How Can EU Legislation Enable and/or Disable Innovation

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Abstract

This short study focuses on the multi-faceted, ambiguous and complex relationship between (EU) regulation and innovation in the economy, and discusses the innovation-enhancing potential of certain regulatory approaches as well as factors that often reduce incentives to innovate. We adopt an 'ecosystem' approach to both regulation and innovation, and study the interactions between the two ecosystems. This general analysis and survey is complemented by seven case studies of EU regulation enabling and disabling innovation. The case studies are preceded by a broader contextual analysis of trends in EU regulation over the last three decades, showing the significant transformation of the nature and quality of EU regulation, largely in the deepened internal market.

Our findings include the following. Regulation can at times be a powerful stimulus to innovation. EU regulation matters at all stages of the innovation process. Different types of regulation can be identified in terms of innovation impact: general or horizontal, innovation-specific and sector-specific regulation. More prescriptive regulation tends to hamper innovative activity, whereas the more flexible EU regulation is, the better innovation can be stimulated. Lower compliance and red-tape burdens have a positive effect on innovation.

We recommend to incorporate a specific test on innovation impacts in the ex ante impact assessment of EU legislation as well as in ex post evaluation. There is ample potential for fostering innovation by reviewing the EU regulatory *acquis*.

Resumé

Ce bref essai se penche sur la relation ambiguë, complexe et aux multiples facettes entre la réglementation et l'innovation dans le monde économique, en mettant l'accent sur le potentiel de certaines approches réglementaires d'encourager l'innovation, ainsi que sur les facteurs qui, le plus souvent, réduisent l'incitation à innover. Nous adoptons une approche « écosystème » tant pour le volet réglementation que pour le volet innovation, tout en étudiant les interactions entre ces deux écosystèmes. Cette analyse plus générale et cette étude sur le sujet sont complétées par sept Études de cas de la réglementation de l'UE ayant favorisé ou entravé l'innovation. Ces Études de cas sont précédées d'une analyse contextuelle plus large des tendances au sein de la réglementation de l'UE, au cours de trois dernières décennies, qui met en évidence une significative transformation de la nature et de la qualité de la réglementation de l'UE, en grande partie dans le cadre d'un marché intérieur de l'UE beaucoup plus profond.

Nos conclusions principales peuvent être récapitulées de la manière suivante. La réglementation peut, dans certaines circonstances, être un puissant stimulant pour l'innovation et le dynamisme commercial. La réglementation de l'UE est importante à tous les stades du processus d'innovation. Il est possible d'identifier différents types de réglementations, au vue de leur impact sur l'innovation. Il est également possible de faire une distinction entre les normes générales, les normes spécifiques pour l'innovation et la législation spécifique du secteur. Une réglementation plus rigide et prescriptive peut freiner les activités d'innovation, alors qu'une réglementation plus flexible est plus susceptible de les stimuler. Plus réduits seront les coûts de mise en conformité et des charges administratives, plus important sera l'impact positif sur l'innovation.

Nous recommandons d'intégrer des essais spécifiques sur les impacts de l'innovation dans l'évaluation ex ante de la législation de l'EU, ainsi que dans l'évaluation ex post. Il y a un large potentiel pour favoriser l'innovation, à travers une révision des acquis de l'UE.

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Executive summary

This short study focuses on the multi-faceted, ambiguous and complex relationship between regulation and innovation in the economy, and discusses the innovation-enhancing potential of certain regulatory approaches, as well as the factors that most often reduce incentives to innovate. We adopt an "ecosystem" approach to both regulation and innovation, and study the interactions between the two ecosystems. This more general analysis and literature survey is complemented by seven Case studies of EU regulation enabling and disabling innovation. These Case studies are preceded by a broader contextual analysis of trends in EU regulation over the last three decades, showing the significant transformation of the nature and quality of EU regulation, largely in the framework of a much deepened and widened (in scope) EU internal market. After a reminder of the New Approach, creating much more flexible, objectives-driven EU risk regulation (without technical specifications) giving ample scope for innovative responses by enterprises, a more market-oriented approach to EU 'better regulation' has gained wide acceptance. On the whole, this trend has led to 'better' EU regulation in many markets and a far more market-driven EU economy which should as a rule be favourable to innovation.

The Case studies are divided into two under 'horizontal' legislation and five under sectoral regulation The first one under horizontal legislation is about the 'refusal to deal' doctrine under the abuse of dominant position (Art. 102, TFEU), as applied in telecoms, which may well have cause uncertainty and hence hindered innovation. The second is about strategic public procurement, a stimulating move to foster innovation. For sectoral regulation, three Cases focus on the enabling or stimulating effect of EU regulation. In different ways, this has been accomplished under energy efficiency regulation for domestic appliances (with interesting attempts to imitate this for cars and outdoor noise equipment, which highlights the complications and incentives), via European standards (for GSM and for smart meters) and for end-of-life vehicles. Another two cases highlight the disabling or constraining effect on innovation of restrictive EU regulation, one being REACH (EU chemical regulation) and another selected aspects of EU biotech regulation (GMOs and cop protection), all inspired or squarely based on rather loose applications of the precautionary principle.

Our main findings can be summarized as follows:

- Regulation can, under certain circumstances, be a powerful stimulus to innovation and entrepreneurship.
- EU regulation matters at all stages of the innovation process, from R&D to commercialization.
- Different types of regulation can be identified, in terms of their impact on innovation. We distinguish between general rules, innovation-specific rules, and sector-specific legislation.
- Different types of regulatory approach can have different impacts on innovation. Typically, more prescriptive, rigid regulation can hamper innovative activity, whereas the more regulation is flexible, the more innovation can be stimulated.
- During the enforcement phase of regulation, the lower the costs of compliance and the administrative burdens, the more positive is the impact on innovation.

In light of the above, we recommend to incorporate a specific test on innovation impacts in the ex ante impact assessment of EU legislation, as well as in the ex post evaluation of

individual pieces of EU legislation, and also in fitness checks on whole areas of EU legislation and cumulative cost assessment in specific industry sectors. Our case studies suggest that in some occasions EU regulation has spurred innovation, whereas in other cases the burdens imposed by regulation, as well as the latter's impact on the whole business environment, have hampered innovation in the EU. This conclusion, in turn, shows that there is ample potential for spurring innovation by reviewing the EU *acquis*.

Note de Synthèse

Ce bref essai se penche sur la relation ambiguë, complexe et aux multiples facettes entre la réglementation et l'innovation dans le monde économique, en mettant l'accent sur le potentiel de certaines approches réglementaires d'encourager l'innovation, ainsi que sur les facteurs qui, le plus souvent, réduisent l'incitation à innover. Nous adoptons une approche « écosystème » tant pour le volet réglementation que pour le volet innovation, tout en étudiant les interactions entre ces deux écosystèmes. Cette analyse plus générale et cette étude sur le sujet sont complétées par sept Études de cas de la réglementation de l'UE ayant favorisé ou entravé l'innovation. Ces Études de cas sont précédées d'une analyse contextuelle plus large des tendances au sein de la réglementation de l'UE, au cours de trois dernières décennies, qui met en évidence une significative transformation de la nature et de la qualité de la réglementation de l'UE, en grande partie dans le cadre d'un marché intérieur de l'UE beaucoup plus profond et large (du point de vue de sa portée). Après un rappel de la Nouvelle Approche, ayant amené à une réglementation du risque dans l'UE beaucoup plus flexible et axée sur les objectifs (sans spécifications techniques) et ayant offert aux entreprises de nombreuses possibilités pour des réponses innovantes, une approche de l'initiative de l'UE « Mieux légiférer », plus axée sur le marché, a obtenu une plus large acceptation. De manière générale, cette tendance a amené à une « meilleure » réglementation de l'UE dans beaucoup de marchés et à une économie de l'UE beaucoup plus axée sur les marchés, ce qui, en règle générale, devrait encourager l'innovation.

Les Études de cas sont divisées de la manière suivante : deux sont l'exemple d'une législation « horizontale » et cinq rentrent dans le cas d'une réglementation sectorielle. La première étude concernant la législation horizontale se penche sur la doctrine « refus de négocier », dans le cadre de l'abus de position dominante (Art. 102, TFUE), comme cela a été le cas dans le secteur des télécommunications, ce qui a amené à un sentiment d'incertitude, qui a donc entravé l'innovation. La deuxième étude concerne les marchés publics stratégiques, un exemple d'action d'incitation pour promouvoir l'innovation. Pour ce qui est de la réglementation sectorielle, trois cas se sont penchés sur l'effet d'incitation ou d'encouragement de la réglementation de l'UE. De manière différente, cela a été réalisé dans le cadre de la réglementation sur l'efficacité énergétique pour les appareils électroménagers (avec des tentatives intéressantes de répliquer cette approche dans le secteur automobile et dans celui des équipements visés par la directive sur le bruit en extérieur, mettant l'accent sur les complications et les mesures d'incitation), à travers les normes européennes (pour GSM et compteurs intelligents) et pour des véhicules en fin de vie. Deux autres cas sont un exemple de l'effet incapacitant ou contraignant, pour l'innovation, de certaines réglementations restrictives de l'UE, telles que le REACH (Règlement des substances chimiques) ainsi que d'autres aspects particuliers de la réglementation de l'UE relative aux biotechnologies (OGM et protection des récoltes), toutes inspirées ou nettement fondées sur des applications plutôt vagues du principe de précaution.

- Nos conclusions principales peuvent être récapitulées de la manière suivante:
- La réglementation peut, dans certaines circonstances, être un puissant stimulant pour l'innovation et le dynamisme commercial.
- La réglementation de l'UE est importante à tous les stades du processus d'innovation, de la R&D à la commercialisation.

- Il est possible d'identifier différents types de réglementations, au vue de leur impact sur l'innovation. Il est également possible de faire une distinction entre les normes générales, les normes spécifiques pour l'innovation et la législation spécifique du secteur.
- Différents types d'approches réglementaires peuvent avoir différents impacts sur l'innovation. Typiquement, une réglementation plus rigide et prescriptive peut freiner les activités d'innovation, alors qu'une réglementation plus flexible est plus susceptible de les stimuler.
- Au cours de la phase d'application de la réglementation, plus réduits seront les coûts de mise en conformité et des charges administratives, plus important sera l'impact positif sur l'innovation.

À la lumière de ce qui précède, nous recommandons d'intégrer des essais spécifiques sur les impacts de l'innovation dans l'évaluation ex ante de la législation de l'EU, ainsi que dans l'évaluation ex post des mesures législatives de l'UE, tout comme dans les bilans de qualité des domaines généraux de la législation de l'UE et dans l'évaluation des coûts cumulatifs de certains secteurs industriels spécifiques. Nos études de cas suggèrent que, dans certains cas, la réglementation de l'UE a stimulé l'innovation, alors que dans d'autres circonstances, les charges imposées par la réglementation, ainsi que l'impact de cette dernière sur l'environnement commercial général, ont ralenti l'innovation au sein de l'UE. Cette conclusion, de son côté, montre qu'il y a un large potentiel pour favoriser l'innovation, à travers une révision des acquis de l'UE.

