharmaceuticals and other medicinal products require pre-market approval by state authorities, while EU and US legislation on foodstuffs (with a few exceptions like e. g. novel foods or food additives) leaves companies free to market their products, if they are safe and do not mislead consumers and afterwards they are subject to post-marketing control by public authorities. Since Functional Food is positioned in a "grey zone" between these two areas, high uncertainty emerges both for commercial activities of companies as well as for consumers. Due to the novelty character of Functional Food, additional questions arise concerning the safety and efficacy of such products, the required testing and monitoring methods, and their impact on consumers' nutritional behaviour as well as the institutional procedures and responsible authorities.

In the EU there is no harmonised or specific regulatory framework nor a precise legal definition of Functional Food, so that the general regulations valid for food are relevant for Functional Food as well. However, there are differences in the practical handling of these general regulations with regard to Functional Food between the EU Member States, thus hindering the development of a common market for such products. Due to the absence of specific regulations, the Novel Food Regulation was used for single Functional Food products applying for market approval in the EU in recent years. Another important bottleneck for Functional Food represents the fact that no harmonised legislation on health claims on Community level exist so far, which results in differences in the practical handling of such claims between the Member States. Under the existing regulatory framework in the EU, it is prohibited to attribute to any foodstuff the property for preventing, treating or curing a human disease or referring to such properties.

In contrast to the EU situation, food manufacturers in USA can use about 13 generic claims to inform consumers about the health benefits of Functional Food products which have been approved by the FDA since 1990. The regulatory framework for these activities was provided with the passing of the Nutritional Labelling and Education Act (NLEA) in 1990. In order to protect consumers from unproven health

claims, the respective claims have to be supported by the totality of publicly available scientific evidence. In addition to labelled food products, Functional Food is often marketed as a food supplement in the USA.

Figure 5.3-3: Market development of different groups of Functional Food in the USA



Source: Centrale Marketing-Gesellschaft der Deutschen Agrarwirtschaft mbH (CMA) (2002): Functional Food – ein Regionalvergleich. Bonn: CMA.

The market of Functional Food has developed faster and to larger market volumes in the USA (Figure 5.3-3) compared to the EU. While the total US market of Functional Food is estimated at 15 to 20 billion US$ (around 2 % of the US food market), the corresponding EU sales figures amount to around € 4 to 8 billion (less than 1 % of the total EU food market). Important product categories of Functional Food in the EU are functional dairy products, ACE drinks and non-alcoholic beverages fortified with other functional ingredients, cholesterol-lowering margarine and a multiplicity of niche products mainly in confectionery, bakery products, breakfast cereals or babyfood. It can be assumed that Functional Food will increase considerably its market volume in the coming years, driven by scientific and technical developments in nutrition-related research, the interest of food companies in growing segments in the food market as well as consumers' interest in innovative products supporting their health and well-being.

A major bottleneck for the future development of Functional Food in the EU represents the unclear legal situation concerning procedure and factual requirements for

market approval of such products as well as the use of health claims. This lack of a clear regulation and definition of Functional Food and non-harmonised procedures between the EU Member States impedes the potential growth of this market. Thus, the EU food industry cannot take full advantage of a potential growth segment in the mature and stagnating food market in the EU.

5.3.5 Organic Food

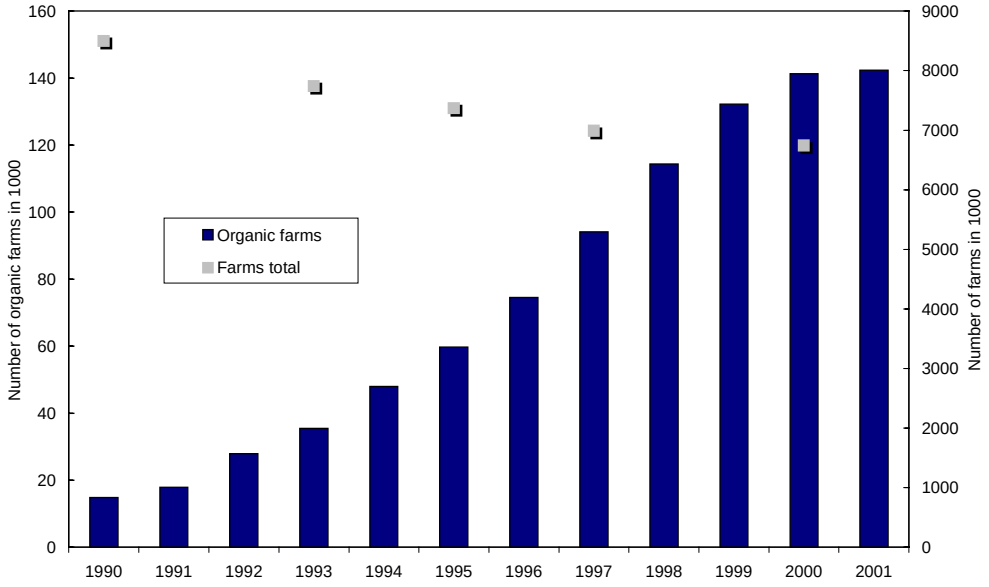
During the 1980s many agricultural markets of the EU were characterised by surplus of production as well as increasing costs for financing the Common Agricultural Policy (CAP). In addition, agriculture was criticised for ecological damage (e. g. loss of biodiversity in agro-ecosystems, pollution of ground water with nitrate, or agro-chemical residues). In this context the shaping of CAP was criticised for causing high costs and indirectly contributing to negative ecological impacts caused by intensive agricultural production. Therefore the European Commission and several Member States took initiatives to support organic farming.

At the end of the 1980s both the EU and USA took initiatives to develop a specific regulatory framework for production, processing and trade of organic products. Major targets of the related policies were reducing costs of market stabilisation measures for conventionally produced agricultural commodities, supporting environmental-friendly ways of agricultural production and protecting consumers from being misled in the area of organic foods. While the US policy focussed solely on defining standards for producing, processing, marketing and importing organic products, the European Commission followed a dual strategy, which firstly supported conversion of conventional farms to organic agriculture using direct payment schemes, and secondly improved market transparency by defining, implementing and controlling clear standards for production, processing and marketing of organic products.

Regarding timing of the respective legislation the USA took the leader when passing the Organic Food Production Act (OFPA) in 1990. However, it took until 2000 before the OFPA was fully implemented and nation-wide standards for organic products were put into force in the USA. With Regulation 2078/92/EC a common regulatory framework was established for EU Member States to implement policies to support organic farming which was introduced in most countries in 1994 and 1995. An important part of this Regulation are direct payments for conversion to organic farming. Another important key element of EU legislation in the field of organic food products represents Regulation 2092/91/EEC which created a common legal definition for organic farming and the respective products, covering all EU Member States and trade with third countries. The same requirements were introduced for animal organic products in 1999.

Both in the USA and in the EU the introduction of the organic food regulation has had a strong impetus for supply and demand of such products, but EU farmers and food processors reacted faster and in much higher numbers (Figure 5.3-4): until 2000 around 2.1 % of all farms which operated 3.1 % of the total agricultural area of the EU have converted to organic agriculture in comparison to 0.32 % of all US farms being organic in 2001 with 0.25 % of the operated farm area. In particular, producers of plant products like fruits and vegetables, potatoes or cereals have increased organic production significantly during the 1990s, but at least in the EU production of organic livestock products like milk or eggs seems to grow at high rates in recent years.

Figure 5.3-4: Number of organic and conventional farms in the EU 1990 to 2001



Sources: Organic Centre Wales 2003**,** Yussefi & Willer 2003

This much stronger increase of domestic organic production in the EU can be linked to the direct payments provided by the European Commission and national governments in order to reduce existing technical, market-related and financial risks for farmers. As shown in the US example it does not seems to be sufficient to solely reduce transaction costs on the market by introducing standards for organic products and inspection systems for controlling these standards, but additional financial incentives seem to be necessary to foster such a development – as it was implemented in the EU. It can be questioned how long such direct payments should be given to farmers willing to convert to organic agriculture.

In the consumer markets, there is a fast growing demand for organic products in the USA and EU. Although there are some difficulties concerning data availability, both markets are estimated at around € 10 to 13 billion with significant regional

differences. In the EU "mature" organic markets in countries like Austria, Denmark, Sweden, Finland can be observed parallel to "emerging" organic markets (e. g. Greece, Portugal). For future growth of the organic market (which is expected by experts both for the USA and EU) clear and reliable standards for organic products and corresponding consumer information, increasing interest and activities of the processing industry, as well as increasing sales in conventional supermarkets are regarded as key success factors. In this sense, the US and EU regulation provided the starting point for innovation activities in the organic food area which was rewarded by consumers in recent years.

Table 5.3-6: Organic products in % of the produced volume of selected agricultural products in the EU in 2000

	Cereals	Potatoes	Vegetables	Fruits	Milk	Beef	Eggs
Austria	2.0	4.2	4.8	0.8	14.1	4.5	3.5
Belgium	0.5	0.3	0.6	0.4	0.9	0.3	0.3
Denmark	1.3	2.2	15.9	-	9.4	2.9	15.1
Finland	3.5	1.0	3.7	8.3	0.9	1.0	1.2
France	0.2	0.6	1.6	1.3	0.6	0.2	2.1
Germany	0.9	1.1	3.7	3.5	1.3	2.9	1.4
Greece	0.1	0.0	0.3	0.0	0.0	0.0	0.0
Ireland	0.1	0.8	0.7	0.9	0.1	0.2	-
Italy	2.8	0.3	0.3	5.1	0.3	0.0	0.3
Luxembourg	1.2	0.8	0.7	0.0	0.0	0.3	5.6
Portugal	2.9	0.2	0.2	1.4	0.0	0.0	-
Spain	0.4	0.4	0.4	0.9	0.1	0.5	0.1
Sweden	2.4	2.4	6.5	2.1	3.0	2.0	2.1
The Netherlands	0.7	0.3	2.2	0.6	0.9	0.3	0.3
United Kingdom	0.2	0.5	1.9	1.8	0.6	0.2	2.0
Average EU-15	**0.8**	**0.8**	**1.0**	**2.3**	**1.5**	**0.9**	**1.3**

Source: Hamm, U.; Gronefeld, F.; Halpin, D. (2002): Analysis of the European market for organic food. Aberystwyth: University of Wales Aberystwyth, School of Management and Business.

5.3.6 Concluding remarks

The focus of innovation activities in the food industry has shifted in recent years. While in the past innovation activities of the food industry strongly depended on technical developments in their supplying industries, currently innovation activities of the food industry are mainly demand-oriented, which results in a high number of new or modified products which are often combined with process innovations.

In many innovative fields with relevance for the food industry, the political and regulatory framework conditions in the EU often do not keep pace with scientific and technical discoveries or developments on the demand side. This relates in particular to regulatory aspects in which intensive discussions and co-ordination activities are required between the different Member States. Such a situation of legal uncertainty or non-harmonised regulatory conditions between the different Member States often impedes innovation activities and may result in a loss of market opportunities. In this sense, a clear and harmonised regulatory framework in innovative fields seems to be a necessary, but not sufficient prerequisite for the development of new products or services. Such a situation of legal and regulatory certainty is in the interest of both industrial companies (as basis for commercial activities) and consumers (in particular for "credence goods"). In this sense there is need for clarification, harmonisation and implementation of regulations in the EU, in particular for those innovative fields with relevance for the food industry in which consumers are interested in the respective products.

In particular in highly interdisciplinary-oriented innovation fields of the food industry (like Functional Food), the institutional framework and administrative responsibilities impede innovation activities, since differing competent authorities are responsible for the implementation, administration and control of existing regulations. In this sense, scientific and technical innovations require organisational changes which often take place with significant time delays. This is valid both for the EU as well as for the Member States. Therefore, a more flexible framework for regulations should be created for newly emerging innovation fields which can be jointly formed by public authorities and early innovators.

As shown in the case study on organic food products, the definition of standards and the creation of labelling and control procedures does not seem to be sufficient for an early and fast take-off on the supply side. Although transaction costs are reduced on the market side with these activities, the high technical and market-related risks impede farmers to convert conventional farms to organic agriculture. In such a case time-restricted and adopted financial incentives seem to be an adequate instrument to speed up the adoption of an innovation.

5.4 The Impact of Regulation on the Development of New Technologies in the Environmental Sector

5.4.1 Background and Objectives

With the economic slowdown of the early 2000s, the analysis of the interaction between regulation and innovation has become even more important than before.[18] There are many reasons for regulation. One reason which is not disputed is the existence of external costs. Environmental problems are one of the most prominent cases for external costs. Thus, since the late 1960s, environmental regulation has been a major political issue in all industrialised countries. Thus, the question arises what the role of regulation has been in shaping new markets with new innovations.

Within environmental regulation, a dichotomy exists between theory and practice. On the one hand, in almost every country, regulation mainly takes the form of command and control policies. Economic theorists, on the other hand, arguing from a top-down view, claim that market-based instruments such as emission taxes or tradable certificates have to be favoured with regard to innovation. However, in contrast to economic theory, other approaches explain the effects of environmental regulation on innovation by the importance of other factors, which are sometimes called soft context factors. This approach claims that factors such as the existence of long-term policy goals, or the style of regulation are much more important for successful innovations than the use of the different policy instruments. Another group of authors argue that constant pressure to adapt to new challenges is necessary to mobilise the innovation potential. Another approach which also plays down the importance of the design of policy instruments is based on the concept of innovation systems. Here the functioning of the system, consisting of all relevant players from R&D institutions over suppliers and users of technology until the end consumers, and their interactions among each other, decides on the level of innovation.

The situation does not become much clearer when analyses of specific case studies are taken into account. Clearly, environmental innovations have taken place parallel to regulations in the form of command and control policies. However, this does not resolve the question if these innovations were fostered by environmental regulations, or if they would have taken place even though there were command and control policies at the same time.

The goal of this section is to examine the relationship between regulation and innovation for two cases: the water sector and wind power. In addition to environmental regulation, aspects of economic regulation of both water utilities and electric utili-

18 The complete case study prepared by Walz and Kotz (2003) can be found as working paper on the Cordis web site at http://www.cordis.lu/innovation-smes/src/studies.htm.

ties play a role too. This emphasises the need to use a multidimensional framework in which various determinants of innovation are accounted for, instead of a linear causal relationship between regulation and innovation. In order to broaden the perspective, a case from the EU was contrasted with the perspective for the USA For the European perspective, a special reference to Germany was taken, which is one of the leading exporters of both environmental technologies and wind turbines. The analysis is based on available literature and was supported by various interviews with experts in the field.

This section is structured as follows: first, the environmental regulatory regime is characterised for both the EU and the USA Similarities as well as differences between the systems are identified, with special reference to Germany in order to compare the systems on the country level. Furthermore, a brief comparison of the environmental innovation output for both systems is presented. The third paragraph describes the results of the case study for water. For each country, the water policy, the innovations which have been observed, and the interaction between innovation and regulation are discussed and compared. In the fourth section, the results of the case study for wind power are presented. The chapter is organised in a similar way as the water case. In the final section, the results are summarised and conclusions for the relationship between innovation and regulation are developed and presented.

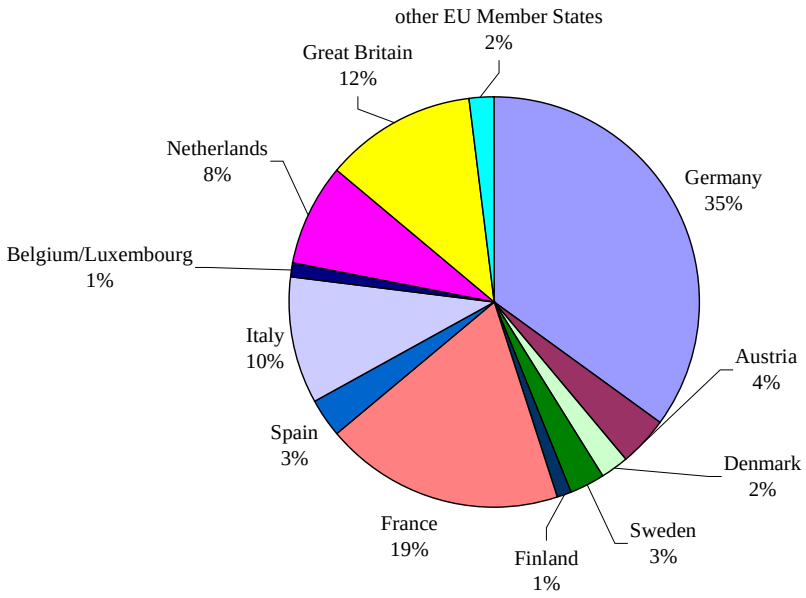
5.4.2 General Overview of the Regulatory Regime in the Environmental Sector in the EU and the USA

The environmental regulation in the USA and Europe, especially Germany, shows various similarities. The increase in environmental regulation in the 1970-1980s was caused in both countries by an increasing public awareness in several fields of environmental protection. In addition, general environmental statutes and regulations applicable to all areas of environmental protection were passed since the late 1980s onwards, concerning environmental impact assessment, environmental liability, or the availability of environmental information. Furthermore, market-based instruments are gaining more importance. Nevertheless, both countries were and still are emphasising command and control policies to counteract environmental problems. However, there are some differences in the emphasis of the different approaches available. In Germany, application of the concept of "best available technology" (BAT) has been widely used. Together with a certain flexibility about how to interpret BAT by the decentralised bodies implementing the regulation, this allows a continuous increase in requirements if technological progress occurs. In the USA, however, the legislation focuses more on emission limits which gives less flexibility to the government body implementing the regulation.