1 Introduction

As recalled on several occasions by the European Commission and other EU institutions, EU's innovation performance has been (on average) rather sluggish over the past two decades[1]. EU Commissioner for research and innovation, Ms. Máire Geoghegan-Quinn, has spoken of an "innovation emergency", the causes of which are often described as related to the lack of a suitable "ecosystem", in which the economic, social, institutional and regulatory factors are conducive to entrepreneurship[2]. Only recently Europe's innovation performance seems to have shown some sign of resurgence[3]: however, the difference between EU Member States in this respect appears to be widening. Until a few years ago, innovation policy was mostly a national prerogative in the EU. The Lisbon strategy in 2000 has marked a stronger commitment in the area of innovation, and soon led to a coordinated strategy at the EU level to reach, *i.a.,* a level of expenditure in R&D of 3% of GDP. These were the days in which the European Commission paved the way towards the creation of the European research Area (ERA) and the launch of a pan-European innovation strategy. The 2006 "Aho Report" on "Creating an innovative Europe" led to a thorough reflection on EU innovation policy, which culminated in the creation of the Innovation Union flagship initiative in 2010. Innovation Union contains at least eight different constellations of initiatives.

Recently, in a stocktaking exercise on the impact of the Innovation Union initiative in its first four years (2010-2014), the European Commission has observed that the initiative "is succeeding in building momentum around innovation, mobilising stakeholders and mainstreaming innovation in key European, national and regional policies"[4]. The Commission also observed that the eco-system for innovation has been greatly improved by putting in place key single market measures, but also that "inconsistencies of rules and practices remain and are hampering the development of high growth innovative firms, which often find it too burdensome and risky to operate on other European markets", with obvious shortcomings for the diffusion of innovative products and services. Also, skills shortage and mismatch are still significant, in particular for what the Commission defines as '21st century skills' for creativity and entrepreneurial spirit.

Today, it is increasingly acknowledged in the literature that public policy can affect innovation incentives in many more ways than simply relying on innovation policy tools *tout court.* However, little systematic attention seems to have been paid, so far, to the interaction between EU regulation and innovation in the Union. The present study attempts to do exactly that, within the constraints of the limited space available. However, as we shall show, whilst a more general economic perspective on the interaction between EU regulation and innovation in the EU is indispensable, and the development of a framework of analysis is most useful, it is equally important to appreciate the often highly specific relationship between the two in different markets and/or with distinct types of regulation. This is so because both innovation and

[1] See the Innovation Union Scoreboard. The Innovation Union Scoreboard (IUS) has provided a comparative assessment of the innovation performance of the EU27 Member States since 2000. IUS includes a selection of indicators, which are proxies of innovation performance, and provides a basis for the analysis of improvements in performance over time. The IUS draws on statistics from various sources, such as the Community Innovation Survey, and groups indicators into 'enablers', 'firm activities' and 'outputs'. See http://ec.europa.eu/enterprise/policies/innovation/ policy/innovation-scoreboard/index_en.htm.

[2] See Máire Geoghegan-Quinn, "From Innovation Emergency to Economic Growth", Innovation Lecture, The Hague, 26 March 2012. European Commission - SPEECH/12/226.

[3] See the EU Innovation Union Scoreboard 2014 (European Commission, 2014a).

[4] See the State of the Innovation Union Report 2014 (European Commission, 2014b).

'regulation' are generic terms for what are in fact numerous complex and diverse activities, both privately and publicly.

Section 1 below defines both innovation and regulation and maps the interactions between the two in a comprehensive manner, also based on the findings of the economic literature in this field. Section 2 then discusses the potential obstacles and incentives created by EU regulation to innovation. Section 3 discusses a number of case studies in which regulation has significantly affected innovation. Section 4 concludes by putting forward a number of policy recommendations.

2 Innovation and regulation: connecting the dots

In this section we first briefly define innovation and regulation, and then discuss the phases of the innovation process that are affected by regulation, and more specifically by EU regulation.

2.1 Innovation: definition, main types and phases

Based on previous literature, Granieri and Renda (2012) give the following definition: (a) the creation of new (or the efficient reallocation of existing) resources (b) which contribute to progress. The first, *ontological*, element of innovation is approached in the broadest possible sense, leaving space for user-generated innovation, automated innovation, industrial R&D projects, public investment, etc. The second, *teleological*, element simply states that a new product is to be considered innovation only to the extent that it contributes to social welfare in the long run, without depriving society of resources that could have been more usefully allocated elsewhere. In a nutshell, innovation's main features are allocative efficiency and progress.

Innovation may well occur in market processes and products, but also outside the marketplace, including among end users and without any need for a research and development (R&D) process. The OECD (2005) distinguishes between **four types of innovation**: **product innovation, process innovation, marketing innovation and organisational innovation**. Another very important distinction in the economic literature is that between **disruptive** (or "radical") and **incremental** (or "follow-on") innovation. The latter occurs when firms make relatively minor improvements to existing products and processes, improving pre-existing attributes in order to meet the minimum standards for compliance; to the contrary, radical or disruptive innovation replaces existing products or processes, and is typically more risky, but also more beneficial when it produces new products or processes.

The (industrial) innovation process comprises the chain beginning with applied R&D, prototyping and development, and commercialisation.

2.2 Regulation: definition and main features

As explained in the previous section, regulation is one of the activities that governments can engage into, which can exert a profound impact on the level and direction of innovation, both in specific sectors and in the economy as a whole. Below, we explain the main precondition for regulation – the existence of a market or a regulatory failure – and then briefly introduce the various phases of the life of a rule, focusing specifically on EU rules.

The most typical precondition for regulation, which becomes its main objective, is the existence of situations in which market forces, by themselves, do not lead to a socially optimal result. These cases are termed "market failures" in economics, and include cases of significant market power (and abuse thereof), public goods, externalities, and asymmetric or incomplete information.

Market failures are, of course, not the only situations that lead governments to regulate. Among the other possible conditions that trigger regulatory interventions, we include regulatory failures (i.e. when existing rules produce suboptimal outcomes); Equity/fairness reasons (when the objective of regulation departs from that of efficiency to embrace more socially or environmentally relevant objectives); and long-term policy goals such as, for example, the need to complete the Internal Market or to achieve Europe 2020 goals.

We distinguish between[5]:

- The **Agenda-Setting** phase of regulation: during this phase, the main preparatory documents (at the EU level, Green Paper, White Paper, Communications) are prepared and adopted. This can include "umbrella" regulations (e.g. framework regulations) that are binding, but which still require the adoption of further implementation measures.
- The **legislation** phase entails the decision-making and adoption of secondary legislation measures, in the form of (at EU level) specific directives or regulations, or delegated acts. This phase can typically imply the setting of targets or requirements or caps, which might be kept fixed or changed throughout the lifespan of the legal rules. In the case of directives, these have to be transposed into national laws and implemented. In some cases, depending on the type of regulatory alternative chosen (see below), implementation measures might have to be adopted by private organizations in the execution of a co-regulatory arrangement.
- The **compliance** phase is not a regulatory phase, but rather refers to the set of actions and behaviour that have to be put in place by targeted stakeholders when having to comply with a specific set of rules. As will be illustrated below, different types of regulatory interventions can have a very significant impact on innovation when it comes to compliance.
- The **enforcement** phase refers to the monitoring of compliance with the rules. It most often entails the involvement of national or local administrations, which perform inspections and might impose sanctions for non-compliance. Also this phase can be delegated to specific agencies, or even private parties depending on the type of regulatory approach chosen.

2.2.1 Main types of regulatory intervention

Regulation can respond to market failures and other policy problems in different ways. The practice of *ex ante* impact assessment of regulation in the European Commission has led, over time, to a definition of a number of "types" of regulatory intervention. For the purposes of this paper, we adopt here a simplified taxonomy.

- **Regulation through information**. This is a very "light-touch" form of regulation, which aims at affecting consumer and firm behaviour by increasing the amount of information available on the marketplace.
- **Self-regulation**. This covers a large number of practices, common rules, codes of conduct and voluntary agreements by which economic actors, social players, NGOs and organized groups establish themselves voluntarily to regulate and organize their activities. Self-regulation can provide greater speed, responsiveness and flexibility as it can be established and altered more quickly than legislation; however it needs to be open and transparent as it may provide an opportunity for collusive arrangements[6].
- **Co-regulation** is "a mechanism in which a Community legislative act entrusts the attainment of the objectives defined by the legislator to parties which are recognized in the field (such as economic operators, the social partners, non-governmental

[5] We rely on a simple conceptualization of the main phases of EU legislation, which partly echoes the one used by the European Commission, as well as the "ANIME" framework developed (mostly for private regulation) by Abbott and Snidal (2009).

[6] Cafaggi and Renda (2011); and Cafaggi, Renda and Schmidt (2012).

organizations, or associations)[7]. Co-regulation combines the advantages of the binding nature of legislation with a flexible self-regulatory approach to implementation that encourages innovation and draws on the experience of the parties concerned. A drawback is the need to set up monitoring arrangements.

- **Standardization**. Another approach that can serve as an alternative to legislation, or can partially replace detailed regulation, is the reference to European Standards. This, at the EU level, requires the involvement of the European Standards Organizations CEN, CELENEC and ETSI. More precisely, the Commission may give mandates to ESOs to write standards, to be officially recognised by the EU as fulfilling particular (health, safety, environmental) objectives in EU regulation. This creates much greater certainty for companies as all they have to do is comply with such (performance) standards, for having an ensured access to the entire internal market. However, such standards are invariably voluntary, leaving (other) innovative options open. ESOs should also be consulted if a proposed policy option refers to European Standards, and might require changes in any of them.

- **Market-based instruments** influence the behaviour of market players by providing (negative/positive) monetary incentives or by guaranteeing some basic rules of the game. Possible alternative types are: (i) Marketable offsets, which allow producers to negotiate with each other and agents to ensure overall compliance, without this being necessarily enforced on all producers at the same level; (ii) Marketable permits; (iii) Taxes or charges, (iv) Property and liability rules; and (iv) Limits to price and/or quantity (licences, quotas, etc.).

- **Prescriptive regulatory actions.** These entail the incorporation of mandatory requirements into legislation (regulations, directives or decisions). The European Commission Impact Assessment guidelines distinguish between:

    - *Traditional 'command and control' policies*. These specify the use of certain practices, technologies, or designs. The advantage is relative ease of monitoring and enforcement. The disadvantages are that they are likely to be less cost-effective and they do not encourage technological innovation or to go beyond standards.

    - *Performance-oriented requirements.* They specify the required performance of the target population (for instance, certain tolerances, etc.). They do not detail the exact mechanisms by which compliance is obtained, but rather specify the criteria to be followed to achieve such compliance. They are often to be preferred to engineering or design standards, since they increase flexibility to achieve the performance desired. Such requirements should be flexible allowing aggregation or offsetting between different plants or agents, even regionally or nationally provided this does not unacceptably affect the overall outcome.