The European environmental protection market in 1994 had a volume of about € 90 billion. One third of that market volume was accounted for by Germany with

€ 32 billion. The second-largest share of the European environmental protection market was accounted for by France with approximately € 17 billion. Great Britain had the third-largest market share with about € 11 billion. Further important environmental protection markets are Italy and the Netherlands. Other European Member States like Austria have market shares with a maximum of only 4 %.

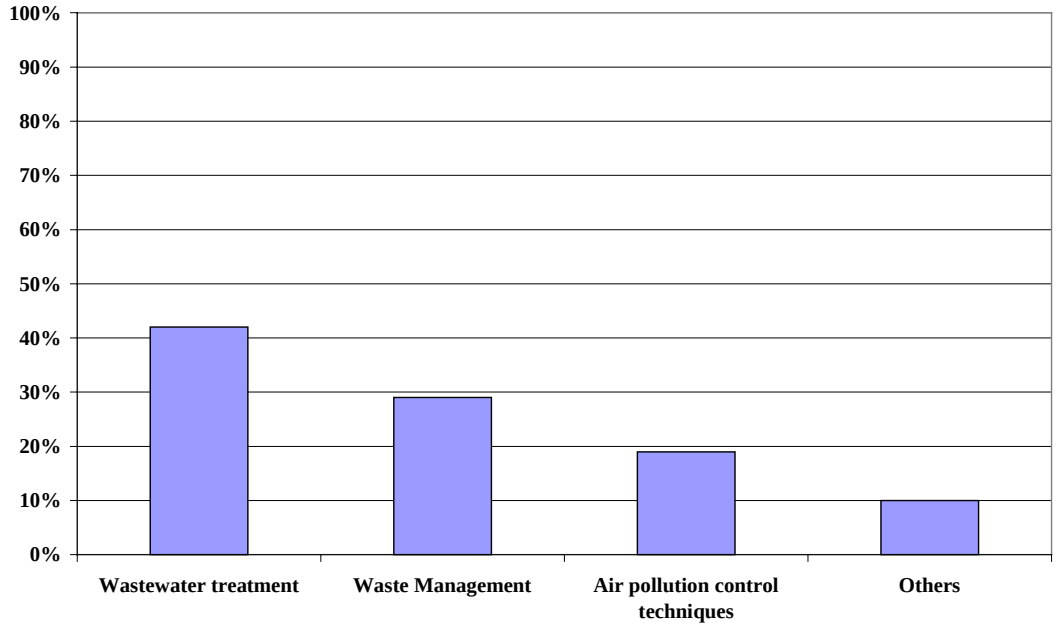
Figure 5.4-1: Market shares of European environmental protection market in 1994



Source: Lemke, M. und J. Wackerbauer (2000): Handbuch der Umweltschutzwirtschaft: Definitionen – Marktstudien – Potentialanalysen. München, Wien: Oldenbourg.

With € 37.5 billion (42 % of all environment protection expenditures) wastewater treatment was the most important market segment in the European Union in 1994. Secondary waste management took a share of € 25.7 billion (29 %) and air pollution control techniques ranked third with € 17.3 billion (19%). These three segments comprehended 90 % of all expenditures for environmental protection (Lemke, Wackerbauer 2000).

Figure 5.4-2: The most important segments in the European environmental protection market



Source: Lemke, M. und J. Wackerbauer (2000): Handbuch der Umweltschutzwirtschaft: Definitionen – Marktstudien – Potentialanalysen. München, Wien: Oldenbourg.

For comparison, the following table 5.4.1 shows a survey of the US environmental protection economy. The business volume in 1993 amounted in total to 110.3 billion US$.

Comparing the innovations which have been taking place requires the use of innovation indicators. The different indicators used can be grouped in input (e. g. R&D expenditure), intermediate (e. g. patents) and output (e. g. production values) oriented indicators (Grupp 1997). Analysing and comparing the indicator values for Germany, the USA and other major players gives an indication how the general rate of environmental innovation might have developed.

Table 5.4-1: Survey of the US environmental economy in 1993

Offer of product	Business volume 1993 in billions US$	
Environmental technology (producer)	**30.7**	**28%**
among:		
Water/wastewater	13.2	12%
Measure and control technology	1.8	2%
Air pollution control	3.8	3%
Waste management	11.2	10%
Integrated technologies	0.7	<1%
Services	**62.3**	**56%**
among:		
Environmental analysis	1.5	1%
Waste management	29.4	27%
Hazardous wastes	8.6	8%
Land reclamation	3.2	3%
Industrial cleaning	5.2	5%
Consulting and engineering	14.4	13%
Resources	**17.3**	**16%**
among:		
Secondary raw material	15.2	14%
Regenerative energy sources	2.1	2%
Total	**110.3**	**100%**

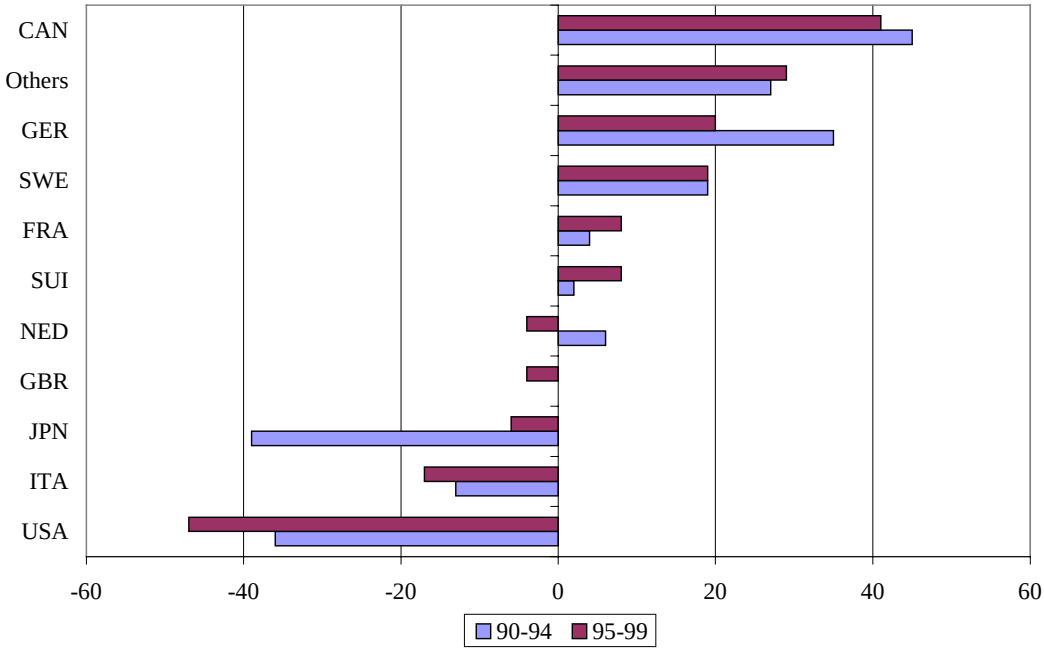
Source: Lemke, Wackerbauer 2000, p. 80.

Figure 5.4-3 shows the patent specialisation of environmental technologies in selected countries. Values higher than zero show an above-average level and vice versa. Two important aspects are worth noting:

- In contrast to the USA and Japan, which both have below average patents in environmental technology, Germany, Sweden and Canada have been specialising in environmental technologies.
- For the USA and Germany, the specialisation in environmental technologies has been substantially lower in the second half of the 1990s than in the first half.

The latter result is also reflected in the development of the overall number of environmental technology related patents: they increased steadily, increasing during the 1980s with a peak level in 1991. However, the proportion of environmental patent applications out of all European patent applications decreased about 20 % afterwards.

Figure 5.4-3: Patent specialisation of environmental technologies in selected countries



Source: Legler, H., Schmoch, U., Gehrke, B., Krawczyk, O. (2002): Innovationsindikatoren zur Umweltwirtschaft, Studien zum deutschen Innovationssystem Nr. 2-2003. Hannover: Niedersächsisches Institut für Wirtschaftsforschung, Karlsruhe: Fraunhofer-Institut für Systemtechnik und Innovationsforschung (http://www.technologische-leistungsfaehigkeit.de/_downloads/2_2003.pdf).

The patent specialisation in partitions of environmental technologies shows that, in international comparison, noise protection and air pollution control are the most important fields for Germany. Also in the field of recycling technologies and wastewater treatment, an above-average specialisation of research findings is achieved. In the case of the United States it is striking that there is an above-average focus on measurement and control technologies, whereas all other environmental technologies got negative specialisation indexes. In the EU, Sweden has the strongest profile in noise protection, whereas Canada is highly specialised in environmental technologies in general, especially in recycling and wastewater management.

The German exports of environment protection technologies can be ranked high. In some environmental technologies, Germany is the front-runner. In 1997 the German economy exported environmental technologies amounting to € 20.5 billion, that is nearly 5 % of all exports. In 2000 Germany was the world market's second largest exporter with a proportion of 16 % after the USA with a proportion of 23.5 %. The EU altogether accounted for 53.2 %

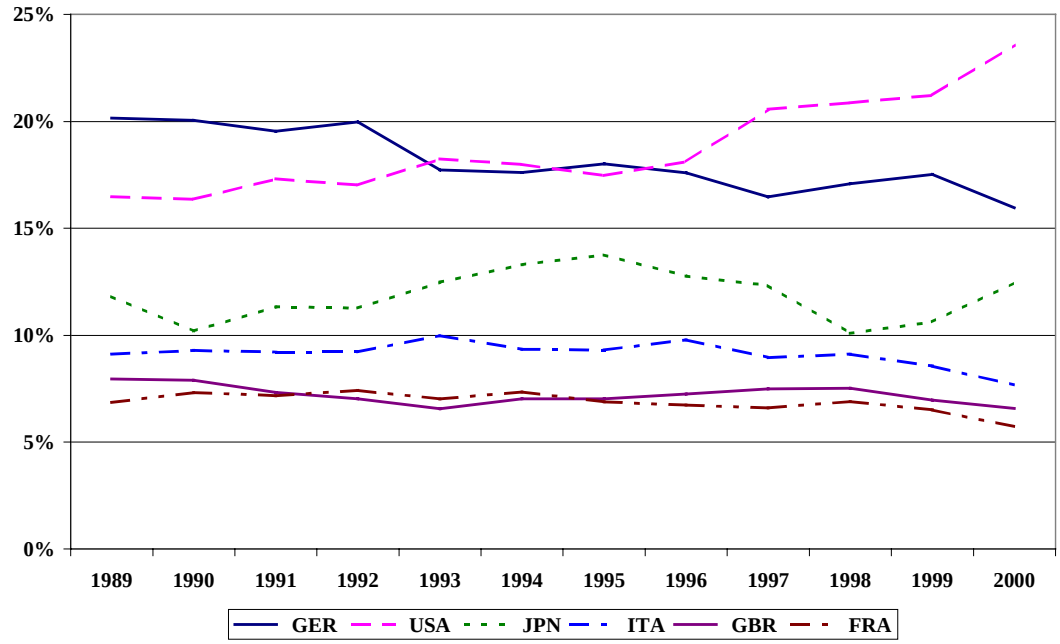
Table 5.4-2: Patent specialisation in partitions of environmental technologies

	Waste management	Recycling	Noise protection	Air pollution control	Measure and control technology	Wastewater management	Total environmental technology
USA	-54	-39	-41	-56	19	-76	-47
JPN	11	-32	-50	50	-35	-29	-6
GER	2	18	47	43	-19	12	20
FRA	48	-29	32	-24	35	3	8
GBR	6	-25	-68	-11	40	2	-4
SUI	49	38	5	-4	-7	-28	8
CAN	29	56	43	-62	-7	68	41
SWE	-24	-12	49	31	28	23	19
ITA	31	23	4	-62	-50	-42	-17
NED	-43	28	15	-79	-25	22	-4
Others	22	61	3	-48	-11	49	29

Source: Legler, H., Schmoch, U., Gehrke, B., Krawczyk, O. (2002): Innovationsindikatoren zur Umweltwirtschaft, Studien zum deutschen Innovationssystem Nr. 2-2003. Hannover: Niedersächsisches Institut für Wirtschaftsforschung, Karlsruhe: Fraunhofer-Institut für Systemtechnik und Innovationsforschung (http://www.technologische-leistungsfaehigkeit.de/_downloads/2_2003.pdf).

The shares in the world market do not account for both the size of a country and the overall specialisation of a country in the global economy. The German economy, for example, is much smaller than the US economy. Thus, the world market share of environmental technologies, which is in the same order of magnitude for Germany and the USA could be interpreted as a clear advantage for the German economy. On the other hand, the German economy in general is much more oriented towards exports than the US economy. In order to account for such differences, innovation indicators such as Relative Trade Share (RTS) and Revealed Comparative Advantage (RCA) are used in addition to world market shares. The positive algebraic sign of the RTS values means that the environmental products share of the world market supply is higher than the total of manufacturing industry. The positive algebraic sign of the RCA values represents that the export/import-relation of that product group is higher than the total of manufacturing industry (Legler et al. 2002).

Figure 5.4-4: World trade shares of environmental technology suppliers from 1989 to 2000

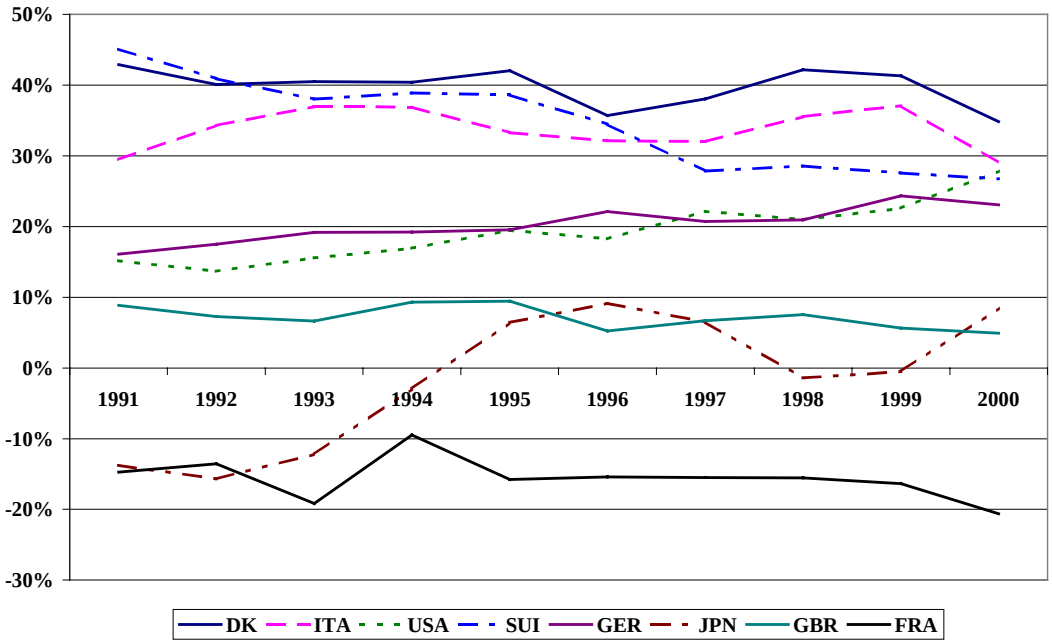


Source: Legler, H., Schmoch, U., Gehrke, B., Krawczyk, O. (2002): Innovationsindikatoren zur Umweltwirtschaft, Studien zum deutschen Innovationssystem Nr. 2-2003. Hannover: Niedersächsisches Institut für Wirtschaftsforschung, Karlsruhe: Fraunhofer-Institut für Systemtechnik und Innovationsforschung (http://www.technologische-leistungsfaehigkeit.de/_downloads/2_2003.pdf).

Germany possesses comparative advantages, i. e. positive values for RCA and RTS indexes in all classes of environmental technologies, particularly in technologies for waste management and air pollution control. Other EU countries with positive RCA values are the UK, Italy, Denmark, Spain. The same results emerge for the USA. Thus, these countries have been specialising in trading environmental technologies.

However, interpreting the data on innovation output, the change over the years also is important. Here, it is interesting to see that the position of Germany as world leader of environmental exports at the end of the 1980s has been somewhat diminished during the 1990s, even though the relative specialisation has remained about the same. However, the same applies for the other EU countries. In sum, the world market share of the EU in environmental technologies fell from 66.5 % in 1991 to 53.2 % in 2000.

Figure 5.4-5: Relative Trade Share (RTS) of selected OECD countries in potential environment protection commodities, 1991 to 2000



Source: Legler, H., Schmoch, U., Gehrke, B., Krawczyk, O. (2002): Innovationsindikatoren zur Umweltwirtschaft, Studien zum deutschen Innovationssystem Nr. 2-2003. Hannover: Niedersächsisches Institut für Wirtschaftsforschung, Karlsruhe: Fraunhofer-Institut für Systemtechnik und Innovationsforschung (http://www.technologischeleistungsfaehigkeit.de/_downloads/2_2003.pdf).

To sum up the arguments, environmental regulation has been established in the EU and the USA following the increasing pressure on the environment and its perception by the public during the 1960s and 1970s. Together with making regulations stricter in the 1980s, this has worked towards an increase in environmental innovations, as indicated by various innovation indicators. However, taking both the development of the patents and the output innovation indicators since the late 1980s together, two possible lines of arguments can be deducted.

- The reduction of the patent specialisation for both Germany and the USA in the late 1990s can be interpreted as a reduced innovation dynamics of environmental technologies. This can be explained by - relative to other areas – a lessening of additional requirements in the 1990s. However, this also supports a positive relationship between environmental regulation and innovation.
- Another line of argument is based on the changes in environmental strategies. In the 1970s and 1980s, environmental technologies were mostly so-called end-of-pipe technologies such as filters, catalytic converters, or wastewater treatment plants. During the 1990s, the so-called integrated environmental technologies

became much more important. Especially in fields gaining political importance, such as energy and climate policy, integrated technologies play a dominant role (Walz 1999). However, in contrast to the end-of-pipe technologies, it is much more difficult to separate the integrated environmental technologies from the overall technological progress (Jaffe et al. 1995). Therefore the innovation indicators mainly reflect changes in end-of-pipe technologies (Legler et al. 2002). Thus, the innovation indicators used for describing the innovation in the environmental field are probably less representative for describing the situation at the end of the 1990s than they were before. Indeed, the reduction in patent specialisation for Germany and – for most European countries – in overall world market shares in environmental technology might reflect a changing strategy of the environmental first movers. They switch to new paradigms of environmental policy, which do not typically fall under the heading of conventional environmental technology.

Thus, under this perspective, the two case studies on water policy and wind power gain additional importance. The water sector can be characterised as a sector with environmental technologies which are until now rather typical for conventional environmental technologies. Thus, the relationship between environmental regulation and innovation at wastewater treatment plants is typical for incremental innovations along an existing technological paradigm, which are covered rather well with the existing data on innovation indicators. The situation for wind power is rather different. Here a new technological paradigm is competing with conventional electricity generation. At the same time, even though these changes are motivated also from the environmental side, they are very different from the environmental technologies such as scrubbers which were a main field of environmental innovations at power stations in the 1980s (Wallace 1995) and which have been covered by the innovation indicators under the heading of air pollution.

5.4.3 Water Treatment

The water sector can be characterised as a sector with environmental technologies which are until now rather typical for conventional environmental technologies. Thus, the relationship between environmental regulation and innovation at wastewater treatment plants is typical for incremental innovations along an existing technological paradigm, which are covered rather well by the existing data on innovation indicators.

The German Federal Water Act and the US Clean Water Act form the basis of water policy in the respective country. Both were enhanced and amended in the 1970s and 1980s. In 1977 U.S. industries had to install "best practicable control technology" (BPT) to clean up wastewater discharges and US municipal wastewater treatment plants were required to meet an equivalent goal, i. e. secondary (biological)

treatment. In 1989 the industry had already to use the economically achievable best available technology (BAT), because the act required now a greater pollutant cleanup than BPT. In Germany, an amendment of § 7 a Federal Water Act in 1986 intensified the standards, especially for hazardous substances.

To sum up the argument, in both countries the foundations of the environmental regulation in the water sector were developed in the 1970s and made stricter in the 1980s. Thus, the broad development of environmental regulation of the water sector was rather similar between the two countries. The German and the US innovation system are also influenced by R&D policies, with a number of government programmes existing in both countries.

Both countries were important exporters of wastewater treatment technologies at the end of the 1980s. With a little over 20 %, Germany's world market share in wastewater treatment technologies was about equal to its overall share in environmental technologies. For the USA, the share of 10 % of wastewater treatment technologies was a little bit lower than its share in all technologies. The same conclusion also holds for the revealed competitive advantage in foreign trade. Thus, both countries had specialised on wastewater treatment technologies, Germany even more than the USA

This strong position clearly was influenced by the environmental regulation. The development of environmental patents in the 1980s for Germany clearly shows a strong increase in the 1980s. However, it was not only the regulation with command and control policies which pushed this development. The German emission charge on wastewater, with increasing tax rates until the early 1990s, also contributed to that effect. Furthermore, long-term policy goals were also very important in Germany, providing continuous guidance for the development of water protection technologies.

For Germany, the innovation indicators in the 1990s still show a high specialisation for wastewater treatment, but the figures have been decreasing. The detailed analysis has also shown that most of the innovation challenges can be traced back to the national regulations during the 1980s. Thus, with few exceptions, the requirements from the EU Urban Waste Water Treatment Directive did not lead to a new strong impulse from regulation. The technological basis, R&D policies, the need to increase water quality in East Germany, plus the elaboration of regulations along existing technological trajectories were strong enough to allow continuity of specialisation in wastewater treatment technologies, but rather with somewhat declining specialisation. Definitely German industry was not able to fully participate in the diffusion of wastewater treatment technology in other countries during the 1990s. Thus, in the 1990s, Germany was not able to fully exploit the role as lead market of wastewater technologies it had acquired during the 1980s. The USA in contrast, was

able to increase its world market share during the 1990s, even though it did not specialise on patenting in this area.

In the introduction, it has been argued that innovation is a complex process which does not follow simple stimulus response mechanisms. Indeed, the following arguments in particular are important to explain the innovation process in the water sector in addition to the development of environmental regulation:

- The water sector has been traditionally viewed as a natural monopoly; public ownership, protection of service areas, and price regulation are important aspects which are sometimes associated with lower competitive pressure on innovations.
- Particularly for Germany, the standardisation organisations in the wastewater sector form very important bodies for R&D spillovers. Nevertheless, it also has been shown that the innovators from the machinery and appliances industries are less integrated in the standardisation process than the rather traditional experts from civil engineering.
- In Germany and the USA, the wastewater treatment institutions are usually locally based, and even restricted to local activities. Thus, they have little incentive or even possibility to engage in the world market.
- Taken together, these aspects help to explain why there is an excellent technological basis in Germany on the one hand, which is, however, not fully reflected in the world market on the other.
- Furthermore, it has to be kept in mind that the innovations discussed so far have been mainly along the traditional trajectory of wastewater treatment. Indeed, there are some new challenges arising from the EU Water Framework Directive which might go beyond the traditional technological path, e. g. with regard to the development of new products and technologies in order to tackle new immission paths not previously considered. Furthermore, new concepts of the water sector employing decentralised technologies and leading towards a new paradigm are getting more and more attention. The strategy of a decentralised water sector not only poses new challenges for the development of innovative technologies, but also opens up the perspective of supplying the world market with concepts also appropriate for developing countries, which will form an important part of the world market demand for wastewater concepts in the future. It remains to be seen whether or not EU countries will be among the first movers seizing these opportunities.

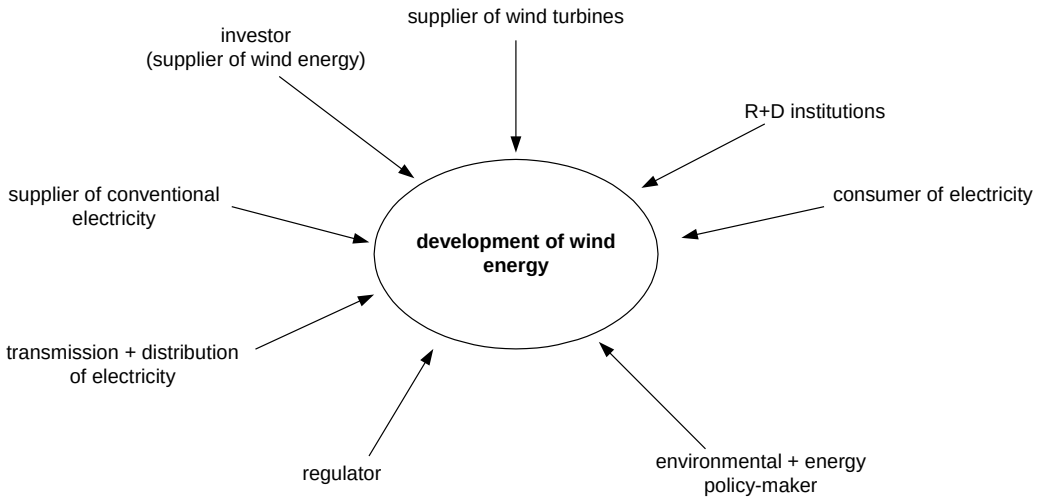
5.4.4 Wind Power

Wind power can be interpreted as a new technological paradigm competing with conventional electricity generation. At the same time, even though these changes are motivated also from the environmental side, they are very different from the environmental technologies such as scrubbers which were used at power stations in

the 1980s and which have been covered by the innovation indicators under the heading of air pollution.

Policies and regulations which influence innovations of wind turbines can be directed to different actors. Thus, it is important to identify the key actors within the field (Figure 5.4-6). First of all, there are the suppliers of wind turbines. They consist of companies which have a quite similar structure such as other companies within the investment good sectors. Secondly, there are the investors in wind power. They consist of the owners of the site, together with the capital owners, which typically are private investors, wind energy funds, and in some instances electric utilities. Thirdly, the electricity produced by the wind turbines must be brought to the customers. Thus, access to the grid is vital for wind power. Here the electric utilities play a key role. They are responsible for the transmission and the distribution of electricity on the one hand, but on the other, electricity from wind is substituting electricity supplied from other conventional power plants. Thus, the electric utilities are at the same time a competitor of wind power.

Figure 5.4-6: Important actors in the interface of regulation and innovation for wind power



Source: own sources.

The electric utility industry has been traditionally viewed as a natural monopoly subject to regulation. Even after liberalisation, which is based on the starting point that the generation of electricity is no longer a natural monopoly, there clearly is a need for some kind of regulation in order to prevent monopolistic exploitation of the ownership of the grid. Thus, the role of the regulation of access to the grid plays a very important role for the development of wind power.

Another important aspect of the innovation processes in the energy sector are the environmental problems associated with the use of conventional energy sources. The increase in renewable energies plays a very prominent role within the debate about sustainable development. This can be attributed to the effect that renewable energy in general tackles various problems discussed in energy strategies:

- Renewable energies are CO_2-free; thus they are an important piece of Community strategy to reach the Kyoto targets, and even more important, if one looks into the long-term reductions necessary to reach a stabilisation of CO_2 concentrations.
- Wind energy is a renewable resource; there are no problems of long-term security of supply which are associated with the depletion of fossil fuels.
- Renewables are not dependent on imports; thus, problems of short to medium security of supply, which are debated with regard to the re-concentration of oil resources in the Middle East, do not occur.

Thus, the role of energy and environmental policy-makers is extremely important to the development of wind industry. As long as the external costs and benefits described above (climate change, fossil fuel depletion, security of supply) are not included in the prices, wind energy cannot compete with conventional electricity supply. Thus, policies which in one form or the other work towards a level playing field are a key necessity for further development of wind energy.

There are different instruments used in most European countries to foster the development of wind power. The most important instruments which are used are:

- support for R&D (EU level and Member State level)
- direct subsidisation of installation of wind power, e.g. by tax measures
- fixed feed-in tariffs (e. g. Germany, Spain, Italy, Austria, Denmark until 2001) in some Member States, and
- quotas/bidding systems (e. g. UK, Ireland, France until 2001, Denmark since 2001).

Table 5.4-3: Instruments used in EU countries to foster wind energy

Instrument	**Implementation before 2001**	**New implementation since 2001 or planned**
Fixed feed-in tariff	BE, GER, DK, ES, GR, LU, PT	AT, FR
Bidding schemes/quotas	IE, SE, UK	DK, IT, NL
Tax measures	GER, DK, ES, FI, NL, SE	

Source: PRETIR (2002): Implementation of Renewable Energy in the European Union Until 2010, Project executued within the ALTENER Programme, Utrecht/Brussels (http://www.ccsindia.org/Electricity/int_european.pdf).

The comparative analysis of the regulatory policies reveals some differences and similarities between the USA, the EU and Germany in particular. The instrument of R&D policies to spur innovation in the early phase of experimentation is used widely. However, the USA was scaling down its effort by about 90 % in the 1980s, marking a substantial break in the continuity of the policy. Furthermore, a substantial part of the California wind energy boom in the 1980s was supplied by Danish firms. Thus, at the beginning of the 1990s, no national wind supply industry existed in the USA powerful enough to participate in the world-wide boom to come in the 1990s. In some European countries, however, the R&D policy evolved constantly over time. Thus, even though the strength of the many German actors was rather weak at the beginning of the 1990s, an innovation system for wind energy with a considerable variety and a substantial accumulation of knowledge existed.

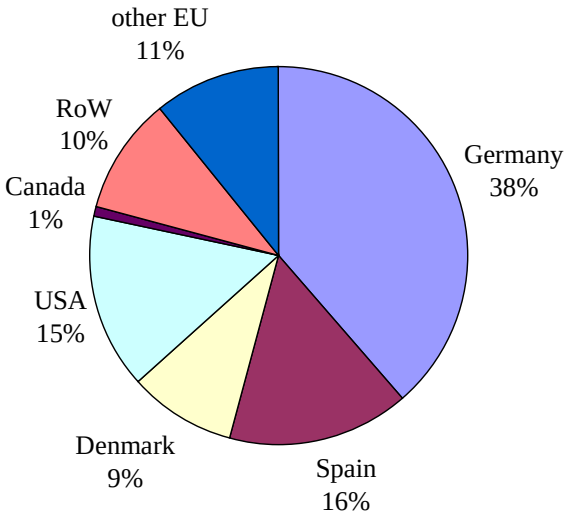
This different starting point on the supply side at the beginning of the 1990s was supplemented by different policies to foster diffusion. In the USA, the primary policy was a subsidy in form of a tax credit, supplemented by a tradable quota system in some states and state subsidies. In some European countries, among them Germany, the main instrument used were fixed feed-in tariffs above the avoided costs of utilities. It is difficult to compare the intensity of subsidisation between the countries. The difference between feed-in tariffs and avoided costs in Germany seems to be larger than the tax credit per kWh granted in the USA. However, for a more complete comparison, the effects of the tradable quota system implemented so far and the state subsidies would have to be included on the USA side. Thus, it can be argued that the intensity of subsidisation will narrow down substantially in a more complete analysis.

Probably more important than differences in the intensity of subsidisation might be the predictability of the paybacks in schemes using fixed feed-in tariffs (e.g. Germany and Spain in Europe) and countries, which use tradable quota systems (e.g. the United States and a few European countries such as the UK, Ireland and Italy). The analysis for Germany and the USA, which also stand as representative for the two different schemes, both revealed that the predictability of paybacks was identified as a key for the availability and cost of capital to the investors. In contrast to the situation in the USA, investors under a fixed feed-in tariff scheme are able to present predictable paybacks for their investments to the financial institutions. The analysis revealed that German investors are much more likely to receive private funds at normal capital costs compared to the investors in the USA, who are much more likely to be paying premium capital costs. This also helps to explain some of the differences of wind power development within the EU. The difference between both schemes might even become more important if the volatility of the electricity prices increases with liberalisation of the electricity markets.

The detailed comparison of the diffusion process in Germany respective other European countries and the USA reveals the importance of both the differences in

the functioning of the innovation system from the 1980s onwards and the effects of the regulation. Compared to Germany with a mere of 20 MW installed at the end of 1989, the USA clearly seemed to have the lead in the diffusion of wind power in the 1980s. However, the situation changed dramatically in the 1990s. The USA did not participate in the take-off of wind power as much as some European countries. Germany, in contrast, had an enormous take-off in the 1990s taking the lead in world installations. Indeed, Germany already installed more than 10,000 MW leading the world in total MW of wind power installed. Given the difference in the size of the countries, it can be argued that the USA at present is lagging substantially behind. The success of the leading European countries was achieved by fixed feed-in tariffs, which were adjusted to the market trends and needs over time (e. g. levelling out between electric utilities, digression of feed-in tariff). In general, the analysis indicates that the predictability of fixed feed-in tariffs used in Germany, Spain and for a long time in Denmark stimulates market growth more than the alternative instruments of direct subsidisation and quota systems used for example in the USA.