2.3 Regulation and innovation: mapping interactions

A review of the scholarly literature on the relationship between innovation and regulation (see Annex 2 to this report) suggests that in order for innovation to occur, entrepreneurs must have the willingness, opportunity/motivation, and capability or capacity to innovate, and that regulation can affect all three aspects[8]. Recent contributions (Stewart 2010, Carlin and Soskice 2006) differentiate clearly between the **incentive impact** and

[7] See the Inter Institutional Agreement on Better Lawmaking, art. 18.

[8] Ashford (2000)

the **compliance cost** of regulations. Stewart also summarizes previous literature in defining three main dimensions that affect the impact of regulation on innovation:

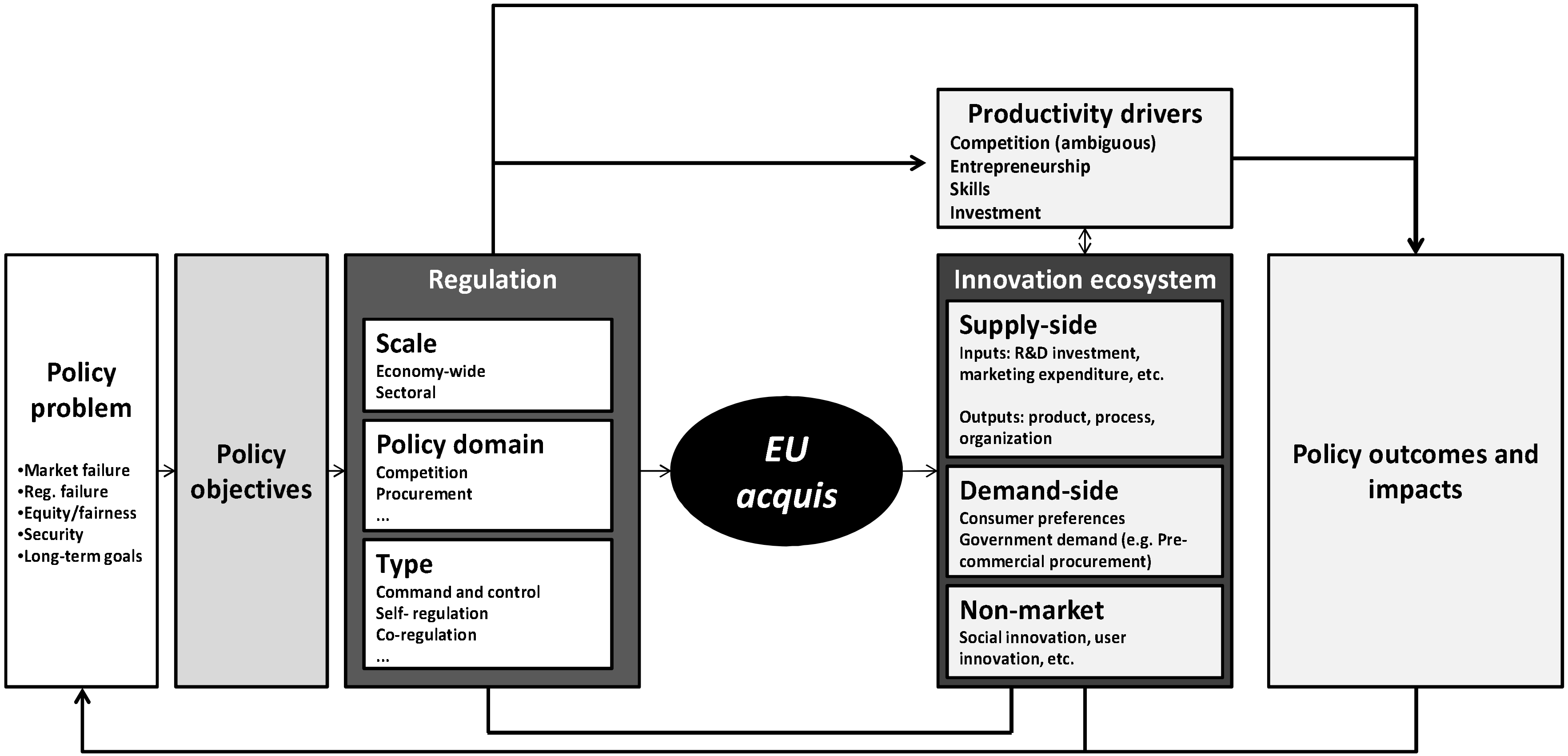
- **Flexibility** describes the number of implementation paths firms have available for compliance.
- **Information** measures whether a regulation promotes more or less complete information in the market.
- **Stringency** measures the degree to which a regulation requires compliance innovation and imposes a compliance burden on a firm, industry or market.

Another important factor is **uncertainty** on the content and scope of future (upcoming) policies. Policy uncertainty reportedly has a mixed effect on innovation, although often it will precipitate the effects of the innovation dimensions of the regulation itself, regardless of whether the regulation is eventually enacted or not. Likewise, the compliance burden may affect firms prior to enactment if, in anticipation, they begin diverting resources toward compliance.

A research paper published by the UK BERR in 2008 explored the main relationships and interactions between regulation and innovation and developed a conceptual model to map the relationship between regulation and innovation, of which we present a modified version in figure 2 below.

In the figure, the relationship starts with the definition of the policy objective and proceeds with the decision to use the regulatory framework (rather than taxes or public spending) to achieve it. Main forms of intervention include general regulation (Economy-wide), innovation-specific measures and sectoral regulation. They contribute to the EU *acquis*, and can affect both the supply-side and demand-side of the innovation ecosystem (see Annex 1). They also contribute to general factors that affect innovation, such as the level of competition, productivity, skills, and investment. Changes in the innovation ecosystem may, in turn, affect policy outcomes. Such outcomes might lead to the need to more policy interventions, if policy problems persist (as in the "policy cycle" concept adopted by the European Commission since the 2010 Communication on Smart Regulation.

Figure 1 – BERR's model of the relationship between regulation and innovation



Source: Authors' elaboration on BERR (2008)

2.3.1 Interactions between phases of innovation and regulation

We observe that regulation affects incentives to innovate in various ways, and certainly interacts with all phases of the innovation cycle. As anticipated above, we assume that the decision to engage in innovation is a rational one, and as such depends on whether the expected "net benefits" of the innovation activity is positive. Everything that affects basic conditions for entrepreneurship and innovation should thus be included in this rather complex picture. More specifically:

- The **R&D and development** phases of innovation are certainly affected by:
    - *General rules* applicable across sectors, such as competition rules, public procurement rules, infrastructure policy, bankruptcy legislation, and also education policy, which can affect the emergence of skills conducive to entrepreneurship, productivity and innovation.
    - *Supply-side and demand-side innovation-specific regulation*, such as patent laws, technology transfer legislation, tax credits on R&D, standardization, pre-commercial procurement regulations, obligations to cross-license (e.g. cases of blocking patents), etc.
    - *Sector-specific rules*, in particular for what concerns their stringency, timing and flexibility (see above).
- All phases of the regulatory process affect R&D and development: however, while the *agenda-setting* phase is relevant, as it implies the definition of the general content of the regulation, often the *legislation* phase can have an even more significant impact on the timing, stringency and flexibility of the regulation itself. Moreover, the extent to which the regulation creates compliance burdens (both administrative burdens and substantive compliance costs) is also a very relevant element, as it can alter the overall expected benefit from the innovative activity. Finally, all phases of the regulatory process contribute to legal certainty, which is another key element of the decision to engage in innovative activity.
- The **commercialization** phase is affected by a partly different set of rules, which include the following:
    - *General rules* such as competition rules, consumer protection rules, trade regulations, unfair competition and B2B unfair commercial practices rules, etc.
    - *Sector-specific rules* related to technology transfer, sectoral competition rules, administrative procedures related to the launch of new products, including authorizations, licenses, etc.

2.4 Key questions

2.4.1 Is regulation always an obstacle to innovation?

- No. The economic literature (starting from the seminal work of Ashford and later with the so-called "Porter hypothesis") has long recognized that regulation can be a powerful stimulus to innovation and entrepreneurship. The ultimate impact of regulation on innovation is an empirical, case-by-case question, and depends on the balance between innovation-inducing factors and innovation-constraining ones including compliance costs generated by regulation.

2.4.2 At what stages of the innovation process does EU regulation matter?

- EU regulation matters at all stages of the innovation process, from R&D to commercialization. Individuals, firms and governments, when deciding on whether to engage with innovation, incorporate in their decisions general rules that shape the business environment, rules affecting market size (including, critically, also free movement, directly from the treaty), innovation-specific rules, but also sectoral rules and even rules that affect the later stages of the innovation process (e.g. rules on consumer protection).

2.4.3 What categories of regulation can be distinguished according to their different impact on innovation?

- We distinguish between general rules, innovation-specific rules, and sector-specific legislation. All three categories can have a significant impact on incentives to innovate, and this impact can, in all three cases, be either positive or negative. More in detail:
    - *General regulation* affects both the expected costs and benefits of innovative activity by affecting the general business environment, creating compliance and administrative burdens, reducing transaction costs, affecting "exit strategies" (e.g. bankruptcy laws), and more generally affecting the risk associated with innovation.
    - *Innovation-specific rules* directly affect incentives to innovate, normally reducing the cost of innovation (e.g. through the provision of dedicated funding in the form of debt or equity, or through exception from general rules as in the case of the technology transfer block exemption regulation). They can also unintentionally (and occasionally) hamper innovation: this is often the case with badly governed public funds, which can crowd out private funding and lead to inefficient selection of beneficiaries (*e.g.* the EIF not being always able to locate the most innovative start-ups).
    - *Sector-specific regulation* directly affects innovation. Based on the literature, the extent of such impact is a function of the stringency, timing, flexibility and uncertainty generated by the rules at hand.

2.4.4 To what extent different types of regulatory approaches affect incentives to innovate?

- Different types of regulatory approach can have different impacts on innovation. Even if a "magic formula" cannot be specified here, it can be tentatively concluded that more prescriptive, rigid regulation can hamper innovative activity by reducing the attractiveness of engaging in R&D, constraining modes of commercialization, and creating lock-in effects that force the economy into suboptimal standards. The more regulation is flexible, such as in co-regulatory settings (and subject to competition law constraints), or in the use of performance-based or outcome-based standards, the more innovation can be stimulated. In addition, during the enforcement phase of regulation, the lower the costs of compliance and the administrative burdens, the more positive is the impact on innovation.
- More generally, an important finding of this Section is the ultimate ambivalence of legal certainty, stringency, timing and flexibility with respect to innovation. Even legal uncertainty can be a stimulus to innovation in some cases, and an obstacle in others. Accordingly, in some cases solutions such as "sunrise clauses" in legislation

can become a powerful stimulus to innovation, but only provided that the timing and stringency of the rules at hand is conducive to innovation incentives.

3 Regulation and innovation: enabling and constraining factors

Moreover, we assume that innovation comes as a result of a rational choice by an individual (entrepreneur) or a firm, even if there are cases of unintentional innovation that occurs by serendipity. From this perspective, the incentive to innovate depends on a number of variables, which certainly include the following:

- **Availability of funding.** The extent to which sources of funding are needed and available to move from the innovative idea to its commercialization.
- **Ease of appropriation.** The extent to which appropriation of the innovative idea is unlikely or impossible, and the cost of securing protection for the innovative idea.
- **Market size.** The size of the potential market for the innovative product, process, or service.
- **Risk.** The consequences of a failure of the innovative product, process or service and the cultural attitude towards failure.

Accordingly, all policies that affect these variables have a general impact on the extent of innovation observed in a given market. Here are some examples:

- Rules that make it easier and less burdensome for young entrepreneurs to secure funding from institutions in the form of equity or debt facilitate the entrepreneurship and innovation;
- Rules on technology transfer from university to industry (e.g. the *Baye-Dole Act* in the United States) can facilitate the implementation of innovative ideas through patenting, acquisition and transfers of innovative ideas from the university to the private sector.
- A simplification of the rules for access to credit guarantee schemes or other sources of funding for SMEs at the EU level can facilitate entrepreneurship.
- Pre-commercial procurement can signal the existence of a large market for a future innovative solution, and as such stimulate innovation in specific fields. Similarly, regulations that impose "competitive dialogue" in public procurement can stimulate innovation by forcing companies to provide solutions to a pre-specified problem.
- Competition rules that weaken property rights by introducing cases of compulsory licensing or mandatory access can, under certain conditions, weaken innovation incentives by reducing the reward from innovation of companies that become dominant in a given relevant market.
- At the same time, very strong property rights might encourage disruptive, pioneer innovation, but might increase costs for follow-on inventors. To the contrary, regulation introducing compulsory licensing of infringed patents to the benefit of follow-on inventions at FRAND (Fair, Reasonable and Non-Discriminatory) conditions might weaken the incentive to invest in R&D in the first place, at the same time improving the business case for incremental innovation. The most appropriate way to act will depend on the specific features of the market at hand, its degree of disruptive innovation versus path-dependency (as illustrated by the enlightening work of Brian Arthur)[9].

[9] In the literature, there are ways to design regulation that can reconcile the incentives of pioneer and follow-on innovators: the literature on "blocking patents" and the blossoming literature on optional law

- Rule on bankruptcy allowing a "second chance" to entrepreneurs that have failed can, if coupled with adequate measures aimed at changing the perception of a failing entrepreneur among its peers, be conducive to more entrepreneurship.
- Finally, rules that increase the level of legal certainty as regards the outlook for investment plans facilitate industrial innovation, as they make R&D easier to design and implement.

Apart from regulatory measures that impact the general conditions and incentives for innovation, regulation can have a direct impact on the level of innovation in specific markets. This, as confirmed by our literature review, normally depends on the balance between the innovation-inducing and innovation-constraining elements of the regulation itself. Below, we discuss the five factors that can determine the impact of specific regulation on innovation.

3.1 Major enabling/constraining aspects of regulation

3.1.1 Administrative burdens

Regulation that creates "red tape" or administrative burdens for businesses can, under certain circumstances, deprive entrepreneurs of resources and time that would otherwise be devoted to more productive activities. On the other hand, innovation itself can be a source of administrative burdens, *e.g.* when market entrance is limited through heavy legal requirements such as pre-market approval (which is especially the case with additives, sweeteners, GMO-related food, supplements, novel and functional foods, as well as novel packaging and enzymes). These tendencies work to the disadvantage of the innovativeness of SMEs, who lack the resources to come up to strict legal requirements. Process innovations are necessary to increase efficiency in a globalising market. For SMEs innovation takes the character of combining new impulses with existing skills and routines (Gielen *et al.*, 2003). The causes for existing administrative burdens and drain of resources, are vested in required systems to guard for food related diseases and food quality.

Governments have attached a growing importance to administrative burdens reduction programmes in the past years. The Netherlands were pioneers in the development of a measurement system for administrative burdens, originally labelled MISTRAL, which gave rise to an international brand (the Standard Cost Model – SCM), that has been adopted by a growing number of countries in recent years. This has provided the impetus for the wide-ranging efforts now in place across Europe to address administrative burdens.

Several contributions in the literature have analyzed the impact of entry requirements and regulatory compliance burdens on entrepreneurship: these include, most notably, the ease of doing business indicators and the ease of entrepreneurship index developed by The Conference Board. More importantly, it is important to single out those pieces of legislation that are considered to hamper entrepreneurship most significantly, without creating substantial social benefits, and possibly design an *ad hoc* regulatory framework for innovative entrepreneurs. Contributions in the literature have demonstrated that start-up costs are considerably higher in more regulated economies (Fonseca *et al.* 2001, 2007), and that regulatory reform results in higher rates of market entry by new firms (Klapper and Love, 2011). A recent paper by Braunerhjelm and Eklund (2013) based on World Bank data from 118 countries for a period of six years finds that the entry rate of new firms is significantly reduced by the

(Ayres, 2005) can provide a first insight into ways to design regulation that can create a balanced environment for different modes of innovations.

tax administrative burden, and that this effect is unrelated to general taxes on corporate profits and is robust to the inclusion of several important control variables.

3.1.2 Compliance burdens (stringency)

Stringency relates to how difficult and costly it is for firms to comply with new regulatory requirements using existing ideas, technologies, processes and business models. According to Ashford *et al.* (1985), stringency is the most important factor influencing technological innovation. A regulation is judged to be stringent if firms need to significantly change their behaviour or develop new technology in order to comply with the regulation. Accordingly, stringency comes with significant compliance costs (see Renda et al, 2014).

A significantly stringent regulation can act as a double-edged sword: when the distance between regulatory requirement and the *status quo* is excessive, firms not able to comply (for technical or financial reasons) with the new requirements might go out of business. When this is the case, the innovation-enhancing potential of stringent rules is replaced by a discouraging effect on existing firms.

Examples of very stringent regulations that have triggered innovation include, according to Gerard and Lave (2005), the US 1970 Clean Air Act, which stipulated 90% reductions in tailpipe emissions over a four to five year period, to be enforced by a newly established Environmental Protection Agency (EPA). They noted that the technical requirements were deliberately technology forcing. They concluded that even though car manufacturers were not able to meet the performance standards by the stipulated deadline, it did lead to two pre-eminent technologies – the catalytic converter in 1975 and the three way catalyst in 1981. These control technologies helped reduce aggregate emissions of hydrocarbons, carbon monoxide and nitrogen oxides between 1975 and 1985 even though the distances travelled by vehicles increased over the same period by 34%.

Similarly, the new crash tests discussed by the European Commission in the proposed regulation on the protection of pedestrians and vulnerable road users were denounced by the car industry as imposing too high compliance costs. More specifically, Directive 2003/102/EC made a limited number of passive safety systems mandatory by 1 January 2005, and triggered investment on the industry side to adapt to the new requirements (so-called "Phase I" requirements); however, the "phase II", mandatory as of 1 January 2010, elicited an early reaction of the industry, which managed to demonstrate that the requirements were not feasible; Phase II requirements were ultimately replaced by a mix of active and passive safety measures[10].

To the contrary, there are cases in which the regulatory requirements are not sufficiently "distant" from current technology. Ashford *et al.* (1985: 464) use the example of the 1972 asbestos standards introduced by the Occupational Safety and Health Administration (OSHA) and conclude that

> *the failure to adopt a 0.1 fiber/cc standard, the lowest level detectable, for worker asbestos exposure inhibited development of substitute products by the asbestos industry. The industry was able to comply with the 2 fiber/cc standard simply by installing existing pollution control equipment. By failing to adopt the more stringent standard, OSHA effectively inhibited new product development and product substitution*

[10] Regulation (Ec) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC.

From available experience and evidence, it seems that regulation can spur innovation through stringent requirements provided that the distance to be covered by targeted stakeholders is not excessive, and that the outcome is specified in a technology-neutral, non-prescriptive way, which allows for experimentation of various solutions and, as such, innovative compliance.

3.1.3 Timing

The amount of time that a regulation gives to the targeted stakeholders for compliance with the regulatory requirements is essential to stimulate innovation. Here too, timing is a double-edged sword: too little time might discourage innovation and determine an unsustainable increase of compliance burdens, too much time might crystallize innovation efforts due to the lack of pressure to meet the requirements. The optimal timing is, once again, a case-by-case issue, but it should be always considered by a regulator when assessing the impact of proposed regulations on innovation.

BERR (2008) and Centre for International Economics (2006) discuss specifically the timing of standardization: here too, the message is that standardization should not occur too early, and also not too late to stimulate and encourage innovation. An early standard can kill alternatives (see our case study on GSM below), creating more intra-standard competition. If the standard is imposed too early, this can generate an undesirable lock-in effect, that leaves society trapped into a suboptimal standard. Similarly, the selection of a rigid, non-scalable standard can inhibit both incremental and disruptive innovation, and as such is highly damaging to social welfare and progress.

3.1.4 Flexibility

As already recalled, flexible, performance- or outcome-based regulation stimulates innovation more than purely prescriptive regulation. To the contrary, rules that prescribe specific materials or technology requirements give no market prospect to those that want to experiment with alternative solutions. Flexibility is particularly important when it comes to (European) standards. The “New approach” to standardization in the EU is a clear example of outcome-based standardization, which can help innovation (this is discussed in section 3.1). The use of functional or performance-based technical specifications from standards offers more room to innovative bidders to propose new products than detailed standards. Also, the early development of a formal open standard during the development of a new technology gives the first mover a competitive advantage, whereas, in the long-run, it increases competition and lowers the cost of the innovative technology.

3.1.5 Uncertainty

Like most of the other variables discussed in this section, also uncertainty can act as a driver and also as an inhibitor of innovation. Under certain circumstances, uncertainty can be beneficial as firms try to anticipate or avoid future regulation by exploring alternatives. Ashford *et al.* (1985) claim that “although excessive regulatory uncertainty may cause industry inaction on the part of the industry too much certainty will stimulate only minimum compliance technology. Similarly too frequent change of regulatory requirements may frustrate technological development.”[11]

More generally, it is fair to state that whenever innovation requires large investment in R&D, the absence of reasonable stability or certainty in the regulatory framework can significantly hinder innovation. Our case study of competition rules applied in the e-

[11] Ashford *et al.*, 1985, p. 426

communications sector below can contribute to shedding some light on this aspect of uncertainty.

3.2 Standards and innovation

Standards serve a number of functions including:

- **Performance/outcome** – standards can define desired performance criteria or desired 'outcomes', enabling products or services to achieve the desired effects without restricting 'innovators' freedom to design their products and services
- **Measurement** – standards can convey technical information in a transparent and consistent manner enabling innovators to benchmark the performance of their products/services and processes and compare it against their competitors.
- **Compatibility/interface** – standards can help innovators work to ensure that new products, services and technologies are compatible with existing ones thereby promoting open and competitive markets.
- **Quality** – standards can communicate to consumers that new products, services and technologies meet socially desired minimum levels of quality and safety (e.g. health and safety and environmental standards).
- **Variance reduction** – standards can promote conformity between products, services and technologies brought to market thereby enabling producers to exploit economies of scale and enabling users to have confidence in their choice of product.