Figure 5.4-7: Shares of installed wind capacity in 2002

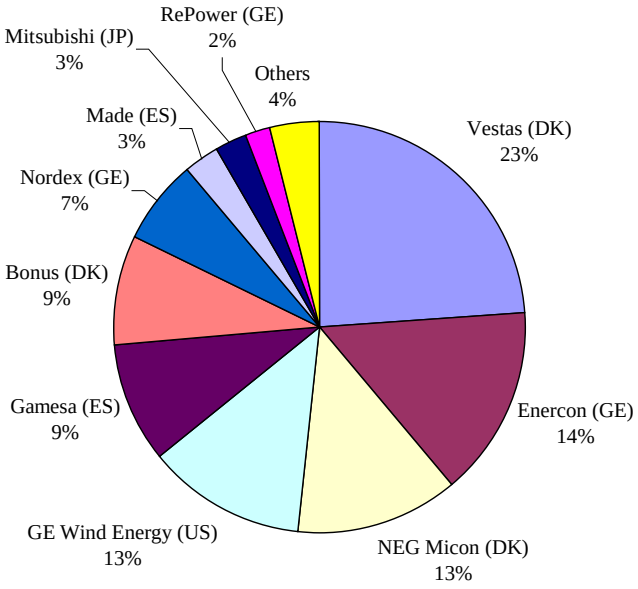


Source: AWEA (2003): Record Growth for global wind power in 2002 (http://www.awea.org/news/news030303gbl.html) and EWEA (2003): Europe 's Wind Capacity–June 2003 (http://www.ewea.org/documents/WIND_CAP_JUNE03.pdf).

The phase of market expansion in Germany led to virtuous circles which let German producers catch up with the Danish ones. Furthermore, the relatively high political weight attributed to environmental issues such as global warming increased the legitimacy of wind power and gave additional guidance for the direction of re-

search. In sum, the German innovation system of wind power had a high functionality during the take-off phase in the 1990s. The result was that, at the beginning of this century, companies in Germany and Spain joined the Danish ones as key players in world-wide wind turbine supply (Figure 5.4-8).

Figure 5.4-8: Market shares of the suppliers of wind turbines world-wide in 2001



Source: Ender, C. (2002): International Development of Wind Energy Use – Status 31.12.2001, in: DEWI Magazin no. 21 August 2002, pp. 24-30, p. 28.

Table 5.4-4 Annual installations of wind turbines in MW in different countries

Country	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**
Germany	529	812	1586	1665	2627	3247
USA	29	577	477	165	1635	410
Spain	116	368	932	1024	1050	1493
Denmark	200	310	325	603	115	497

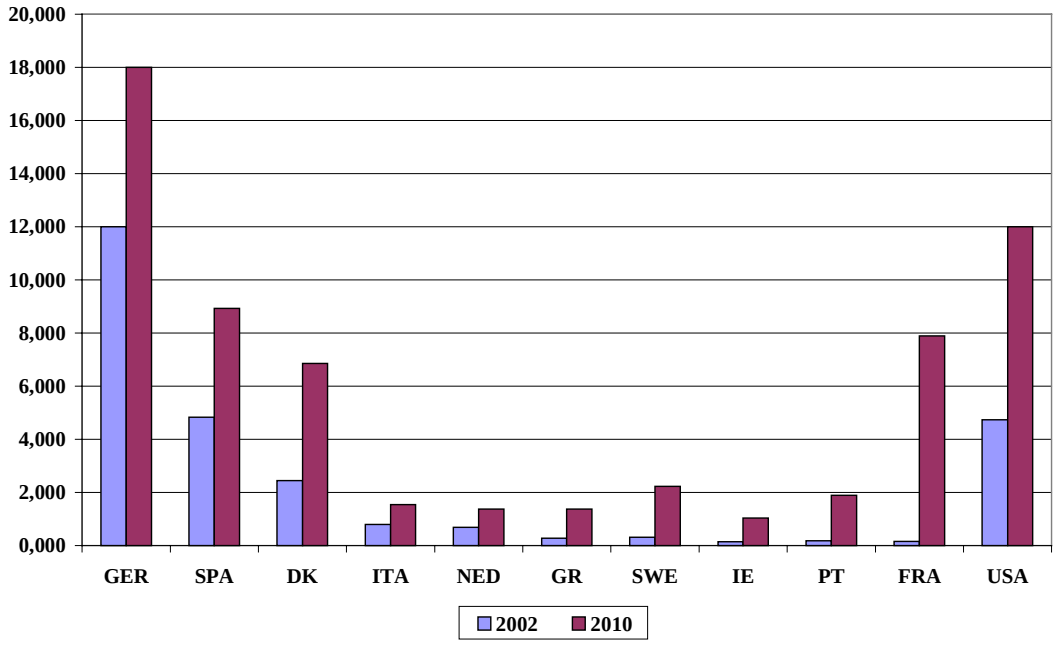
Source: AWEA (2003): Record Growth for global wind power in 2002 (http://www.awea.org/news/news030303gbl.html) and EWEA (2003): Europe 's Wind Capacity–June 2003 (http://www.ewea.org/documents/WIND_CAP_JUNE03.pdf).

The future of wind power in the different countries is difficult to forecast. It depends, among others, on the market strategies of the actors involved and especially on the policies implemented. Within the European Union, some countries have in-

troduced new policies. In France, for example, it can be expected that the introduction of the fixed feed-in tariff scheme will lead to an expansion of wind power. For the USA, one crucial point will be the nation-wide implementation of the Renewable Portfolio Standard.

Some indications about a likely outcome for the year 2010 are shown in Figure 5.4-9. The numbers for the European countries are based on the forecasts performed in the EU project PRETIR (2002), assuming that the policies listed in Table 5.4-3 are implemented. The numbers for the USA were forecasted from the US Energy Information Service (2003) calculating the effects of a nation-wide 10 % Renewable Portfolio Standard to be phased in until 2020. The numbers quoted apply for the year 2010.

Figure 5.4-9: Projections of installed wind power for different countries



Source: AWEA (2003): Record Growth for global wind power in 2002 (http://www.awea.org/news/news030303gbl.html); EWEA (2003): Europe 's Wind Capacity–June 2003 (http://www.ewea.org/documents/WIND_CAP_JUNE03.pdf).); PRETIR (2002): Implementation of Renewable Energy in the European Union Until 2010, Project executued within the ALTENER Programme, Utrecht/Brussels (http://www.ccsindia.org/Electricity/int_european.pdf).

The results from the forecasts seem to imply some catching up of countries which have implemented new policies, such as France. However no substantial change in the lead of the EU over the USA can be observed. Nevertheless, the development of the past 25 years has shown that reversals in the world leadership of wind power are possible to achieve. Thus, it will take additional efforts to continue the European

success story of the last 15 years in the long run. There are indications that the role of the USA in the world market might become more important. The take-over of the German producer Tacke by GE Wind has formed an important German-American player. A law suit pending before US patent courts between GE Wind and its competitors can also be interpreted as an attempt to close the growing American market for the European companies. Perhaps most important, however, are the indications from the long-term R&D policy. If the USA is successful in linking basic research and application as stated in their R&D programmes, they might be better suited to tackle some of the key challenges lying ahead. This could substantially improve their relative technological competitiveness, unless the European countries are travelling the same road.

5.4.5 Concluding Remarks

Reflecting on the results of the case analysis performed, several conclusions can be drawn. The results indicate that environmental regulation indeed has fostered environmental innovations. The analysis also demonstrates that the technological lead can change in rather short time frames. In the field of traditional water technologies, in the 1990s Germany lost some of the technological advantage it had acquired at the end of the 1980s. However, in the field of wind power, Germany has caught up with the leading Danish firms at the same time and leads world development right now.

Integrated environmental technologies, decentralised water systems technologies, and renewable forms of electricity supply form new technological paradigms which differ from incremental innovations along existing technological paths such as conventional wastewater treatment or conventional power stations. In order to reach or keep world leader status in environmental technologies, it is necessary to establish lead market positions at these new paradigms. This emphasises the need for R&D policies and transition management policies, which in the early phases of technology development create variety among technological solutions and strategic technological niches, and for environmental regulations which help form a mass market in the later stages.

Various aspects proved to be very influential in deciding on the innovative effects of environmental regulation: the existence and performance of economic regulation, the institutional processes which determine the interaction between R&D institutions, suppliers of technology and users to create knowledge spillovers, or the existence of long-term policy goals such as water quality class II in Germany or the doubling of renewable electricity supply in the EU, which help to guide the search processes. Thus, the analysis clearly supports the approach to analyse innovation processes within a systems approach.

The design of instruments matters for the effects on innovation in various ways: within the design of command and control policies (e. g. mechanisms to increase the requirements), within the design of economic instruments (e. g. the importance of fixed feed-in tariffs), and between the different forms of instruments (e. g. the supportive function the German emission charge on wastewater had). However, there is no easy solution favouring one instrument design only.

In general, the analysis emphasises the need to investigate possibilities for regulatory improvement. However, with different instruments used in parallel, this task gets even more complicated because the different interaction effects between the instruments must be accounted for. There is a certain path dependency of policy-making, which constrains the implementation of new instruments, and which makes it necessary to search for transition strategies. Perhaps the approach of innovation systems and the debate on transition management of large technological systems – e.g. the creation of technological niches – could also give interesting input into the future analysis of policy instrument innovations and regulatory improvements.

5.5 The Role of Standards for Shaping New Markets

5.5.1 Introduction

Besides governmental regulations, technical standards are crucial for the diffusion of new technologies. Technical change, or rather the innovations accompanying it, are the guarantee for our economic prosperity. However, it is not enough that our researchers and inventors produce lots of new ideas. In order to trigger off significant, positive economic effects, these product and process innovations must be successfully positioned in the market and diffused. Diffusion however can be fostered by a functioning standardisation system.[19] In network industries, like telecommunication and software, the diffusion of new technologies and services is almost impossible without standards implemented. Existing standards may also present hurdles for new technologies and products, because they compete with existing technologies and products, which are more familiar to the users and in which additional human and physical capital has been invested.

However, we will concentrate on the positive market shaping function of standards, since we are able to present some examples where standards played a key role, not only for the market introduction of single products, but for the development of a

19 See Blind (2004) for a comprehensive overview on the role of standards in the innovation system and the economy as a whole.

whole new market. The section is structured as followed. In paragraph 2, different types of standards and their general impacts are described. Paragraph 3 presents some success stories of standards which were essential for the development of new markets. Then, we derive some lessons from the case studies regarding the function standards can play in the development and shaping of new markets. Since standards are increasingly linked with regulation at the European level via the "New Approach", we conclude this section with the assessments of representatives of standardisation bodies regarding the connection between standardisation and regulation and their impacts on innovation.

5.5.2 Types of Standards

A classification of standards can be performed in several ways, not only depending on the respective scientific discipline, but also within the same discipline. David (1987) proposed a categorisation based on the economic effect of a standard. This is a useful approach in order to analyse both the economic driving forces for standardisation and the economic impact dimensions. It has been widely accepted and used (e.g. Nicolas and Repussard 1988; Swann 1990), though some later writers have extended the number of categories (e.g. Tassey, 2000). In our classification we use the dimensions of compatibility, quality, variety-reducing and information standards. However, even if standards are developed just to serve one purpose they often fulfil multiple functions. Therefore, it is not likely that each standard will fall exactly and exclusively into a single category, but very often several economic aspects are touched by a single standard. However, a distinction is important for the theoretical discussion, because standards have different economic effects, and the analytical models used to analyse and understand these effects are different.

Table 5.5-1 summarises these four different purposes of standardisation and highlights their positive and negative effects. The usefulness of this distinction lies in what it contributes to our understanding of the variety of standard types and their sometimes ambivalent effects. Compatibility and interface standards are crucial for network industries like the telecommunication and computer sectors, since they allow the communication between different users or the interplay between hard- and software. Minimum quality and safety standards prohibit that inferior and even risky goods and services are offered by suppliers. The concept of "regulatory capture" has to be explained and is the idea that some producers may lobby so skilfully that they persuade the standardisation development organisations to define regulations in the interest of the producers rather than in the interest of the customer (as originally intended). Since standards define very often a certain specification, they automatically exclude other options and reduce the variety, if the standard succeeds. Standards of information and product description are usually treated as a distinct category from the above, but for many purposes it is sufficient to treat these as a hybrid of the above three categories. A standardised product description has often

the function of a quality standard, eases compatibility with other products and is an expression of product variety.

Table 5.5-1: General Effects of Standards

Type of Standard	Positive Effects	Negative Effects
Compatibility / Interface	• Network externalities • Avoiding lock-ins • Increased variety of systems products	• Monopoly
Minimum Quality/ Safety	• Correction for adverse selection • Reduced transaction costs • Correction for negative externalities	• Regulatory capture "Raising rival's costs"
Variety Reduction	• Economies of scale • Building focus and critical mass	• Reduced choice • Market concentration
Information	• Facilitates trade • Reduced transaction costs	• Regulatory capture

Source: own overview modified after Swann (2000)

5.5.3 Selected Examples of Standards

The following examples are successful standards in industries, like consumer electronics or telecommunication, with strong network effects. Here common standards are essential for the success of a new technology and the respective products, but in case of competing technologies and companies the player with the broadest support and the widest diffusion of his standard is likely to be successful.[20]

Case Study: VCR

VCR (Video Cassette Recording) in general is often regarded as a successful substitute for movie theatre visits. Though entertainment is not the only application for magnetic video signal recording and playing, this is the battlefield in which the standard was ultimately set. Other VCR applications are in the fields of security

20 Further case studies on the linkage between innovation respective IPR and standardisation can be found in Blind et al. (2002).

(e.g. monitoring, in connection to camera sets), visual media archiving (e.g. broadcasts for television stations), and long distance, professional communication (e.g. real life visualisation of design objects). In many of these applications, magnetic data storage has been replaced by more durable and reliable optic data storage devices.

Video Cassette Recording as a system for recording and playing magnetic tapes in connection to a TV set was first introduced in 1970 with Philips‘ N 1500 system. Moreover, up till then, there was no VCR system on the market. In 1976, Sony followed with the Betamax system which required tapes that are different from Philips‘ original. Soon, Philips improved their system with the introduction of the N 1700 version. Around the same time, the VHS system was introduced by Matsushita. In reaction to these more compact and user-friendly VCR systems, Philips introduced the technologically superior V2000 system.

In the early 1980s, VCR became a widespread technology and these rivalling systems defined the market, leaving no space for alternative systems. Each of the companies touted its own system as the standard. But three different systems was still two too many, because consumers were not able to exchange tapes. The outcome of the battle was a clear victory for Matsushita’s VHS system, later on even adopted, through in-licensing by Philips and Sony. Sony’s Betamax initially survived in some niches, but Philips’ V2000 became defunct in the 1980s.

After years of fierce competition, Matsushita’s VHS became the standard in the VCR market. The victory of this system over Sony’s and Philips’ is often explained by a quick dissemination of pre-recorded, adult entertainment videotapes which mainly affected the US market. In those days, the US electronics manufacturers had already lost their home market in visual entertainment to Japanese imports of TVs. In getting VHS adopted as a de facto industry standard, Matsushita is claimed to have been more receptive to the notion of complementarity in their marketing. This complementarity is based on the view of the system as composed of two basic elements: the machine/apparatus and the tape/cassette. This relation is particularly of significance in ‘de facto standardisation’, where outcomes result from market processes. Though the question seems of a chicken and egg nature, it is in this case answered in terms of consumers’ substitution behaviour. Success in Matsushita’s marketing strategy was found in the customer’s needs where they were met with tapes containing that kind of content for which one changed behaviour more easily. The key was defining that segment of movies for which people would most likely replace theatre visits, as outdoors watching, by watching video on the TV set at home.

In general, the main difference in the way the video system was perceived by the actors involved can be described as: marketing tapes not as a derivative of marketing the playing and recording devices, but the other way around. So, it is important

to realise that marketing actions – such as pricing, the choice of distribution channels, timing, etc. – considering the tapes are intertwined with marketing actions considering the machines. Matsushita perceived the relation between the two as ‘machines following tapes‘, rather than ‘tapes following machines‘.

As a market-driven process, standardisation in VCR resulted not only from the availability of the technology to manufacturers in different market places and segments, but also from the adoption of the format by consumers. The first can be referred to as technology push and the second as market pull strategies. The latter means influencing consumer behaviour so that they produce an effective demand for products that depend on your proprietary format. As explained in the following, Matsushita followed what can be referred to as a two-tier market strategy. Their attention was not only focussed on (out)licensing their proprietary technology in so-called factor markets, but also on commercialising their products through effective marketing. De facto standardisation is probably by nature the result of both push and pull strategies. The key of the push strategy here was Matsushita’s encouragement of technology adoption through licensing of the VHS system to Sharp, Philips, GE, RCA, eventually Sony, and other competitors. In comparison, VHS technology was much more easily accessible for third parties than Betamax and V2000 technologies were. A high acceptance in the consumer market and a high appropriability made Philips decide to adopt VHS technology and in-license the format at the expense of its own V2000 system. This decision ultimately topped the balance in the VHS-Betamax battle in favour of VHS.

In many management text books this VCR case is used to show how seemingly trivial phenomena in consumer behaviour and counterintuitive IPR strategy can be decisive in breaking the case in de facto standardisation processes. Seemingly, the general perception of the VCR systems involved was one of uncontended quality differences. Technologically speaking, V2000 was considered superior to Betamax which was considered superior to the ultimate winner, VHS. But the latter has been considered the most user-friendly solution and the technology was made more easily appropriable. However, in explaining the winning position of VHS after this battle, the difference is best understood in terms of complementarity in technologies and timing in marketing actions. In general, the user’s value is very low if there is not a proportionate and timely relation between the two. Providing machines without the matching tapes or in insufficient numbers is as useless to the consumer as providing sufficient numbers of (pre-recorded) tapes without the matching machines to use them. Between the three rivalling formats, the supposedly most critical factor in adoption success was the positioning of video in the consumer’s mind. More precisely, the key in substituting theatre visits for video purchasing was the provision of privacy in the needs of the ‘innovators‘ and ‘early adopters‘ to enjoy adult entertainment. Another reason for Matsushita’s success in the US market was that the company was able to exploit the growth in the 1970s of new, deep discount retailing channels, such as Wal-Mart, to gain a wide initial distribution for its for-

mat. In other words, companies can broaden their distribution base by focusing on newly emerging channels.

The strategy of Matsushita had three effects:

- it increases the number of companies that use the firm's proprietary technology, ensuring a wide distribution and increasing a returns potential
- it marginalises competing technologies by building momentum behind the firm's technology; and
- it sends a positive signal to the suppliers of complementary products.

Allying as a result of learning from market dynamics changed the nature of standardisation to a more formalised, but not externally regulated, process. As a self-regulating mechanism it can be very effective without external intervention, as long as competition policy regulators make sure that conditions for an effective market process are met.

Case Study: CD

Compact Disc (CD) technology was first marketed as the optic version of an audio playing system. In these early days, it competed with LP, the long playing vinyl record. Many record shops switched to or adopted the much smaller, silver shining laser read, digital disc. And many hi-fi shops stopped selling record playing turntables.

In the course of its technological development, the recording function became integrated into the system, referred to as CD-R/CD-WO or CD-rw. The CD as a data storage medium carries many applications and concomitant format standards: CD Digital Audio (including CD Graphics, CD Text, and CD Single), CD-ROM (8 and 12 cm), CD-i, recordable CD, CD-Video/Laser Disc, Photo CD, and Video CD. Recently, the application of CD-R systems in PC configurations has more or less become a standard in the home PC market, together with a built-in DVD system.

CD technology was developed in the late 1970s, early 1980s with Philips and Sony as the leading actors, but competing with largely the same companies as in VCR. As indicated in the introduction to the electronics sector cases, Philips and Sony had every reason to join hands in new product development in this field. Though intentionally of a technological nature, they also had reasons to join hands for strategic reasons. Philips had, after six years of work, developed the prototype for the CD system by 1978, realising that it would be difficult for the company to turn the concept into a world standard. Philips had previously experienced the commercial failure of the video laser disc system, especially on the European market. Therefore, Philips approached Sony in 1979 to form a strategic alliance. Sony was chosen because it had the requisite development and manufacturing capability, and provided

access to the Japanese market. And, like Philips with its V2000 system, Sony had recently suffered commercial defeat with its Betamax video format.

Philips had unilaterally developed basic prototypes of the recording technologies, but the two firms jointly developed the commercial chips necessary for the modulation, control and correction of the digital signal. Sony also developed three integrated circuits that eliminated 500 components, making the CD player smaller, cheaper to manufacture and more reliable.

Moreover, both companies used their in-house recording and pressing facilities to produce CD recordings; CBS/Sony in Japan and Philips/Polygram in Germany, thus ensuring a supply of music titles creating a market pull for their format. In 1982 the CD was launched in Japan, and in Western Europe and the USA in 1983. Sales of CD players and (pre-recorded disc) titles exceeded all forecasts: 3 million players in 1985, 9 million in 1986 and a cumulative total of 59 million CD recordings by 1985, and 136 million by 1986. The sales of CD recordings went up to much more than 10 billion in recent years, until the possibility to download music files from the Internet and burn CD at the home computer emerged.

This dominant position of Philips and Sony in CD technology was built through a joint licensing programme, managed by Philips. The licensing programme initially involved audio CD only, exclusively commercialised with Sony, but later on included Kodak for Photo CD, and JVC, Matsushita and Sony for the Video CD standard specifications. Patents and therefore royalties on these CD technologies are more recent and will continue to generate cash flows for the companies involved. By the end of 1981 over 30 firms had signed agreements to license the Philips-Sony technology, and Telefunken, Thomson, RCA and JVC had withdrawn their rivalling prototypes.

After entering into their alliance, Philips and Sony quickly moved to establish their technology as the international standard, both by official and de facto means. Their format was adopted by the influential Electronics Association of Japan, which effectively blocked competing standards from other Japanese manufacturers. In 1981, it was formalised by the International Electrotechnical Commission.

The fact that Philips and Sony went into a strategic alliance instead of a cross-licensing arrangement, made it much more likely for them to establish an industry standard. Within the framework of an alliance, the risk that a partner opportunistically appropriated valuable technology can be reduced by extracting some form of credible commitment from the partners. In this case, the in-house production of complementary products, such as pre-recorded disc manufacturing and sales, and the provision of pressing services, express such commitment. Similarly, the alliance – especially in cases where a joint venture is involved – includes an equitable contribution of technology towards the development of a new standard (audio CD).

The alliance between Philips and Sony had many motives, including access to technologies, economies of scale in production, establishment of international standards and access to international markets. It was successful because in each case the motives of the respective partners were complementary, rather than competitive. Using an alliance to co-opt a capable potential competitor that is already developing its own incompatible format can send a clear positive signal to the rest of the industry regarding the likely commercial viability of the jointly sponsored technology standard, as occurred in the Philips-Sony case of (audio) CD. By combining two potentially incompatible standards into one, the alliance reduced confusion in the market place and helped swing the momentum behind the joint programme. Not only does the creation of such positive expectations help persuade other potential competitors to commit to the jointly sponsored standard, it also increases the incentive that other enterprises have to invest in the development and production of complementary products in advance of the market launch of the core product. By shifting technology co-operation from a post-marketing outcome with negative side effects of sunk costs to a pre-marketing alliance, a bandwagon effect is created. Not only did a large number of other consumer electronics companies agree to license the core audio CD player technology from Philips and Sony, but many recording labels, seeing growing commitment to this standard, committed themselves to issuing a wide selection of CD discs. In turn, the wide availability of CD discs helped to ensure a successful launch of audio CD technology.

Case Study: DVD

Digital Versatile Disc (DVD) technology is, even more so than CD technology, a configuration of distributed but (architecturally) related technologies and actors. Today, many more companies are involved in research on related technologies than there were at the outset of the CD. Digital convergence is one of the developments explaining this phenomenon. For instance, technology on the blue laser beam as an improvement over the present red laser beam is held by a relatively small Japanese company: Nichia. Overall, Philips (and Sony) do not hold such dominant positions in this technology as they (still) do in CD technology.

DVD comprises both audio and video applications of optically read and digitally processed data on a small disc in different sizes and formats. Each of the formats is defined by the function (playing and/or recording) and its capacity, resulting in different disc sizes. The main differences in use in comparison to rewritable CD lie in its video recording capability and extension of its storage capacity. DVD systems include the handling of previous CD formats and are therefore able to play (most) audio CDs. DVD has also become a standard in PCs and game computers. Its applications are potentially in all areas where audio, photo or other forms of data carrying systems are used.

The consumer's general perception is that CD is an audio and DVD is both an audio and video system. This also means that consumers may feel potential restraints in accepting the DVD as an equal audio system. The introduction of the Super Audio CD format seems to hamper such substitution further. Whether the consumer will on a large scale substitute VCR for DVD, remains to be seen. DVD sales would grow rapidly (an estimated 250 million world-wide in 2000), but seriously lag behind the sales of CD, yearly 12 billion. According to other analysts, DVD would be accepted quicker than the CD, because the consumer is now used to the optic disc. At the time of CD introduction it was used to a large vinyl record with an artistic cover to be replaced by a much smaller, visually less attractive CD. Others claim that its impact will be larger if all CD functions and present DVD technologies would be integrated into one system to replace all other optic and magnetic audio-visual data carriers.

At the time leading actors in the consumer electronics industry started developing DVD technologies, lessons from previous experiences had been learned. Networks of alliances were formed in order to select complementary technologies in order to develop a basic design, to set standards, and to control further commercialisation of the technologies in joint licensing and marketing programmes. Initially, from 10 actors involved in DVD technology, the exploitation of patents on the apparatus were pooled in a licensing program handled by Philips. Because of a conflict over royalties, this programme was split in two groups in 1997: Matsushita left the consortium with Hitachi, Mitsubishi, Time-Warner, Toshiba, and Victor Company of Japan (JVC). They established their own licensing programme. Specifications of the formats for DVD discs and logo licensing are handled by the DVD FLLC (excluding DVD-RW), a collective joint venture based in Japan.

In the field of DVD recording, the standard has not yet been set in favour of any of the three systems: DVD-RW, DVD-RAM and DVD+RW, contrary to DVD-ROM. The actors are still involved in a chicken run on rewritable DVD. The first to give in will lose ('winner takes all'), meaning that actors will try to postpone a decision to license in an other's technology in favour of its own. The DVD Forum accepted Pioneer's specifications of the RW-format in 1998 as an improvement more similar to pre-recorded DVD-ROM and DVD-Video and more often rewritable than DVD+RW (from Hewlett-Packard, Sony and Philips) and the Forum-approved DVD-RAM (from Hitachi, Toshiba, and Panasonic).

Overall, the case of DVD illustrates the process of allying aimed at developing and setting standards. After a systemic technology has been created, the alliance network involved will have to expand. Partners along the chain are recruited into the network. Whereas in the first stage of R&D, learning is to be achieved by contributing complementary pieces of technology for the basic design, at the second stage supply relations are added on the basis of product complementarity in order to secure (the compatibility of) hardware and software components that are still lacking.

The third stage refers to marketing activity, where distribution channels are contacted and other firms are invited to become licensees.

Standardisation in this technology was initiated with the formation of a pre-competitive consortium of 10 different actors. Formation of this group, whose main purpose it was to establish an industry standard, was the result of a painstaking negotiation process that took 4 years. Along the way, all kinds of specifications and subsystems had to be formulated and selected.

These purposes are met through alliances to increase firm capabilities in the different stages of the innovation pipeline: technological learning (R&D), supply networking (manufacturing), and accumulating sources and contacts to speed up distribution and acceptance (marketing). Standardisation is no longer confined to technological deliberations, but is a rather complex market process that is ultimately formalised in licensing programme contracts and SDO documents.

The appropriation of rights in the technological trajectory of DVD development differs from the other standardisation activities in that it is a more dispersed activity than in the VCR case and the positions of the dominant companies are relatively weaker than they were in the CD case. Combining video and audio technologies into one medium, widespread adoption still hinges on the recording capabilities of DVD.

Case Study: MP3

MP3 stands for a format for music files which delivers the latest hits or live recordings to your home computer. Without this format the audio data would be far too large and the small transmission capacity of the World Wide Web would not be sufficient. Three minutes of a song would take several hours to travel through the Internet. Therefore, MP3 helps Internet users to reduce the data rate of their music files. Technically speaking, without data reduction, digital audio signals typically consist of 16 bit samples recorded at a sampling rate of more than twice the actual audio bandwidth (e.g. 44.1 kHz for Compact Discs), i. e. more than 1,400 Mbit to represent just one second of stereo music in CD quality. By using MPEG audio coding, the original sound data from a CD is shrunk by a factor of 12, without losing sound quality. Basically, this is realised by perceptual coding techniques addressing the perception of sound waves by the human ear.

MP3 has shaped a new market in the hardware sector also. Several companies develop recorders for the reduced audio data. In 1998, Saehan Information Systems introduced the first MP player, the MPMAN, into the market. Meanwhile, more than 60 mobile digital recorders exist. Panasonic, Hitachi, Sanyo and JVC already offer radio receivers with an integrated decoder able to receive reduced radio transmission with MP3, like the broadcasts of WorldSpace. WorldSpace licensed MP3

technology for a new satellite radio system which is about to change the radio scene drastically.

In 1987, the Fraunhofer IIS-A started to work on perceptual audio coding in the framework of the EUREKA project EU147, Digital Audio Broadcasting (DAB). Besides well-known European companies like AEG, Bosch, Philips and Thompson, various research institutes belonged to the 16 project partners. The common goal of the project was initially to demonstrate the technical feasibility of the digital terrestrial radio network and to work out the most promising solution from a number of different approaches. The most important result of the project should have been a digital radio standard which should be jointly supported and implemented by all participants in the project, since this standard was a prerequisite in order to enable the firms participating in the development work to minimise the R&D risk involved in this high-tech challenge. In 1987, a EUREKA project was initiated by some ministries of economic affairs and technology for the development of digital audio broadcasting in order to reach CD quality for radio transmission. European standards for data reduction and transmission had to be developed. In fall 1988, the ISO published its aim to produce a world-wide standard for moving picture coding, including audio-coding. For the standard an expert panel was founded with the name MPEG (Moving Pictures Expert Group).

The story of MP3 is an example for the effective and efficient interrelationship between research and industry and between intellectual property rights and standardisation. The actors have successfully taken over control of the development of the technology by setting up very early under the EUREKA project a patent pool integrating all relevant partners, including both research institutes and companies. This complementary relationship unified the strength on the technological ground and the market knowledge of the commercial participants, who have insights into strategies on how to build up a broad base of users very quickly.

Besides the connection between research and commercial interests, the development of MP3 benefited by the recognised need of many national ministries for economic affairs and technology to develop a European standard for digital radio which supported the EUREKA project. This favourable framework condition coincided with the call of ISO for the development of a world-wide solution. Three aspects worked in favour of the long-term success of MP3, despite the loss against the competing technologies. First, the range of commercial applications turned out to be broader for the MP3 technology. Second, the ISO call supported the foundation of an even broader coalition of companies which develop similar technologies. Finally, the consortium had already integrated a world-wide alliance of companies with major commercial interests.

After the acceptance of the standard as an ISO standard, a licensing strategy was developed which has taken into account both the stream of revenues and the broad

and fast distribution of the technology by giving away the technology for free to the private users and charging professional users. At the same time, the development of improved follow-up technologies guaranteed that competitors could not bypass the existing technology with new and improved solutions.

Case Study: GSM

The "Global System for Mobile-communications" (GSM) is today the most widespread platform for mobile communications. At base, the GSM system is a cellular radiocommunications technology that permits relatively high traffic rates on a digital platform. GSM includes a small family of systems, the principal member of which is the GSM-900 system (at 900 MHz with a frequency allocation of twice 25 MHz). The GSM standards were extended in 1990 (the Delta Specs) to specify a system at 1800 MHz (with a frequency allocation of twice 75 MHz) for urban areas. GSM handsets are in use in more than 60 countries around the world.

When the standardisation process got under way in 1982, there were several persuasive forces that brought the various European telecom operators of the day together. The deciding factor emerged in 1978 when the radio-bandwidth around 900 MHz was reserved for mobile communications in Europe. This made it imperative to make the most out of the scarce resource of bandwidth. Meanwhile, the various systems that emerged during the 1980s showed the limitations of nationally-based, analogue systems. A major limitation that these analogue systems faced was capacity problems. In addition, they lacked cross-country roaming capabilities, which effectively sealed off markets within the many national borders in Europe, making cell-phones less interesting to the target-customer, the businessman.

Standardisation at the European level made sense because it was at this level that economies of scale could be realised, against which the large costs necessary to develop a high-capacity, cellular technology could be dissipated. It also fit into the single-market objectives of European politicians as these took shape. Since then, it has also laid the basis for the competitive export of the standard, with advantages for home players (e.g. Ericsson, Nokia, Siemens, etc) and it has provided the basis for new services which would become popular like SMS (Short Message Services). It also set in motion the next-generation UMTS coalition (SMG5) which is active today.

Three main types of actors became involved in the standardisation of GSM during the course of its decade-long evolution. One important feature of this evolution in fact is that participation changed fundamentally. At the end of the 1980s, the GSM work was moved from the CEPT (Conference Européenne des postes et telecommunications) standardisation arena, in which it had been a discrete entity (Groupe Spécial Mobile), to the newly institutionalised ETSI, where it became a technical committee. The CEPT was the arena of more than 20 European post and telecoms

administrations (PTT), which were national monopolies. Eleven countries were present at the first GSM meeting.

In the formative stage, the PTTs (with the participation of their associated equipment manufacturers) were brought together by common interests as national monopolists. Their concerns were to reduce the uncertainty of which radiocommunications technology would win, to increase the potential of a large European market, and to maintain monopoly rents.