In 2010, Swann (2010) provided a comprehensive update of the state of the art in the economics of standardization, and reports, on the basis of a detailed literature review, that several detailed econometric studies carried out for the UK, Germany, France, Canada and Australia have established a clear connection at a macroeconomic level between standardization in the economy, productivity growth and overall economic growth. Importantly, while it is commonly believed that standards obstruct innovation, the evidence suggests a rather different story. Surveys of innovating firms find many enterprises say that standards are a source of information that helps their innovation activities. Moreover, while many say that regulations do also constrain their innovation activities, these constraints do not necessarily prevent innovation. Moreover, these 'informing' and 'constraining' effects tend to occur together. In addition, standards can help: (i) the exploitation of economies of scale; (ii) the effective division of labour; (iii) the building of competencies; (iv) to reduce barriers to entry; (v) to build network effects; (vi) to reduce transaction costs; and (vii) to increase trust between trading partners.

Recently, Blind (2013), in its paper for NESTA, shows the positive and negative impacts often correlated with different types of standards.

Table 1 – Standards and innovation: positive and negative effects

Type of standard	Positive effects on innovation	Negative effects on innovation
Compatibility/ interoperability	▪ Network externalities ▪ Avoiding lock-in old technologies ▪ Increasing variety of system products ▪ Efficiency in supply chains	▪ Monopoly power ▪ Lock in old technologies in case of strong network externalities
Minimum Quality/Safety	▪ Avoiding adverse selection ▪ Creating trust ▪ Reducing transaction costs	▪ Raising rivals' costs ▪ ▪
Variety Reduction	▪ Economies of scale ▪ Critical mass in emerging technologies/industries	▪ Reducing choice ▪ Market concentration ▪ Premature selection of technologies
Information	▪ Providing codified knowledge	

Source: Blind (2012)

4 EU Regulation and innovation: trends and case studies

4.1 Context and structure

The present section deals more concretely with how EU regulatory trends as well as specific EU regulation (in seven selected cases) enable and/or disable innovation. Section 3.2 underlines the fundamental reason why regulation is EU's 'core business', followed in section 3.3 by a sketch of EU regulatory trends over three decades showing that, broadly, EU regulation has become more facilitating for innovation, especially by removing excessive restrictiveness in many instances (except in a few cases where the precautionary principle is loosely applied) as well as a drive to make the EU more market-driven. The key word in these trends is invariably the deepening and widening (in scope) of the EU single market. Section 3.4 presents two cases of horizontal EU regulation, one fostering innovation via an exemption in EU competition policy, the other being about strategic public procurement with a view to innovation. Section 3.5 comprises five cases of sectoral EU regulation, three examples where EU regulation enables, if not stimulates, innovation (energy efficiency regulation for domestic appliances, innovation facilitated by European standards such as GSM and for smart meters, and EU regulation for end-of-life vehicles) and two where EU regulation hinders or disables innovation (REACH for chemicals and selected EU biotech rules).

4.2 Why regulation has become EU's 'core business'

The 'hard core' of what the EU does is summed up in the term: internal market, including many 'common' policies employing EU regulation. Some such EU regulation is horizontal, most of the regulatory 'acquis' is however sectoral. Based on the foundation of the four free movements (goods, services, capital, labour) [12] and the right of establishment, which in and by themselves are also likely to exert a positive influence on innovative activities given that market size has a well-known positive effect on innovation, EU regulation is a response to market failures (and to Member States employing very different regulatory approaches to overcome such market failures, making a mockery of the single market) which would render the 'proper functioning' of the single market either impossible or at least suboptimal. It is for this fundamental reason that, nowadays, with the free movements and the right of establishment so firmly agreed and accepted, EU's 'core business' is essentially the making or improving or possibly the removal of EU regulation. A good understanding of how the EU influences innovation requires a profound appreciation and assessment of the EU regulatory 'acquis'. At first sight, such an ambition might be regarded as a massive undertaking. One may illustrate this with some basic figures: given a fairly narrow concept of the internal market, this regulatory 'acquis' would comprise some 1500 directives and nearly 2000 EU regulations, often highly complicated ones [13].

As the Monti report (Monti, 2010) reminded us, no less than 15 DGs of the Commission work routinely on internal market rules. Many of these directives and

[12] One may wish to add the free movement of codified technology and knowledge as a 'fifth' free movement, although this is now guaranteed by secondary EU legislation on copyright, trademarks, rules on designs, neighbouring rights and, recently, also a European patent. This is the result of Art. 345, TFEU on national systems of property rights, an article (never changed since the Rome treaty) which does not distinguish government ownership of, say, land and companies, from IPRs. The single market logic strongly suggests to 'unbundle' these two and amend the treaty by inserting the fifth free movement, reflecting the acquis with a more powerful legal basis.

[13] Not counting many Decisions (to specific addressees) and recommendations.

regulations have a sectoral slant and frequently these are likely to have a direct impact on incentives to engage in innovative activities as well as on the direction of innovation. Furthermore, some directives are mainly concerned with commonly agreed (health, safety, environmental, consumer protection) objectives, while leaving the technical specifications to European standardization bodies via mandates or otherwise. Some 3000 CEN standards and many CENELEC/ETSI standards are directly linked to such EU objectives in secondary legislation, thereby giving companies, using these standards correctly, a 'presumption of conformity'. This presumption amounts to free movement, that is, access to the huge internal market, a formidable incentive to innovate. In addition, one should also have regard to rules on (national and regional) public procurement as well as EU rules on competition in the wide sense[14].

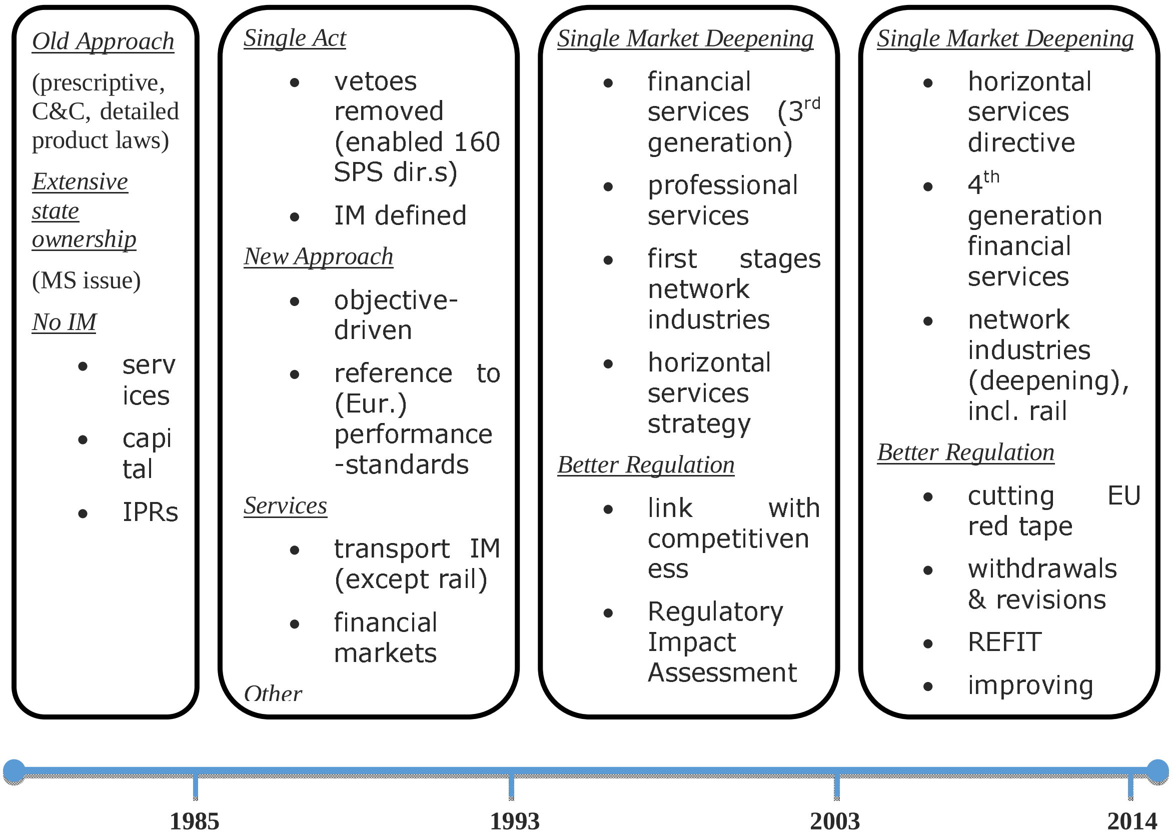
4.3 EU regulatory trends over three decades

Trends in EU regulation since the mid-1980s have to be understood in the context of a continuous deepening and widening of the internal market and against the backdrop of more general trends in the OECD, if not worldwide, to let market forces determine the dynamics in the economy (including innovation) unless there are market failures. Thus, a tendency can be observed that risk regulation dealing with e.g. health, safety and environmental objectives is justified but needs to be least-cost and backed up by scientific and factual evidence in sound risk assessment and in regulatory impact assessment. Where regulation interferes with market mechanisms but without the justification of market failures, the tendency has clearly been one of reducing or abolishing such regimes, or (as in network industries) only regulating the natural monopoly segments as well as access to networks whilst using regulators so as to nip anti-competitive conduct against new entrants effectively and swiftly in the bud. This was accompanied by a gradual but consistent move to privatise numerous companies.

Figure 2 below summarises the trend in EU regulation over four periods since the early 1980s: the days before the Single European Act of 1985 with many rigidities and countless obstacles in the internal market still, the period between 1985 and 1993 when the famous EC1992 programme was successfully pursued, between 1993 and 2003 when competitiveness became increasingly linked to EU regulation, leading among other things to EU regulatory impact assessment, and finally the period from 2004 until today, with Better Regulation and impact assessment dominating most EU regulation. In periods after 1993, the deepening of the internal market was continuing, even in areas formerly considered as too sensitive (e.g. many services and network industries). It is not exaggerated to say that these trends have radically transformed the EU regulatory landscape, with essentially far 'more market' and better conceived and better justified EU regulation, whilst old rigidities in EU rules or unjustified interventions have either been abolished or significantly revised. Also interventionist policies such as the common agricultural policy and e.g. EU and national industrial policies have become more market-friendly or more horizontal. It is of course hard to generalise about the effects on innovation, but it would seem justified to hold that, at least in many instances, these trends have worked out favourable on the innovation climate in the EU. But as we shall see in subsection 3.5 on sectoral cases, there are exceptions to the trend and these are typically related to the (too loose) application of the precautionary principle: these tend to hinder or cripple innovation more often than not.

[14] This implies strict disciplines on abuse of dominant position, cartels and other forms of cooperation between firms, mergers and take-overs, the functioning of companies in network industries (usually closely related to EU regulation of such network markets) and state aids, often sectorally differentiated.

Figure 2 – Trends of EU Regulatory Reforms 1985 – 2014



Notes: C & C = command & control regulation; SPS = health and safety measures in food, feed and plants (e.g. diseases); IM = internal market; IPRs = intellectual property rights; MS = Member States; RIA = regulatory impact assessment; MR = mutual recognition

Starting from 1985, in EU regulation, the Union has gradually moved from a rather political approach to harmonise the different national regulations at the Member States' level into common EU directives, at first often based on hard fought compromises under a veto system in the Council, to a much more rational and far less costly system of 'better' EU regulation. This transformation is favourable for innovation. This lasting benefit is the result of several improvements in the EU regulatory regime.

- First, the veto system for (most) internal market regulation was removed, with further limitations to the application of vetoes in later treaty amendments. Qualified majority voting tends to generate a more functional attitude to the substance and proportionality of EU legislation and 'blocking minorities' usually require concessions from what formerly would have been a vetoing Member State. Also, all kinds of idiosyncratic but costly exceptions or even blockages (due to veto threats) have largely disappeared or have to be justified.
- Second, the EC-1992 programme generated a far more constructive spirit in Council, often led by a troika of three successive presidencies pushing for a rapid and disciplined pursuit of the seven-year calendar to deepen and widen the internal

market. Once the European Parliament obtained near-complete co-legislative powers (between the Single Act and Lisbon, in steps), this spirit has often been decisive for the EP as well.

- Third, the thinking about 'good' EU market regulation received a major boost with mutual recognition and the New Approach initiated in 1985[15]. The central idea underlying the New Approach, inspired by the mutual recognition doctrine of the CJEU, is that, when risks are not too serious, EU regulation can be 'light' – that is, a mere agreement on health, safety, etc. objectives, plus some procedural issues – and the technical specifications can better be done in European standards, as long as (i) it is ensured that such standards are serving these EU objectives, (ii) the standards are 'performance' standards (and not design standards; performance standards are flexible and non-prescriptive, leaving a lot of scope for innovation) and (iii) all this is backed up by a reliable conformance system all the way up to accreditation and ex post market surveillance.

- Fourth, the New Approach prompted a re-think in other areas of EU regulation, first in goods and later in services as well. This was largely driven by competitiveness concerns. Eventually, this led to a much greater preoccupation about the costs and benefits of EU regulation, culminating in the introduction of RIAs, regulatory impact assessments of all legislative proposals in 2003. RIAs and the Commission Guidelines have improved significantly since those early days. The logic of these Guidelines is rooted in the economics of 'good' regulatory practices, driven by the economic literature and by stimulating OECD work. The quality of RIAs is controlled by a semi-independent Impact Assessment Board since 2007 and this has had a healthy effect[16].

All these reforms in EU regulation, in combination with firm case law by the CJEU on free movement and unjustifiable barriers, have had a positive influence on innovation, as compared to prior practices of EU regulation. It has improved (internal) market functioning, made life easier for new entrants and greatly facilitated market access between Member States, whilst at the same time reducing compliance burdens (including 'red tape'), thus freeing resources. As noted, both rules and European standards have purposefully retained significant scope for innovative solutions. For environmental regulation, the EU has increasingly opted for market-driven instead of command-and-control regulation, in particular by setting end-targets without too much (or any) specification of how these targets ought to be met (hence, allowing innovative approaches based on entrepreneurial choices) or by cap-and trade systems (e.g. for CO_2) with similar entrepreneurial discretion.

4.4 Horizontal legislation: case studies

4.4.1 Case study: refusal to deal in competition law and e-communications regulation

A good example of a general rule that can affect the overall incentives to engage in innovation is found in the field of antitrust law. One of the most frequently cited is the

[15] Nowadays called the 'New Legislative Framework' since 2008, based on Reg. 765/2008 (mainly on accreditation and market surveillance on New Approach and other goods), Reg. 764/2008 on mutual recognition procedures (facilitating intra-EU market access for companies, with greater legal certainty) and Decision 768/2008 with a complete 'model' for new directives and revisions of existing directives in these markets for testing & certification (with various modules), accreditation and market surveillance. This should be read together with the new EU standardisation package, enacted in Reg. 1025/2012 of 25 October 2012, in OJEU L 316, and the proposed product safety and market surveillance package proposed in COM (2013) 74 of 13 Feb 2013.

[16] See Fristch *et al.* (2013)

approach to 'refusal to deal', *i.e.* a case of exclusionary abuse of dominance, as such regulated by Article 102 TFEU. The significance of this example is even greater since this specific rule has had a profound impact on *ex ante* regulatory regimes such as the one for electronic communications in force in Europe since 2003 (Renda, 2010; Pelkmans and Renda, 2011).

The European Court of Justice has clarified on several occasions the cumulative conditions that have to be met before compulsory third party access to networks can be enforced under community competition law. These conditions include that the refusal relates to a product or service that is objectively necessary to be able to compete effectively on a downstream market, is likely to eliminate effective competition in the downstream market, is likely to lead to consumer harm and is not objectively justified.

The 2008 Commission Guidance document on exclusionary abuses clarifies that

> *"The existence of … an obligation [to supply] — even for a fair remuneration — may undermine undertakings' incentives to invest and innovate and, thereby, possibly harm consumers. The knowledge that they may have a duty to supply against their will may lead dominant undertakings — or undertakings who anticipate that they may become dominant — not to invest, or to invest less, in the activity in question. Also, competitors may be tempted to free ride on investments made by the dominant undertaking instead of investing themselves. Neither of these consequences would, in the long run, be in the interest of consumers."*

The delicate balance struck by the CJEU ruling on refusal to deal has been shaken a few times over the past years. In addition, in the European Commission's decision against Microsoft of April 2004, the "exceptional and cumulative set of circumstances" test has been partly rejected by the Commission, but decided to condemn Microsoft anyway. This situation created a serious problem of legal certainty within the EU: the set of circumstances under which antitrust rules could lead to the imposition of mandatory third-party access to the dominant firm's own assets was now uncertain, and as such unpredictable. The Court of First Instance decision on the same case in September 2007, and the already mentioned guidance paper on the treatment of exclusionary abuses under article 82 (now 102 TFEU) partly solved the problem.

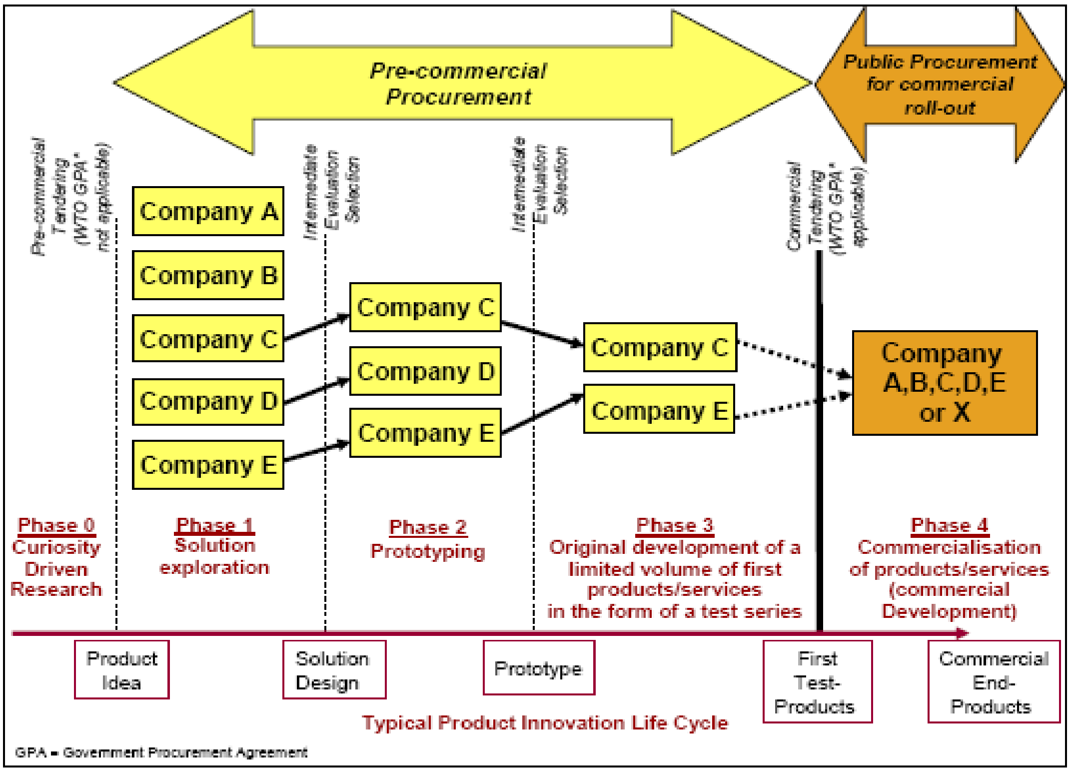
What remains to be fully ascertained is whether a rather rigid application of the rule in both antitrust and ex ante regulation could lead to a weakening of incentives to innovate. In principle, first inventors should be discouraged by a rule that allows competitors to access the winning rival's own assets. At the same time, however, incremental innovation could be facilitated by the application of an essential facilities rule.

4.4.2 Case study: the strategic use of public procurement

One of the most widely acknowledged forms of demand-side innovation policy is the use of public procurement in support of innovation, and in particular of the "competitive dialogue" as well as the so-called "pre-commercial procurement". The latter guarantees significant demand for new products and services

Figure 3 below shows a representative scheme for pre-commercial procurement and public procurement for commercial roll-out of innovative products, as interpreted by the European Commission. As shown in the figure, procurement can be launched even at very early stages of innovation, such as the development of product ideas and the elaboration of solution designs; but also at the prototype phase and successive launch phases of innovative products up to the development and procurement of commercial end products.

Figure 3 - Pre-commercial procurement: a European Commission scheme



It is widely acknowledge that public procurement is insufficiently used to stimulate innovation in Europe for many reasons, including the following:

- Wrong incentives. Procurers tend to favour low cost, low risk, and "off the shelf" solutions even when there are longer term benefits to the public service provider in testing and procuring new technologies and solutions. Moreover, there is a first mover problem.
- Lack of knowledge and capabilities of public procurers on what new technologies and innovations are, or could be, available in the markets – in particular for developments outside their regions/ countries. This is compounded by the lack of dialogue between procurers and supplier companies.
- No strategy that links public procurement with public policy objectives (e.g. health, environment, transport) and Research, Development and Innovation (R&D&I) support initiatives (typically grant funded). Fragmentation in demand with individual procurements too small for companies to make innovative investments, and no mechanisms to allow the pooling of risk and resources across countries.
- SMEs cannot cope with public procurement at the first stage, more often they act as subcontractors. This hampers the access of public authorities to the innovative potentials of SMEs, while SMEs are important creators of innovations and innovative solutions.

In 2006 the European Commission launched the “Lead Market Initiative” (LMI) as a first attempt to engage in demand-side innovation policy. The long-term goals of the Lead Market Initiative are: to remove obstacles to enable European enterprises to enter new and fast growing global markets; to facilitate a faster uptake of new products, services and technologies; and to fill the gap between the generation of new products, services and technologies and the success of those innovations on the market that need to be bridged.

Six lead markets were chosen: sustainable construction, technical textiles for intelligent personal protective clothing and equipment, bio-based products, recycling, eHealth and renewable energy. These markets are highly innovative, and provide solutions of broader strategic, societal, environmental and economic challenges. The impact in the six lead markets were regarded as positive in a 2011 evaluation report, but LMI requires a more consistent application through the EU28 in order to produce even better impacts.