Equipment manufacturers were first formally involved in the standards after the PTTs had agreed among themselves to a Memorandum Of Understanding (MoU in 1987). At this point equipment manufacturers were invited to tender for equipment in a set of countries on the terms laid out in the MoU. Equipment manufacturers were attracted by some of the same motives as the PTTs; they wanted to avoid the uncertainty about the winning technology and they wanted to realise the scale economies promised by a European system. In several prominent cases, there were traditional allegiances between the equipment manufacturers and the national PTTs (Ericsson, Nokia, Siemens, Alcatel). The fifth main equipment manufacturer (Motorola) held a wild-card position: its home-market was outside the EU, it had pioneered certain aspects of radiocommunications, and the structure of its markets were different (technically and geographically) from the other actors. It was interested in strengthening its position in Europe while limiting the potential for competition with its other markets (for example, the USA).
The third main actor was the European Commission whose active support for the GSM standards became visible in the mid 1980s. This support began to materialise in the face of a variety of national strategies bent on taking a leading role in the standardisation process. The Commission's interest in the GSM was primarily to promote a unified European market. During the de-regulation of telecoms in the late 1980s, it also became a vehicle to promote a tentative opening of markets to competition. In addition, the GSM system held a series of links to other technologies that the Commission had invested in: links with the chips industry (ESPRIT) and Integrated Services Digital Network (ISDN), an indirect link with the RACE programme. European involvement sent a powerful signal about the importance of the system and its success.

In many ways the GSM case involved a very comprehensive standardisation process. The process involved a wider systems-building project in which technical, political and institutional aspects of the system were engineered in great detail. The epicentre for this work was the committee-based standardisation environment of CEPT and later ETSI, where the design for the digital mobile system was negotiated according to five basic sets of requirements (cost aspects, network aspects, radiofrequency utilisation, service, and quality of service and security). The process took more than a decade. The specifications cover all aspects of the mobile system, from

switching, to radio transmission and reception, to channel coding, to terminal specifications to service recommendations etc.

GSM's major achievement was that it co-ordinated the design for a digital mobile system and that it orchestrated the concerted launch of this large technical system in a large area (i.e. Western Europe) at a critical time. The GSM case holds several lessons. Some are isolated to the special circumstances of the time, by which we mean the transition from the monopoly-providers paradigm to a paradigm which included a more heterogeneous set of participants. Instrumentally this meant that a wider set of participants were introduced to the standardisation process. As the case demonstrated, this brought together actors with different IPR portfolios and strategies and with different attitudes to their use. One lesson that European participants learnt was to become much more active in securing and exercising IPRs.

5.5.3 Lessons from Selected Examples of Standards for Shaping New Markets

We have presented the evolution of five standards which are the basis for the development of large consumer electronic markets and mobile telecommunication worldwide. Summarising the experiences and lessons of the case studies regarding the role of standards for shaping new market, we can derive the following conclusions.

The final breakthrough of VCR was possible by the concentration on one standard after an intensive standards war. The winning standard had not the highest technological performance, but it was very user-friendly. And the winning company was able to succeed by gaining partners in complementary technologies and distribution channels.

The development of the standard of CD was easier, since from the very beginning a coalition of large and complementary partners created confidence among other companies in the success of the technology, which created incentives to develop complementary applications of the technology. These positive feedback loops were the basis for the development of this prosperous technology and its numerous applications.

The starting position for the DVD standard was rather favourable, because a coalition of important actors was founded rather early in the development process. However, this coalition split up and prohibited a uniform solution especially regarding further applications. Nevertheless, DVD technology is a success story, although the different standards caused confusion among the customers and prevented the full exploitation of network effects and economies of scale.

The story of MP3 illustrated the efficient transfer from results of publicly funded R&D projects into international standards, which was supported by the co-ordination of R&D and standardisation activities. However, the broad success of MP3 was realised by the formation of a broad coalition between institutions performing R&D, manufacturing companies and distributors.

The GSM standard is the core key of the infrastructure of mobile telephony. It was possible because of the backing by political forces which wanted to reach a common European-wide standard and therefore solved conflicts between conflicting parties. The common European mobile standard was also the key for the fast and successful development of the European mobile producers, like Nokia and Ericsson.

Table 5.5-2: General Effects of Standards for New Markets

Type of Standard	**Possible Effects for New Markets**
Compatibility / Interface	• Support network externalities to reach critical mass of users (VCR) • Compatibility between old and new technologies avoids lock-ins in old technologies (CD and DVD) and increases attractiveness of new technologies • Increased variety of systems products based on basic standards (GSM)
Minimum Quality/ Safety	• Reduced transaction costs especially for new products • Protection of early adopters • Creating confidence among early adopters
Variety Reduction	• Allowing economies of scale which decrease prices and increase number of potential buyers (VCR) • Building focus and critical mass supports the development of positive network externalities (CD)
Information	• Facilitates trade by reduced transaction costs important for new products

Although the examples presented deal mostly with compatibility and interface standards, we complete in Table 5.5-2 the overview of different types of standards and their role for new technologies and markets. First, finding a common compatibility and interface standard allows to build up critical masses which are a necessary condition for network technologies, like the described telecommunication and consumer electronic examples underline. However, the price of these breakthroughs is a reduced variety and a monopolisation especially if the standards are proprietary and third parties have no chance to obtain licences. Compatibility between existing and new technologies avoids the lock-in in old technologies, but increases also the confidence and attractiveness in new technologies. The basic GSM standard shows

that some crucial features of network technologies have to be standardised in order to build a platform for a broad variety of new mobile applications. Variety reduction is important both for reaching critical masses of new users and for exploiting economies of scale, leading to lower prices for product novelties. Minimum and quality standards reduce transaction costs and protect especially early adopters from risks, which increases the acceptance of and the confidence in new products and services. Information standards have the same impact, which allow consumers to assess easier and better the benefits of new products. In total, all kind of standards play an important role for the development of new markets, although compatibility and interface standards have a special relevance for the crucial network industries, like consumer electronics and telecommunication.

5.5.4 Regulation and Innovation from the Perspective of Standardisation Organisations

The European standardisation bodies CEN, CENELEC and ETSI play an important role in shaping the regulatory framework, because the "New Approach" requires that these standardisation bodies organise the development of standards which specify the European regulations and directives. Therefore, they provide the platform for the development of regulations. Since the three institutions together cover all fields with CENELEC responsible for electrotechnical regulations and ETSI in charge of standards for telecommunications, they are involved in all areas of regulatory issues.

Common Views and Conflicting Themes

Although the standardisation bodies are responsible for openness and transparency of the standardisation process, the interested parties are the stakeholders who try to influence the content of standards and standardisation policy as well. Consequently, the reported conflicting views are those of the interest groups involved in standardisation processes.

The major driving force for standardisation activities is industry, because companies have both the need for standards securing compatibility, assuring quality and allowing the exploitation of economies of scale. In addition, the "New Approach" enables industry to influence the regulatory framework according to their interests. Other interest groups involved in standardisation activities are consumers and environmental groups. At the European level, ANEC, the European Association for the Co-ordination of Consumer Representation in Standardisation, is the voice of the European consumers. Some, but not all national standardisation bodies have also such organisations. Since the beginning of 2003, ECOS, the European Environmental Citizens Organisation for Standardisation, represents the opinion of the environmental NGOs.

Due to the involvement of the different interest groups, we find also conflicting views within standardisation. In general, industry wants to improve and enforce the stock of standards and therefore the regulatory framework for its commercial activity, while removing unnecessary burdens on business. For the consumer organisations active in standardisation, product and service safety and quality are of highest priority. Finally, the environmental groups favour standards which are effective for the protection of the environment. An example for a conflict are the standards for packaging which were developed by industry, but failed to be sustainable from the environmental perspective. On the other hand, standards for child-safe lighters are a success from the perspective of the consumer organisations active in standardisation.

Impacts of Regulation on Innovation

The relationship between standardisation respectively regulation and innovation is a crucial issue for both the standardisation bodies themselves and for industry involved in standardisation, because standards are important for the promotion of innovations due to their positive impact both on the production side via economies of scale and the demand side by building up consumer confidence. The interest groups representing consumers and environmental issues follow a more conservative approach by trying to protect the safety of the consumers on the one hand and the environment on the other hand. Innovation is therefore only an issue if these improvements increase the benefits, especially the safety, of the consumers or reduces the damage for the environment. However, these organisations see a high potential of these more incremental innovations, which should be exploited more effectively.

Possible Future Developments

The current relation between standardisation and regulation is under discussion. Whereas industry, especially large companies, and the standardisation bodies themselves favour the "New Approach" and tend even to demand more self-regulatory elements, consumer and environmental organisations complain about the missing resources in order to represent their interests effectively in standardisation processes. Due to the lack of resources, they favour a restriction of the "New Approach" to fields which do not concern consumer or environmental interests and more specific regulations, which take into account their interests. Standardisation bodies and industry demand more flexibility to allow even informal standardisation processes in dynamic fields like information technology in order to reach faster and more flexible standardisation solutions, which are also more open to innovations. Currently, there are obviously some coordination problems between the standardisation bodies and the regulatory bodies at the European level, which lead to uncoordinated duplication of standardisation respective regulation processes. Furthermore, the increasing heterogeneity of the implementation of standards and regulations in the

Member States and the related surveillance problems challenge the "New Approach". Nevertheless, the "New Approach" is supported by all stakeholders, because it gives the stakeholders the option to shape the specification of the regulatory framework in a way that allows and supports the introduction of new products and services, which is documented by several examples, i.e. in telecommunications. It is necessary to consider and involve all stakeholders and to organise the consultation process in a proper way. Furthermore, the approach of standards defining specific product or process requirement ex ante is preferred to the US system with less specific regulations and standards, but a stronger liability.

5.6 Comparative Summary

In the previous section we presented the results of three case studies in the pharmaceutical, the food and the environmental technology sector. Finally, some selected examples of the development of successful standards especially in information and telecommunication technology were displayed and current issues regarding the relationship between standardisation and regulation were reported based on interviews with representatives of standardisation development organisations.

The illustration of the cases in the three sectors demonstrated that regulation is rather technology-specific and consequently also the link between regulation and innovation. However, some crucial factors of the regulatory system can be identified which have a strong impact on the development of new products and services. First, we observe a harmonisation of the regulatory framework in the pharmaceutical sector. However, differences in the implementation of the regulation still exist. Especially, the length of approval procedures are crucial for the investment in R&D and the development of new medicinal products. Although the standards for clinical trials are harmonised, we find rather significant differences of the number of such trials between countries, which can be explained by diverging price regulations creating different demand-side impulses. Reducing the risk at the demand side by restricting the access to pharmaceuticals relevant only for a small group of patients by the orphan drug regulation is obviously an effective instrument to create sufficient incentives for companies to perform research and development which lead to the market introduction of numerous new drugs. Legal insecurity is also a hindering phenomenon for introducing new product in the food sector. Both the development of markets for food products based on GMOs and functional foods in Europe is hindered by the unclear legal situation regarding the marketing of these products, which has even negative impacts on the research activities. Regarding GMOs, restricting market approval to ten years and the requirement of post-market monitoring of each GMO means a de facto moratorium on the commercialisation. In the case of Functional Food, it is not possible for the suppliers in Europe to use claims about the health benefits of their products which reduces the consumer acceptance and therefore the demand. In both cases, the regulatory system in the USA is both

more liberal regarding the marketing of GMOs and allows producers of Functional Foods using health claims, which leads to a much stronger market development for these new products. In contrast, the market for organic food grows more strongly in Europe, because European farmers converting to organic production receive additional payments, whereas the regulatory framework conditions are similar to the USA. This case shows that the transaction costs occurring in transition phases have to be compensated for by restricted financial subsidies, because favourable framework conditions are not sufficient. This phenomenon can also be found in the case of wind energy, whose success in some European countries can only be explained by the fact of offering stable demand conditions through guaranteed prices. The perspective of a continuous demand created incentives to invest both in research and development and to provide the necessary infrastructures. The resulting efficiency gains resulted in an increased competitiveness of wind energy compared to other conventional energies, which allows in the long run to relax the price guarantees and confront the wind energy producers with the competition of other energy producers.

The selected examples of technical standards make obvious that standards are essential to reach critical masses of users of new products and services especially in network industries, like telecommunication. In addition, compatibility standards allow also the transition from old to new technologies. Finally, standards are, besides governmental regulations, an instrument to increase the acceptance of consumers for new products and services, a necessary condition for the sustainable development of new markets. The increasing interrelationship between standardisation and regulation especially on the European level open up the possibility of sharing tasks, whereas the governmental bodies set the framework conditions and the involved parties in the standardisation processes specify the details. The advantages of labour division need on the other hand an efficient co-ordination and it has to be ensured that the self-regulation within the standardisation bodies allows all involved stakeholders an effective participation, because otherwise the acceptance of standards as one output of self-regulation is threatened.

Summarising the main results out of all case studies it becomes evident that legal security for the producers of new products and services is essential, especially also in the implementation phase of regulations. In addition, stable and predictable demand creates incentives for companies to perform long-term investments in R&D, but also market introduction and infrastructures necessary for new products and services. Nevertheless, especially for the transition from old to new technologies, direct payments or subsidies for producing new products are necessary, which can be justified by positive impacts for health, safety and the environment, but needs also to be timely restricted. Finally, standardisation as an instrument of self-regulation is successful, but co-ordination with governmental regulatory bodies and the openness to all involved stakeholders must be effective in order to secure the acceptance and therefore the efficacy and the efficiency of this instrument.

6. Future Challenges for Regulatory Policy Shaping New Markets

6.1 Introduction

All the different approaches to identify and analyse the role of regulation for shaping markets for new products and services have shown various challenges, problems and shortcomings. First, the variety of regulations have different and often ambivalent impacts on innovation. This general background information has to be taken into account. Second, there is a significant lack of awareness regarding the issue of innovation within the regulatory bodies. This opens up a broad variety of options for future regulatory policy. Third, the various interest groups and stakeholders and even regulatory bodies involved in the regulatory process are also often not aware of the opportunities innovation can have for their own interests. Besides the generation of regulation, the implementation thereof is crucial for the incentives of companies to develop and market new products and services. Based on these general insights, we present first proposals on how to integrate the promotion of innovation into the set of other objectives of the regulatory bodies. Second, we discuss how to increase the quality of the regulatory framework regarding the promotion of innovation. Due to the complexity of the innovation process, the regulatory policies of different bodies have to be co-ordinated in order to be successful. Finally, the implementation of regulation is crucial also for the promotion of new products and services. Therefore, we present some ideas to optimise the implementation, respectively to achieve the goal of promoting innovation.

6.2 The General Role of Innovation for Regulatory Policy

Within regulatory policies, innovation is only an objective for those institutions responsible for competition. The regulatory bodies responsible for other objectives, like the protection of health and safety or the environment, do not adequately consider the opportunities of new products and services. However, even within the competition policy authorities, a simple understanding of the link between competition and innovation dominates which assumes that more competitive pressure leads automatically to more innovation. This is certainly the case especially when considering the liberalisation of former monopolised markets, like the network industries telecommunication and several transport sectors, because the entry of new companies in these markets leads to more competitive pressure and to more actors with new ideas and often using new technologies. However, companies in markets underlying a high competition often do not have the necessary resources to conduct very risky research and development leading to radical innovations. Consequently,

they are restricted to less challenging projects causing only product improvements and incremental innovations. Therefore, regulatory authorities responsible for competition policy have to extend their perspective and in sectors where “too much competition” prevents significant and risky innovation activities, a new balance between securing competition and creating incentives for innovation by restricting competition has to be found. A positive example of a policy which restricts competition in order to foster radical innovation is the orphanan drug regulation which has been a success both in the USA, Japan and Europe.

The majority of regulatory bodies which do not consider innovation in their set of objectives have to take innovation into account and to check whether promoting the development of new products and services may be beneficial for achieving their other goals. It is already common sense and proved that the development and marketing of environmental friendly products is positive for the quality of the environment. In addition, those regulatory bodies responsible for citizens´ health are also very interested in fostering the development of new medicinal products by reducing the time of approval procedures, which may save people´s lives. Consequently, those regulatory bodies in charge of food products should be more sensitive to new food products, like Functional Foods, which may also be positive for people´s health. This systematic checking of complementarity between the traditional objectives of regulatory bodies and the impacts of innovation has to be performed for all regulatory bodies.

However, not only within regulatory bodies but also among the major stakeholders, besides industry, involved in regulatory processes there is an obvious lack of awareness of the positive impacts of innovation. Consequently, in the same manner as for regulatory bodies, the various organisations of interest groups, like consumer associations or trade unions, have also to check the impact of new products and processes on their objectives. Especially the identification of possible positive impacts may increase the willingness of rather conservative interest groups to support regulatory changes allowing the market introduction of innovative products and services.

6.3 Approaches to Increase the Quality of the Regulatory Framework regarding Innovation

Besides the general approach to consider the promotion of innovation as one essential objective for regulatory bodies, the concrete development of specific regulations has to take the dimension of innovation better into account.

At the moment, the regulatory bodies react passively to changes in science and technology which lead to the development of new products and services by adapting the regulatory framework more or less fast to the new technical opportunities. Ac-

cording to this reaction time a delay of marketing of new products and services is caused, which may lead to a long-lasting disadvantage for domestic companies in comparison to foreign companies working within a faster reacting regulatory framework. Consequently, regulatory bodies have to intensify their contacts with the science and research community in order to perceive on-going changes relevant for the adaptation of the regulatory framework faster. These activities could even be performed in a more systematic and comprehensive way by establishing mechanisms like "regulatory foresights" which aim to identify in advance upcoming trends, not only in science and technology, but also in markets and society as whole with a possible impact on the regulatory framework. The insights of such foresight activities would allow to convert the more passive role of regulatory bodies in the development of science, technology and markets into a more active and promoting one. The adjustment of the regulatory framework to changes in science and technology has to be differentiated according to their intensity. Radical changes like the possibility to use GMOs in the food industry, which open up totally new market opportunities, require the release of framework directives or regulations in a timely manner. Incremental progress in the one or other area should be reflected in adjustments of ordinances or via the "New Approach" in modifications of standards.

Another source of information about on-going trends in the development of technology are the activities of standardisation bodies, whose participants from industry have often very close contacts to on-going research, the results of which are fed into the standardisation process. This means that in addition to the "New Approach" as top-down approach, under which the regulatory bodies define general framework directives, which are specified later by the European standardisation bodies, a bottom-up approach should be installed which feeds the relevant results of standardisation processes into the activities of regulatory bodies.

This proposal does not only improves the information base of regulatory bodies, but leads in general to a better coordination between standardisation and regulation activities. This is in general necessary in order to improve the efficiency of the division of labour between regulatory and standardisation bodies. Although the "New Approach" is perceived as a success of self-regulation, a move towards more self-regulation finds no majority, because in numerous fields this would threaten the legitimacy and also the acceptance of the regulatory framework due to the de facto restricted participation of all stakeholders. However, the trade-off between the gains of self-regulation, like flexibility and adaptability of the regulatory framework, and its weaknesses, like the restricted access of certain stakeholders to standardisation processes and the reduced acceptance, is different according to the characteristics of the technology and the market. Consequently, the optimal degree of self-regulation has to be determined according to the respective circumstances, which may also change under time.

One example of the importance of self-regulation is the role of standardisation for network industries, like telecommunication. Especially in the phase of deregulation and liberalisation of the markets, the regulatory bodies were only able to set the framework conditions for the development of the new liberalised markets. The need to harmonise technical details has been delegated successfully to standardisation bodies. However, after the completion of this transition phase, this division of labour has to be reconsidered and a new balance has to be found according to the trade-off described above. This example makes obvious that self-regulation has to play a different role according to the life cycles both of technologies and of markets.

Both in the theoretical discussion about the impacts of regulations on innovation and in the analysis of the empirical evidence in the company survey, the interviews with the stakeholders and the case studies, we found a strong ambivalence. Since we observe positive and negative impacts of regulations on the development and market introduction of new products and services, the regulatory bodies have to concentrate – if possible – on those types of regulations or have to shape the regulations in a way, which maximises the positive and minimises the negative impacts. More concretely, this means that regulations regarding the market introduction of new products and services should be so drafted that they increase the acceptance of consumers and legal security for companies. On the other hand, their negative effects on the costs for development and market introduction of new products and services, the time-to-market and the costs of other input factors, like labour, energy, and materials, have to be taken into account and to be minimised. One example of regulations with little negative and significant positive impacts for the introduction of new products and services are labelling policies. Again, also this trade-off is very technology- and market-specific, so that for each individual technology and product or service a check of the impacts on the various dimensions relevant for innovation has to be performed.

The numerous and heterogeneous impact dimensions of regulations have to be explicitly taken into account in regulatory impact assessments. The European Commission introduced impact assessment a an instrument to improve the quality and coherence of its policies by a Communication from the Commission on impact assessment (European Commission (2002a)), for all its major initiatives, i.e. those which are selected in the Annual Policy Strategy or later in the Work Programme of the Commission as priority initiatives from the year 2003 on. Impact assessment identifies the likely positive and negative impacts of proposed policy actions, enabling to identify trade-offs and synergies between different objectives of the policy, and to make informed political judgements on proposals to adjust the policy under development or possible accompanying measures. This approach seeks to a more coherent implementation of the European Strategy for Sustainable Development.

The technical guidelines for the implementation of the impact assessment have been issued in October 2002. They include methodological aspects as well as lists of possible impacts. Among the possible economic impacts, aspects of market development and technological innovation are already mentioned in the guidelines but only within illustrating examples and in the annexes to these guidelines. The system of impact assessment is being introduced gradually and will be fully operational in 2004/2005. Therefore, no practical experiences with the methodology or first reports are available yet. However, the results of our study show that aspects of the development of new products and services and the shaping of new markets could be introduced in this instrument in a much more emphasised and stringent way.

Finally, the performance criteria of regulatory bodies have to be reconsidered. We have already discussed to integrate the promotion of innovation explicitly into the set of objectives of regulatory bodies. However, this is not sufficient to increase the quality of the regulatory framework regarding innovation. It is required to establish a set of evaluation criteria in order to assess the performance of regulatory bodies regarding the promotion of innovation besides their general responsibility to protect competition, health, safety or the environment. Since the promotion of new products and services may contradict the one or other traditional goal, a new balance must also be found between the traditional performance criteria and the new criteria in relation to innovation, like the number of approvals, permits and licenses for new products and services. A further step would be even a comparative performance assessment of competing national regulatory bodies in Europe respective to the dimension of innovation. This would not only increase the competition, but this kind of benchmark analysis would allow to identify at least good practice which could be transferred to all other regulatory bodies.

6.4 Coordination of Policies of Regulatory Bodies to Foster Innovation

From innovation research we know that the innovation process is not a simple linear process from research to development, market introduction and diffusion, but a rather complex process including several feedback loops. Consequently, the promotion of innovation by regulatory policies requires a comprehensive approach, coordinating or even integrating the regulatory policies of all the regulatory bodies which have an impact on the various stages of the innovation process. This means that often it is not sufficient to provide a positive regulatory framework for research, because companies engage only in research activities if they expect a significant return. Therefore, it is necessary to consider also the demand side by reducing the risk of insufficient demand or low consumer acceptance. We have identified various positive examples for the success of demand focusing regulatory policies, like the orphan drug and other reimbursement policies in the pharmaceutical sector or the

fixed-feed tariffs in the case of wind energy. Positive examples for the integration between research and regulation policies can be found in the case of standards, where the results of publicly funded research projects have been transferred into European standardisation process. The resulting standards then provided the basis for the emergence of a new generation of products, like in mobile telecommunication. Since the innovation processes differ between industries, comprehensive regulation policies trying to promote innovation have to take these specifics into account.

As we have already argued above, it is necessary to shape the regulatory framework for new products and services in a way which stabilises the demand side by increasing the consumer acceptance. Here, one should not only concentrate on national consumers and users, but should consider also the preferences, e.g. for product safety and quality, of consumers abroad in order to maximise the group of potential consumers. In the context of co-ordinating the policies of regulatory bodies, those regulatory bodies responsible for the demand side should exploit windows of opportunities to foster the establishment of lead markets by shaping an adequate regulatory framework, like successfully accomplished in the case of wind energy or the GSM standard for mobile communication. These lead markets are characterised by significant export activities and therefore a source of growth and employment.

6.5 Improved Implementation of Regulations to Foster Innovation

The analysis of the empirical evidence has shown that often not the regulation itself, but the factual implementation represents a serious problem for companies introducing new products and services. First, we find heterogeneous implementations of European regulations in different Member States. Second, even within one country the implementation may differ. These frictions have serious impacts, especially for the introduction of new products and services, because both the costs and the risk of market introduction increases. This reduces especially the incentives of companies to develop and market products with high development costs and foreseen for international distribution. Consequently, the implementation of regulations has to be harmonised, which will decrease the regulatory costs and the risk of successful market introduction and increase the potential market volume. Especially the reduction of approval procedure at one single European institution or at one national body applying mutual recognition agreements increases the incentives to develop and market new products and services for a European market.

Furthermore, approval times have significant impacts on companies´ incentives to develop and market new products and services, because the longer the time required for market approvals, the less the expected returns on investments in long-lasting

R&D. In addition, very often with an increasing duration of approval procedures the risk of not receiving market approval goes up, which is again negative for the incentive structures of innovative companies. On the other hand, reducing approval times too much increases the risk of making false decisions in the sense of permitting dangerous products or denying approval for harmless, but beneficial products. Bodies responsible for the implementation of regulations have to be aware of this trade-off, but it has to be decided differently according to the characteristics of the technologies and products and their possible risks and benefits.

Respective to the USA, we observe on the one hand an increasing harmonisation with the regulatory framework in Europe. On the other hand, the implementation in the USA is obviously in some sectors more favourable for companies. One crucial difference is the different attitude of some regulatory bodies in the USA, which understand themselves more as a service provider for companies trying to market new products and services. Therefore, they offer services which reduce the costs of the regulatory process for the companies. The transition of regulatory bodies into service providers for the general public, but also for companies, represents a promising strategy also to promote their general support for the introduction of new products and services.

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Annex I

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Annex II

Fraunhofer Institute
Systems and
Innovation Research

European Survey on the Role of Regulation for Innovation: Company Questionnaire

The importance of innovation for the creation of a dynamic and competitive European economy is broadly acknowledged. An administrative and regulatory environment that is conducive to the development of new products and services is critical in facilitating innovation. This survey is conducted within the framework of an innovation policy study on "Regulations Shaping New Markets" for the DG Enterprise of the European Commission. The objective of this study is to review the issues at stake and the trends relating to the relationship between regulation and the shaping of new markets. This questionnaire aims to collect the opinions and attitudes of companies towards the current regulatory framework relevant for the introduction of new products and services. Your individual answers to the questions of the survey will be treated with absolute confidentiality. We will only analyse data on an aggregated level and include them in the final report of this project to be published by the DG Enterprise of the European Commission.

We know about your time constraints, but would deeply appreciate your cooperation and your opinions in order to support the development of an innovation-friendly regulatory framework in the European Union.

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Definitions:

An ***innovation***, as defined in this survey, is a new or significantly improved product (good) or service introduced to the market, or the introduction of a new or significantly improved process within your firm. The innovation is based on the results of new scientific or technological developments, new combinations of existing technology or utilisation of other knowledge acquired by your firm. The innovation should be new to your firm; it has not necessarily to be new to the market (source: Community Innovation Survey III).

Regulation in total refers to the diverse set of instruments by which governments set requirements for enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of *government* (incl. EU), and rules issued by *non-governmental* or self-regulatory bodies to whom governments have delegated regulatory powers (e. g. standards development organisations, industry confederations). Regulations fall into three categories: ***Economic regulations*** intervene directly in market decisions such as pricing, competition, market entry, or exit. ***Social regulations*** protect public interests such as health, safety, the environment, and rights of workers. ***Administrative regulations*** are paperwork, qualification requirements and administrative formalities ("red tape") though which governments collect information and intervene in individual economic decisions. They also accompany economic and social regulations (source: OECD).

Contact data:

Please give us some information (confidentiality is guaranteed), which allow us to send you the summary of the results.

e-mail address

Company Name

Country

0. Position of the person answering the questionnaire

Please indicate your position or responsibility in your firm.

Chief Executive Officer (top management) ☐
Member of Legal Department (e.g. Regulatory Affairs) ☐
Member of R&D Department ☐
Member of Marketing Department ☐
Other position ☐
Please specify:_____

1. Basic economic information on your firm

What is your company's core business or primary sector of activity?

Total turnover market sales of goods and services including export and taxes except VAT (in €) in year 2002:	
Exports of goods and services (in % of total turnover) in year 2002:	
Number of employees (full-time) in year 2002:	
Expenditure for "innovation" activities (i.e. intramural and extramural R&D, acquisition of machinery, equipment, and other external knowledge, design, training, market introduction of new or improved products or services) (in % of total turnover)	
Expenditure for intramural and extramural R&D (in % of total turnover)	

2. Innovation activities

During the period 2000-2002, did your enterprise introduce any new or significantly improved products (goods) or services to the market or did your enterprise introduce any new or significantly improved production processes including methods of supplying services and ways of delivering products? If yes, what are the impacts?

	No	Yes	If yes	%
Product innovation	☐	☐	Approx. share of turnover generated by new or significantly improved products (goods) or services introduced in the period 2000-2002	
Process innovation	☐	☐	Approx. reduced operating and/or labour costs in 2002 as percent of total cost	

3. Objectives of innovation activities

Which objectives has your enterprise tried to reach with innovation activities performed in the period 2000-2002? Please grade the importance of the following goals for your firm.

	Importance				
Objectives of innovation	very low	low	medium	high	very high
Increase range of goods or services	☐	☐	☐	☐	☐
Increase market or market share	☐	☐	☐	☐	☐
Improve quality of goods and services	☐	☐	☐	☐	☐
Improve production flexibility	☐	☐	☐	☐	☐
Reduce labour costs	☐	☐	☐	☐	☐
Reduce material consumption	☐	☐	☐	☐	☐
Reduce energy consumption	☐	☐	☐	☐	☐
Fulfil governmental regulations (e.g. directives)	☐	☐	☐	☐	☐
Fulfil non-governmental regulations (e.g. standards)	☐	☐	☐	☐	☐
Reduce negative environmental impact	☐	☐	☐	☐	☐
Others: Please specify:_____	☐	☐	☐	☐	☐

Have specific governmental and non-governmental regulations (e.g. environmental protection directives require new environmental technologies) created additional incentives and business opportunities for your firm to develop new products, services or production processes?

No ☐⇒ please go to question 4
Yes ☐

Please provide some details:

4. Factors hampering innovation

Your activities to develop and introduce new products and services into the market could be hampered by various factors, which could e.g. prevent the start of these activities, slow them down, stop them in progress or even prevent them being planned.

Please grade the importance of the following hampering factors for your firm during the period 2000-2002.

Hampering factors	**Importance**				
	very low	low	me-dium	high	very high
Not feasible from a scientific/technical point of view	☐	☐	☐	☐	☐
Problems with intellectual property rights of other companies/institutions	☐	☐	☐	☐	☐
Perceived excessive economic risks	☐	☐	☐	☐	☐
Innovation costs too high	☐	☐	☐	☐	☐
Lack of appropriate sources of financing	☐	☐	☐	☐	☐
Organisational rigidities within the enterprise	☐	☐	☐	☐	☐
Lack of qualified personnel	☐	☐	☐	☐	☐
Lack of appropriate co-operation partners	☐	☐	☐	☐	☐
Lack of information on technology	☐	☐	☐	☐	☐
Lack of information on markets	☐	☐	☐	☐	☐
Governmental regulations (i.e. directives, laws)	☐	☐	☐	☐	☐
Implementation of governmental regulations (e.g. administrative burdens)	☐	☐	☐	☐	☐
Non-governmental regulations (i.e. standards, voluntary sectoral agreements)	☐	☐	☐	☐	☐
Implementation of non-governmental regulations (e.g. administrative burdens)	☐	☐	☐	☐	☐
Lack of customer responsiveness to new goods or services	☐	☐	☐	☐	☐
Others, please specify: _____	☐	☐	☐	☐	☐

Are there specific governmental or non-governmental regulations that hamper your activities to develop and introduce new products or services? Please name them and explain their hindering effect.

5. Importance of regulations relevant for new products and services

There are numerous regulations relevant for the introduction of new products and services. Please assess the importance of the following types of regulations for the business of your firm during the period 2000-2002.

Type of regulation	**Importance**				
	very low	low	me-dium	high	very high
Price regulations	☐	☐	☐	☐	☐
Regulation of competition among firms	☐	☐	☐	☐	☐
Constraints for the supply of specific products (e.g. public monopolies) and services (e.g. one single carrier in transport)	☐	☐	☐	☐	☐
Regulation of production times or opening hours	☐	☐	☐	☐	☐
Quality standards	☐	☐	☐	☐	☐
Safety regulations (e.g. health aspects)	☐	☐	☐	☐	☐
Regulation of occupational safety	☐	☐	☐	☐	☐
Environmental regulations	☐	☐	☐	☐	☐
Regulations of licenses and permits (e.g. market approval)	☐	☐	☐	☐	☐
Regulation of product liability	☐	☐	☐	☐	☐
Labelling, consumer information	☐	☐	☐	☐	☐
Intellectual Property Rights	☐	☐	☐	☐	☐
Others: please specify:_____	☐	☐	☐	☐	☐

6. Impact of regulations on new products and services

Regulation may be a hampering factor for the development and market introduction of new products and services. However, regulation may also have a positive influence on these activities by forcing firms to search for new products and services. Furthermore, regulation may create new opportunities for new products and services by providing an adequate framework. Please assess whether regulations in the direct context of introducing new products and services into the market (see question 5) are more likely to have positive or negative impacts on these aspects.