It is also of interest that the new public procurement directive 2014/24 comprises several improvements with a view to foster innovative solutions. Thus, there are now more possibilities for additional flexibility to choose a procurement procedure which provides for negotiations, relevant for authorities having difficulty in predefining full technical solutions for complex contracts. If the market does not offer ready-made solutions, contracting authorities can establish a long-term partnership for the development and subsequent purchase of a new innovative product or service.

4.5 Sectoral regulation: case studies

4.5.1 Case study: Energy efficiency regulation for equipment and cars and innovation[17]

An instructive example of the positive interaction between EU regulation and innovation, also dynamically over time, is found in energy efficiency regulation of household equipment, other small (e.g. office) equipment and cars. The general purpose of this category of EU regulation is to reduce energy consumption for a given use of equipment or of cars, in the light of the overall EU climate strategy aiming to cut greenhouse gas emissions. An associated EU benefit of such regulation is the positive effect on energy security. Three regulatory instruments are of importance: consumer-friendly colour labels, mandatory energy limits and credible compliance. Labelling's first purpose is to inform the consumer before or at the moment of purchasing the equipment or the car, and to do so in non-jargon terms. Colour labels can thus function as incentive regulation: incentive for consumers to buy greener products and incentives for suppliers to innovate and satisfy the incipient demand for greener products which reduce consumer expenses for energy.

However, ever since the early 1990s, many OECD countries (and meanwhile other ones as well) have added 'hard' energy targets by means of specific energy limits for many types of equipment [18] and for personal cars. This would seem to be 'command-and-control' regulation, but that is only correct with respect to the energy limit. In fact it has been employed in a fairly sophisticated, incentivising manner in combination with colour labels, also over time. The colour label preceded the introduction of 'hard' targets. For the producers, the function of the colour label in the case of home appliances was to allow them some time to adapt their offerings and make them greener – a direct stimulus of innovation – before the hard energy limits became mandatory. Once ambitious compulsory targets were set, the colour labels appeared to be identical but, in fact, only referred to appliances still allowed on the market. The EU's first energy labelling directive was enacted in 1992 (92/75). Later revisions have tightened the mandatory targets considerably and the industry has responded with

[17] This case is based on Ellis (2007); Pelkmans *et al.* (2014), and informal sources and interviews.

[18] For home appliances and office equipment, these targets are called 'MEPS', minimum energy performance standards. Strictly, this is a misnomer as standards are, by definition, voluntary.

successive innovations in order to comply or even stay ahead of new constraints. It is telling that the problem nowadays has transformed: almost all appliances have reached what originally was the A status on the labels (green colour), thereby significantly reducing the incentivising effect and information clarity for consumers. The colour labels will have to be revised in order to maintain the same effectiveness as before (possibly, by a new classification of energy use per appliance underlying the colour labelling system).

The enormous success of energy efficiency regulation for appliances, also with consumers, is mainly due to the unexpected outcome of the interaction between regulation and innovation. Some 25 years ago it was widely feared that compulsory energy efficiency targets, leading to greater energy savings than the market had generated in response to colour label incentives for consumers, would lead to rising costs and prices, for a relatively marginal improvement of energy performance. But this did not happen, quite the contrary: "…all products examined have experienced a decline in real prices of between 10 % to 45 %, while energy efficiency increased by 10 % to 60 % …"[19]. These gains have been accomplished without a decline in service. Only top products reduced in price very little but that turned out to be caused by other (e.g. luxury; high quality) features.

Comparing this happy 'win-win' of lower prices and better energy performance with cars and e.g. (noisy) outdoor equipment can help one to understand better the interaction between EU regulation and product innovation. For personal cars, a similar emission colour label has been introduced. Eventually, however, tightening of the emission requirements forced companies to focus on disruptive rather than mere incremental innovation, by focusing on new types of engines (e.g. on hydrogen directly or with fuel cells, or hybrids; electric vehicles; use of natural gas or LPG although this technique is hardly new) whilst radically improving the performance of diesel engines (some 25 % of the car fleet uses diesel in Europe). Disruptive innovation of car engines is hindered by a chicken-and-egg problem, in that hydrogen or electric (or, for that matter, LPG) cannot be sold before widespread and costly infrastructure is available, but investment in such infrastructure is held back by the slow emergence of consumer-friendly features of such new technologies. What is comparable with appliances is that the real prices of personal cars, with much more features and greater safety than decades ago thanks to permanent and successful innovation, have not changed since the early 1980s.

The case of noisy outdoor equipment is also instructive for another reason. In order to prevent building or gardening equipment used outdoor to cause too much noise annoyance, noise limits have been regulated in dir. 2000/14 for 22 types of equipment, including a noise label based on technical jargon. A user-friendly colour label to incentivise purchasers to buy low-noise equipment would not work, because there is no pecuniary incentive whatsoever: no lower taxation (for cars) and no savings over the life time (appliances). This implies that the only effective regulatory option would seem to be to lower the noise limits of regulated outdoor equipment. However, lower noise is regarded as a costly issue for producers, due to the fact that engine heat and emission requirements may well cause a trade-off, leading to higher prices, hurting competitiveness in export markets. The EU has never dared to push for the experiment of lower noise targets, and finding out by practical experience whether such hard requirement would induce more radical innovation

[19] M. Ellis (2007: 13). The OECD/IEA report covers data collection from the late 1980s to 2005.

4.5.2 Case study: innovation via European standards. GSM and smart meters[20]

Standards can sometimes inhibit innovation, especially when compatibility or interoperability is essential. But (European) standards can also be used explicitly to pursue innovation. Two such cases will be very briefly set out. One is the European 2G digital mobile telephony standard GSM, the other is about 'smart meters. The rationale for setting out two standards examples is that it is next to impossible to generalise about European standards.

GSM is known as a successful example of a European standard stimulating a breakthrough (disruptive) technology in mobile at the time, with a highly positive (though temporary) impact on the EU mobile equipment industry's competitiveness. In terms of the economic literature on network compatibility standards, it is a cooperative industry-wide standardisation strategy but with explicit direct as well as indirect government intervention at national and EU level. It is in many ways a unique experience, very hard to be repeated for other areas, in view of the huge costs and the fact that the early stages were fully funded by telecoms monopolies. GSM is open, non-proprietary, and interoperable and offers high systems capacity (compared to analogue), high voice capacity and some other sophisticated functions. In order to appreciate the innovation aspect well, one should not merely concentrate on the technical standardisation itself, even though this was impressive. It is the 'standard adoption strategy' which rendered GSM so special, with various pre-commitment mechanisms agreed and intensified over time. There was a Memorandum of Understanding between telecoms operators with detailed principles of joint pro-competitive procurement, cross-border roaming and planning. The EU level enacted directives on frequencies, on competition in telecoms terminals (like handsets) and on mutual recognition of conformity of telecoms terminals, besides a recommendation and, later, a Commission mandate to ETSI taking over the technical standards issues. There were drawbacks, too, but these did not hold back innovation; on the contrary they may have helped innovation to be so successful (but with costs and risks). One drawback is that the non-proprietary GSM turned out to be less open than foreseen, due to a kind of patent pool with free cross-licensing only for those few companies having patented (some 140) 'essential technologies' for GSM. As a result, companies with markets in analogue had almost no chance to join effectively; neither could the Japanese equipment suppliers get in. Another drawback was that a few cheap and very simple applications of digital mobile were suppressed on purpose in order not to dilute the expensive drive to mass market introduction. A third drawback turned out to be the lock-in effect for 3 G, for which the CDMA airface (from Qualcomm) is better suited than the TDMA one underlying GSM. The longer run consequence has been very costly for EU equipment suppliers as their initial competitive advantage melted away with new competitors, and even further with newer software applications (e.g. Android) and 4G. In June 2014 EU and Korean companies decided to try to be a first mover on 5G. Nevertheless, there is no doubt about the phenomenal success of GSM in and outside Europe and the positive effects on EU manufacturers' competitiveness. Also the telecoms companies, mostly privatised by (say) 2000, benefitted due to mass consumption of services, new business models (e.g. pre-pay) and excessive roaming charges long after the set-up costs had been recouped. Because GSM was introduced simultaneous with telecoms liberalisation in the EU, also the consumer could benefit not only from the highly popular new technology, but also from far lower services tariffs except for roaming.

A smart meter is an electronic device that records consumption of electricity (or gas or water) and communicates this information to the supplier of electricity very regularly;

[20] The two instances in this case are based on Pelkmans (2001); Bekkers *et al.* (2002); CEN/CENELEC/ETSI (2011, 2012); and European Commission (2011).

however, modern smart meters enable two-way communication between the meter and the central system. The drive behind modern smart meters is explained by energy savings (i.e. efficiency). No less than 80% of electricity consumers ought to have such a meter by 2020. However, it was quickly understood that such meters better be standardised in the EU for scale and cost reduction to be realised. Some 110 different standards were found to exist in the Member States in 2009; there were battery and mains-powered meters and distinct national architectures. Therefore, in order not to inhibit technological developments, a common 'toolbox' of standards has been defined which do facilitate metering deployments. The two critical technological areas in this field are communication and information technology. There is a strong innovation drive behind the programme, in that the entire Advanced Metering Architecture and not just the meters are covered, permitting explicit links with smart grids and eMobility standardisation, two highly dynamic areas. In addition, all kinds of potential applications became feasible based on the digital communication with the network operator. This in turn led to much more radical thinking about what are now called 'smart grids', of which smart meters would be only one component. In the 2011 report on the relevant Commission mandate M/441, a first list of existing standards and 37 suggested new standards ideas is reported. By the end of 2012, in a second report, 56 standards have been defined or are up for voting. The coordination group is expected to stay active until 2020 for new applications and links with smart grids in particular.

4.5.3 Case study: the End-of-life Vehicles Directive[21]

The End-of-Life vehicles directive 2000/53, and subsequent (comitology) regulations (e.g. in 2003) and Decisions on regular updates of technical Annex II (last in 2013) aim at reduction of waste arising from end-of-life vehicles (ELV) for cars and light commercial vehicles. There are four stakeholders: the producer, the recycling industry, the last holder and the authorities (mainly, the Member States); however, the leading principle involved is EPR, extended producer responsibility. An ELV can no longer be part of the second-hand car market for technical or economic reasons, but it may still have economic value for the parts/components collectors, recyclers and/or shredders (of the car hulk). This implies that 'regulation' may take the form of a voluntary agreement, if enforceable, possibly between different industries as they might have conflicting interests and these have to be internalised, or a compulsory rule. However, to a considerable degree, ELVs can be dealt with by markets themselves, if subject to strict environmental rules for dismantling, recycling and waste disposal (in the US there is no ELV regulation but the EPA maintains strict monitoring of the environmental aspects), because of the value in ELVs. The EU has clearly opted for targets going (gradually) beyond what a market-based approach might be expected to achieve.