Aspects affected by regulation	**The impact of the regulatory framework for our company is**					
	very negative	negative	neutral	positive	very positive	not relevant
Turnovers and profits with new products and services	☐	☐	☐	☐	☐	☐
Costs for the development and market introduction of new products and services	☐	☐	☐	☐	☐	☐
Risks for the development and market introduction of new products and services	☐	☐	☐	☐	☐	☐
Material and energy costs	☐	☐	☐	☐	☐	☐
Labour costs	☐	☐	☐	☐	☐	☐
R&D or technological flexibility	☐	☐	☐	☐	☐	☐
Organisational flexibility	☐	☐	☐	☐	☐	☐
Flexibility in the production or service-providing process	☐	☐	☐	☐	☐	☐
Time to market for new products and services	☐	☐	☐	☐	☐	☐
Product and service assortment	☐	☐	☐	☐	☐	☐
Product and service quality	☐	☐	☐	☐	☐	☐
Domestic market share	☐	☐	☐	☐	☐	☐
Foreign market share	☐	☐	☐	☐	☐	☐
Development of markets for new products and services	☐	☐	☐	☐	☐	☐
Health or safety of consumers	☐	☐	☐	☐	☐	☐
Health or safety of the work force	☐	☐	☐	☐	☐	☐
Consumer and user acceptance	☐	☐	☐	☐	☐	☐
Environmental quality	☐	☐	☐	☐	☐	☐
Legal security	☐	☐	☐	☐	☐	☐
Protection from liability claims	☐	☐	☐	☐	☐	☐
Others, please specify:_____	☐	☐	☐	☐	☐	☐

7. Assessment of the current regulatory framework relevant for your firm

Please express your attitude towards the following statements concerning the factual relationships between regulation and the development and market introduction of new products and services.

	Attitude				
Statements	totally disagree	disagree	ambivalent	agree	totally agree
Regulation hinders the development and market introduction of new products and services by our firm.	☐	☐	☐	☐	☐
Specific types of regulation create market opportunities for new products and services.	☐	☐	☐	☐	☐
The regulatory framework is essential for the economic development of our sector.	☐	☐	☐	☐	☐
The regulatory framework is essential for the economic development of our firm.	☐	☐	☐	☐	☐
The number of regulations is too high.	☐	☐	☐	☐	☐
The specifications of regulations are not transparent enough.	☐	☐	☐	☐	☐
Regulations contradict each other.	☐	☐	☐	☐	☐
Frequent changes impede the development and market introduction of new products and services of our firm.	☐	☐	☐	☐	☐
Regulations stimulate the improvement of the quality of our products and services.	☐	☐	☐	☐	☐
Regulations do not correspond to the needs of consumers.	☐	☐	☐	☐	☐
Regulations do not correspond to the needs of the environment.	☐	☐	☐	☐	☐
Regulations do not keep track of the development of technology.	☐	☐	☐	☐	☐
There is a lack of regulations regarding the current needs of consumers.	☐	☐	☐	☐	☐
There is a lack of regulations regarding the current need for environmental issues.	☐	☐	☐	☐	☐
There is a lack of regulations regarding the current potential of technologies.	☐	☐	☐	☐	☐
Approval procedures take too long.	☐	☐	☐	☐	☐
Approval procedures are too costly.	☐	☐	☐	☐	☐
The factual implementation of regulations is not transparent enough.	☐	☐	☐	☐	☐

The factual implementation of regulations is not flexible enough.	☐	☐	☐	☐	☐
Firms do not possess the necessary know-how to comply with regulations.	☐	☐	☐	☐	☐
SMEs have disadvantages in complying with regulations compared to larger companies.	☐	☐	☐	☐	☐
Public support (e.g. help-desks) regarding the fulfilment of regulation is not sufficient.	☐	☐	☐	☐	☐
Regulation-related services offered by private consulting companies are insufficient.	☐	☐	☐	☐	☐
The administrative burden ("red tape") accompanying regulations can be decreased without endangering their effectiveness.	☐	☐	☐	☐	☐

Please describe your experience with the concrete relationship between regulation and the development and market introduction of new products and services:

8. Future of the regulation system

Several approaches are currently being discussed or have even already been introduced to improve the present regulatory framework. Which of the following approaches are suitable to make the regulatory framework more conducive to the development of new products and services as far as your firm is concerned?

	Effectiveness				
New approaches to regulation	not effective	ambivalent	effective	very effective	cannot be assessed
The amount of governmental regulations will be decreased.	☐	☐	☐	☐	☐
The level of detail of governmental regulations will be decreased.	☐	☐	☐	☐	☐
The regulatory framework especially regarding product requirements for market approval will become less rigid and the (product) liability will become stricter (US paradigm).	☐	☐	☐	☐	☐
Regulations will be shaped more according to the risk-cost balancing approach instead of the zero-risk approach.	☐	☐	☐	☐	☐
The flexibility of the development of regulations will be increased.	☐	☐	☐	☐	☐
The development process of regulations will be accelerated.	☐	☐	☐	☐	☐
The flexibility regarding the implementation of regulations will be increased.	☐	☐	☐	☐	☐
There will be a general policy requiring plain language when drafting regulations.	☐	☐	☐	☐	☐
Each new regulation will go in for an impact assessment (taking into account the market introduction of new products and services).	☐	☐	☐	☐	☐
Each existing regulation will be regularly adjusted to the state-of-the-art in science and technology.	☐	☐	☐	☐	☐
New regulatory bodies will be created for new technologies.	☐	☐	☐	☐	☐
Regulation policies of different regulation bodies will be harmonised and co-ordinated.	☐	☐	☐	☐	☐
Companies will have to contact only one regulatory body responsible for all regulation-related aspects ("One-Stop Shop").	☐	☐	☐	☐	☐

Certification and conformity assessment will become faster and cheaper without changes in the existing regulatory framework.	☐	☐	☐	☐	☐
The "silence is consent" rule (i.e. that licenses, permits and approvals are issued automatically if the competent regulatory body has not acted by the end of the statutory response period) will be applied.	☐	☐	☐	☐	☐
The information flow between regulatory bodies and the regulated stakeholders will be stimulated by various instruments (obligations and incentives).	☐	☐	☐	☐	☐
Participation during the development of regulations will be extended to more relevant stakeholders by active measures (e.g. hearings).	☐	☐	☐	☐	☐
The public will be informed about the steps of the regulation process, including background information and expert statements.	☐	☐	☐	☐	☐
The principle of co-regulation will be introduced where the objectives are defined by the legislator, but the implementation will be carried out by parties recognised as being active in the field concerned.	☐	☐	☐	☐	☐
Governmental regulation will be substituted by self-regulation of the involved parties.	☐	☐	☐	☐	☐
Voluntary sectoral agreements of firms will substitute governmental regulations.	☐	☐	☐	☐	☐

Please provide further approaches in order to improve the present regulatory framework with respect to the development and market introduction of new products and services:

9. General framework conditions for introducing new products and services world-wide

Please assess first the importance which the following conditions have for the initial introduction of new products and services world-wide. Then, please assess in which of the following countries or regions the following framework conditions are most attractive for the initial introduction of new products and services world-wide. (Multiple answers possible)

	Importance	**Country or region of highest attractiveness (multiple answers possible)**			
	(1 = low to 5 = high; 9=not assessable)	European Country * (please specify)	USA	Japan	Others** (please specify)
R&D capacities			☐	☐	
Production capacities			☐	☐	
Labour costs			☐	☐	
Industry-oriented infrastructure			☐	☐	
Regulatory framework (e.g. permission and approval system)			☐	☐	
Expected total market volume			☐	☐	
Expected market growth			☐	☐	
Expected individual market share			☐	☐	
High income /willingness to pay			☐	☐	
High acceptance of new products			☐	☐	
Others, please specify:			☐	☐	

* Austria, Belgium, Denmark, France, Finland, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom, European Union in general, candidate countries, associated countries

** Canada, China, Russia, South East-Asia, Asia, Africa, Middle America, South America, Australia

Please send the questionnaire via fax or post to the following address:

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Fraunhofer Institute for Systems and Innovation Research
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D-76139 Karlsruhe
Germany

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Thank you for your co-operation!

Annex III

Distribution of the company sample

	Central Europe	Benelux	Northern Europe	Southern Europe	Rest of World	
Food	5	7	5	1	2	20
Pharma	13	10	6	9	3	41
Mechanical Engineering	14	13	11	4	2	44
Electrical Engineering	14	5	6	0	2	27
Environment	10	4	5	2		21
Transport + Telecomm.	7	8	7	8	1	31
Other Services	10	11	3	2	8	34
Others	24	10	4	3	3	44
	97	68	47	29	21	262

Annex IV

Study funded by the European Commission DG Enterprise/Innovation Policy Unit, in the framework of the Innovation /SMEs programme, part of the Fifth Research Framework Programme.

Fraunhofer Institute Systems and Innovation Research

"New products and services. Analysis of regulations shaping new markets"

Interview Guide

0. Position of the person answering the questionnaire

Please indicate your position or responsibility in your organisation:

1. Basic information on your organisation

Which stakeholders or which interest group does your organisation represent?

Companies/Industry ☐
SMEs ☐
Environmental concerns ☐
Consumer concerns ☐
Work force concerns ☐

Are the activities of your organisation linked mainly to a certain economic sector?

No ☐
Yes ☐ Please indicate the sector: _____

How many individual members does your organisation have?

How many institutional members does your organisation have?

On which geographic level does your organisation operate?

Regional ☐
National ☐
European ☐
International ☐

2. Targets of the organisation

Which are the main targets of your organisation? How important are regulation aspects within the target setting of your organisation? How relevant are innovation aspects?

In which ways do you try to achieve the targets of your organisation? What are important instruments used for this purpose? How does your organisation try to influence the shaping of the regulatory framework in the field(s) in which your organisation is active?

3. Framework for innovation in the EU and globally

How do you assess the framework conditions for innovation activities in the EU in the field(s) in which your organisation is active? Which are factors which favour innovations, which factors hamper innovations in the EU? How relevant are regulatory aspects for innovations?

How do you assess the framework conditions for innovation activities in the EU in the field(s) in which your organisation is active in comparison to other countries (e. g. USA, Canada, Japan)? In which areas do you see specific advantages or disadvantages for the EU in this respect?

4. Regulatory framework in the EU and globally

How do you assess the regulatory framework in the EU in those field(s) in which your organisation is active? Which are the most important regulations or areas of regulation? According to the view of your organisation which targets should be achieved with the respective regulations? How important are innovation aspects in this respect?

Does the current EU regulatory framework fulfill the requirements/targets of your organisation? If not, what should be changed in your opinion?

Are the significant differences in the regulatory framework between EU member states in those field(s) in which your organisation is active? How do you assess potential differences between EU member states?

How do you assess the regulatory framework outside the EU in the field(s) in which your organisation is active outside the EU (e. g. USA, Canada, Japan)? What can we learn from these countries with respect to regulatory aspects in the relevant fields?

5. Examples of regulations shaping new markets

In the following I would like to discuss with you a few examples in which – according to the view of scientists and politicians – regulatory aspects are of high relevance for innovation activities and the introduction of new products and services in the market.

6. Future of the regulation system in the EU

Several approaches are currently being discussed in order to improve the present regulatory framework (see below). Which approaches are in favour of your organisation? Do you think some of these approaches are able to fulfill the requirements of your organisation and are suitable to make the regulatory framework more conducive to the development of new products and services?

Annex V

List of interview partners and organisations

Consumer Organisations:

- Franz Fiala, Austrian Consumer Council,Vienna, Vice-President European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC), Vienna
- Jens Henriksson, International Secretary, Swedish Consumer's Association, Stockholm
- Michael Müller, Project Manager,Verkehrsclub Deutschland (VCD), Bonn
- Dr. Gottlobe Fabisch, European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC), Brussels

Pharma:

- Peter Marx, Manager Healthcare Management, Pfizer GmbH, Karlsruhe
- Christine-Lise Julou, Manager Scientific, Technical & Regulatory Affairs, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels
- Charlotte de Roo, Health, Safety and Environment advisor, Bureau Européen des Unions de Consommateurs (BEUC), Brussels
- Dr. Kees de Joncheere, Regional Adviser Health Technology and Pharmaceuticals, WHO Regional office for Europe, Copenhagen
- Dr. Marianne van Maarschalkerweerd, Chairperson of Education Committee, European Society for Regulatory Affairs, London/Paris
- Prof. Dr. Susanne Keitel, Director Pharmaceutical Quality and European Affairs, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Bonn, Member of the German Society for Regulatory Affairs
- Dr. M. Papaluca Amati, Deputy Head of Sector Safety and Efficacy of Medicines, European Agency for the Evaluation of Medicinal Products (EMEA), London
- Rodney Elgie, President of Executive Committee, European Patients' Forum, Luxembourg

Food:

- Marcus Girnau, German Federation of Food Law and Food Science (BLL), Bonn
- Christina Rueda Catry and Magdalena Lewandowski, Committee of Agricultural Organisations in the European Union - General Confederation of Agricultural Co-operatives in the European Union (COPA-COGECA), Brussels
- Dominique Taeymans, Confederation of the Food and Drink Industries in the EU (CIAA), Brussels
- Garlich von Essen, European Seed Association (ESA), Brussels

- Beate Kettlitz, Bureau Européen des Unions de Consommateurs (BEUC), Brussels
- Geert Ritsema, Friends of the Earth Europe, Brussels

Environment:
- Peter Ahmels, President, Bundesverband Windenergie (BWE, German Wind Energy Association), Osnabrück
- Dominique Gatel, Director of Technical Environmental Affairs, Veolia Environment France, Paris
- Pia Olson, Environmental Policy Officer, International Affairs, Danish Society for Nature Conservation,
- Christian Hey, General Sectretary, Expert Council on Environmental Questions (SRU), Berlin
- Dörte Fouquet, Managing Director, European Renewable Energies Federation (EREF), Brussels
- Wolfgang Lohbeck, Greenpeace Germany, Hamburg
- Karl-Friedrich Ziegahn, former President, Confederation of European Environmental Engineering Societies (CEEES),
- Markus Liechti, Project Manager, European Federation for Transport and Environment (T&E), Brussels

Mechanical Engineering:
- Keith Warren, Executive Director (Representation), Mechanical & Metal Trade Confederation (METCOM), London
- Harald Riekeles, Secretary of the Standardization Committee for Mechanical Engineering (Normenausschuss Maschinenbau), German Institute for Standardization (DIN), Berlin
- Eero Hovi, Task Force on Innovation, European Metalworkers Federation, Brussels
- Peter Günther, Head of Dept. Technology and Environment, Verband deutscher Maschinen- und Anlagenbau (VDMA, German federation of the engineering industries), Frankfurt/M.

Electrical Engineering:
- Gisela Eickhoff, Haimo Huhle, German electrical and electronic manufacturers' association (ZVEI), Frankfurt
- Volker Wanduch, German Association of Engineers (VDI), Frankfurt
- Volker Schanz, Information Technology Society within the Association for Electrical, Electronic & Information Technologies (VDE-ITG), Frankfurt

Communication & Transport:
- Stefan Grob, German Association for Information Technology, Telecommunications and New Media (BITKOM), Berlin
- Volker Schanz, Information Technology Society within the Association for Electrical, Electronic & Information Technologies (VDE-ITG), Frankfurt
- Dr. Peter Bumann, Council of European Professional Informatics Societies, Frankfurt

- Harald Radeck, German Regulatory Authority for Telecommunications and Posts (RegTP), Bonn
- Markus Liechti, European Federation for Transport and Environment (T&E), Brussels
- Michael Müller, Project Manager, Verkehrsclub Deutschland (VCD), Bonn
- Michael Bartl, German Trade Union Transport and Telecommunication (TRANSNET), Berlin/Frankfurt
- Bernadette Tesch-Segol, Union Network Europe (Uni-Europa), Brussels
- Doro Zinke, European Transport Worker's Federation (ETF), Brussels

Standardisation Organisations

- Stephen Munden, British Standards Institute (BSI), London
- Ross Howie, British Department of Trade and Industry (DTI), London
- Michel Jeanson, Secretary General, European Environmental Citizens Organisation for Standardisation (ECOS), Brussels
- Yves Chauvel, European Telecommunications Standards Institute (ETSI), Sophia-Antipolis
- Reinhard Scholl, International Telecommunication Union, Telecommunication Standardization Bureau (ITU-T), Geneva
- Saburo Tanaka, International Telecommunication Union, Telecommunication Standardization Bureau (ITU-T), Geneva
- John Ketchell, European Committee for Standardisation, Information Society Standardisation System (CEN/ISSS), Brussels
- Dr. Gottlobe Fabisch, European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC), Brussels

General

- Prof. Dr. Masayuki Kondo, Yokohama National University Graduate School of Environment and Information Sciences, Yokohama
- Robert Alter, Head of Department responsible for Regulatory Reform, Organisation for Economic Co-operation and Development (OECD), Paris
- Herbert Steinwender, Union of Industrial and Employers' Confederations of Europe, (UNICE), Brussels
- Ray Lambert, British Department of Trade and Industry (DTI), London