To have a rough idea of the ELV process, cars (in terms of weight) are made for some 75 % or so from ferrous and non-ferrous (esp. aluminium) metals and 25 % from materials such as tires, fluids, plastics and other materials. The quantitative targets are: reuse and recycling of 80 % of the car weight in 2006, up to 85 % by 2015; reuse and recovery at least 85 % in 2006 and 95 % in 2015. In 2011 the number of ELVs in the EU was probably 7.8 million, of the 14 million deregistered cars. The remainder is either exported legally or illegally to third countries or simply kept in private garages for a while.

ELV has had and still has a significant impact on innovation in the car and car-related industries. Already in 2000 Zoboli, Barbiroli & Leone list the following ten innovative developments*:* (i) creation of special technical competences in car manufacturing companies*;* (ii) creation of dismantling and recovery/recycling networks (contracted

[21] This case is based on Zoboli *et al.* (2000); European Parliament (2010); and Sakai *et al.* (2014).

by car companies) with incremental innovation; (iii) advances in design for dismantling; (iv) advances in design for recycling; (v) adoption of life-cycle strategies; (vi) material regime simplification in cars; (vii) material competition and substitution; (viii) advances in automotive plastic recycling; (ix) research and development in innovative recovery technologies for ASR [= automobile shredding residue], the most problematic element in ELV techniques; (x) cooperative research at the industrial level. This list shows that innovation takes place at the very beginning of the life cycle of cars, namely at the design & planning stage, followed by manufacturing as a result, and at the very end of the cycle, ELV treatment. In Europe and Asia, regulation or even the threat of it is strongly shaping the whole innovation process. The greatest difficulty is presented by targeting a higher recycling rate for ASR (which otherwise ends up in landfills). Japan has recently reduced the share that can go to landfills to 1 % - 2 %, lower than the EU at the moment. This requires still more advanced techniques to recover materials from the ASR and to make progress with 'detoxification' of ASRs; also, more exhaustive dismantling (which might be costly) would decrease the recycling costs of ASR. On the other hand, ASRs also contain rare earth compounds like dysprosium, as well as materials the price of which is expected to go up strongly before 2030 (copper, palladium), which amounts to a powerful incentive to develop new technologies. Moreover, electric vehicles should not have permanent magnets, ideally.

Altogether, ELV regulatory regimes are a powerful stimulant of innovation, beyond what market incentives combined with environmental rules, may achieve. Innovation has taken place and is still vigorously undertaken both at the very beginning of the life cycle of a car and at the very end of ELV treatment, and these processes also influence one another directly and via regulatory specifications.

4.5.4 Case study: how EU chemicals regulation hinders innovation[22]

One of the objectives of the REACH regulation 1907/2006 was to promote innovation in the EU chemical industry, a world leader in fine chemicals. Unlike bulk chemicals, competitiveness in fine chemicals depends on strong and sustained innovation capacity throughout the chemical value chain, especially for 'integrators' and 'formulators' but also for entirely new chemical substances by (usually) the large chemical companies upstream. REACH has been introduced for several reasons related to better risk management, but equally because the post-1981 regulatory environment of chemicals generated an anti-innovation bias. One among several reasons for this bias consisted of the burden of proof which was assigned to Member States' authorities when assessing a new chemical substance and allowing it on the market, whereas 30 000 existing chemical substances (registered in or before 1981) were allowed on the market without testing (subject to exceptions for known hazardous substances, and safeguards).

However, on first sight, the design of REACH does not seem a priori to be pro-innovation. Essentially, this is due to two features. One is the imposition of fairly heavy testing requirements for all existing and new substances alike. While this removes the discrimination against new substances from before REACH, it brings with it an enormous burden for existing substances, irrespective of risk, a cost to be entirely borne by producers. It would have been rational, and in keeping with 'better regulation' principles, if testing requirements had been risk-based. One way to do this is making a ranking of groups of substances with decreasing degrees of risks, as known from the literature, testing or experience over a long period. Direct testing costs and the indirect costs of substitution of risky substances by other ones –

[22] This case is based on the following sources: Eurostat (2012); CSES (2012); European Commission (2013); Pelkmans *et al.* (2013); and RPA (2012).

possibly new ones - would only fall on the relatively limited groups of substances where there is uncertainty about risks.

The other feature of REACH, caused by its ambitious precautionary approach of 'no data, no market' (access), is that this entire process of testing before being allowed on the market, takes no less than 11 years. Most laboratory capacity in Europe is bound to be occupied by the massive testing required, which reduces the capacity to test really new substances arising from innovation.

By 2014 several interim reports of REACH are available and they confirm these fears. What is found worrisome is that R & D expenditure is shifted away from planned project and towards technical compliance activities, that compliance costs for SMEs divert resources that cannot now be spent on any R & D, that extra costs reduce profits considerably in some cases and that much uncertainty throttles new product initiatives. The incentive structure under REACH is adverse for companies, since the costs of testing, finding substitutes as well as value-chain compliance costs are all upfront for as much as 11 years, whereas the societal benefits are (a) most uncertain and (b) at best expected years after 2018 or much later still. There is also the risk of losing competitiveness vis-à-vis competitors in the rest of the world, except if, and to the extent that, 3rd countries would adopt a REACH-like approach (which is only weakly the case for Korea, possibly China partially).

4.5.5 Case study; EU biotech regulation as a penalty on innovation[23]

Two of the core principles of 'better regulation' are that regulation should be science and evidence based, and that risks – not hazard properties – of a substance or good should be the focus of health, safety and environmental benefits for society. Hazard-based approaches therefore lead to overregulation, possibly heavily so. In turn, risks should be established by globally respected rigorous science and evidence based risk assessment methods. Since 'better regulation' principles are increasingly accepted as rational and least-cost in the EU by all stakeholders, those advancing political conjectures or echo consumer aversion have embraced the 'precautionary principle' as the respectable route to restrict or prohibit new products or initiatives, even when little or no hard scientific evidence is available.

This is the predicament of two submarkets of biotechnology in Europe, namely for GMOs and for crop-protection. GMOs have significant and proven societal benefits. Worldwide, many millions of farmers have greater certainty and less poverty due to GMOs protecting their harvests better. This is certainly true in large quantities for developing countries' farmers growing cotton (80 %) and soy-beans (70 %). It is essential that more food be produced sustainably worldwide, with less land, less water available and fewer fertilisers. In EU regulation as well as in debates in the two bodies co-legislating the rules, these formidable benefits seem to play no role. The upshot in the EU is that only two new GMO products have been allowed to be cultivated: NK603 GM maize and the Amflora potato. In 2012, after having waited for more than 13 years, BASF gave up on Amflora and migrated that activity to the US. The maize is practically only cultivated in Spain, no other EU country accepts it or NGOs discredit the cultivation or the company. As a result, the EU has hardly been able to innovate in this area, a growth sector in the rest of the world. From a regulatory point of view, the restrictiveness of GMO regulation brings no benefit to European society whilst damaging the biotech industry, even though there is no scientific empirical evidence of any risk. The state of denial is so bad in the EU that no less than 23 national academies of science in the EU felt compelled to write a report (Planting the future) in

[23] This case is based on the following sources: European Academies Science Advisory Council (2013); European Commission (2009); Cantley and Lex (2011); Alemanno (2013).

June 2013, stressing that there is nothing in the scholarly literature giving a reason to suspect societal risks for GMOs so far allowed in non-EU OECD countries.

The EU biotech industry is not dead, far from it, it is doing well by avoiding specialising in GMO or selected other crop-protection products. But even that is not without dangers. Recently, a very controversial decision to temporarily ban a (much used) neonicotinoids pesticide because of a suspected connection to the decline of Europe's bee population – again, under the precautionary principle – although several other reasons are at least as likely to have caused this decline, show that science-based risk assessment is by-passed, with damaging results for a relatively new and successful product, and with unknown discouragement effects for the industry.

5 Conclusions and policy recommendations

This short paper has shown that the interaction between regulation and innovation is complex, multi-faceted, and often ambiguous, such that assessing the impact of a given piece of regulation on innovation is often an empirical, case-by-case exercise. That said, our analysis has shed light, with the help of pre-existing literature, on the types of regulation that affect innovation, and the way in which different types of regulation can affect innovation. More specifically, our main findings imply that:

- **Regulation can, under certain circumstances, be a powerful stimulus to innovation and entrepreneurship**. The ultimate impact of regulation on innovation is an empirical, case-by-case question, and depends on the balance between innovation-inducing factors and compliance costs generated by regulation.
- EU regulation matters at all stages of the innovation process, from R&D to commercialization.
- **Different types of regulation can be identified,** in terms of their impact on innovation. We distinguish between general rules, innovation-specific rules, and sector-specific legislation. *General regulation* affects the general business environment, creating compliance and administrative burdens, reducing transaction costs, affecting "exit strategies" (e.g. bankruptcy laws), and more generally affecting the risk associated with innovation. *Innovation-specific rules* directly affect incentives to innovate, normally reducing the cost of innovation. *Sector-specific regulation* directly affects innovation in a way that depends mostly on the stringency, timing, flexibility and uncertainty generated by the rules at hand.
- **Different types of regulatory approach can have different impacts on innovation.** Typically, more prescriptive, rigid regulation can hamper innovative activity by reducing the attractiveness of engaging in R&D, constraining modes of commercialization, and creating lock-in effects that force the economy into suboptimal standards. The more regulation is flexible, such as in co-regulatory settings (and subject to competition law constraints), or in the use of performance-based or outcome-based standards, the more innovation can be stimulated. In addition, during the enforcement phase of regulation, the lower the costs of compliance and the administrative burdens, the more positive is the impact on innovation.
- **The EU *acquis* is disseminated with "positive" and "negative" examples**: our case studies span from the early adoption of standards that gave largely stimulated adoption (e.g. the GSM) to cases of overly excessive regulatory burdens (chemicals). This suggests that, in the revision of the *acquis* in various sector (especially within the current REFIT programme), there are likely to be ample opportunities for stimulating innovation by identifying possibilities to reduce regulatory burdens and improve the stimulus effect of legal rules.

In light of the above, we recommend the following:

- **Impacts on innovation should be put at the core of the EU impact assessment methodology**. The current review of the guidelines (currently under consultation) will be a valuable opportunity to strengthen the analysis of the balance between innovation-enhancing and innovation-constraining effect of the various alternative policy options scrutinized in each impact assessment. Key criteria to be included in the analysis would then be the timing, stringency, flexibility and certainty effects of alternative policy options: they could be translated into a checklist to ease the work of the desk officer in charge of impact assessment. The checklist could also refer to alternative types of policy intervention, which typically create different policy concerns (see Section 1.2.1).

- **A specific "innovation test" for smaller firms could be included in the impact assessment guidelines**, possibly within the context of the "SME test". This is important as smaller firms are typically the most dynamic actors in the innovation ecosystem (see Annex 1).
- **Ex post evaluation of individual pieces of EU legislation should entail an analysis of the impact on innovation**. Currently the European Commission is in the process of defining guidelines for ex post evaluation (a consultation was run in the first months of 2014): the new version of the guidelines could incorporate an analysis of the timing, stringency, flexibility and certainty effects of existing rules, in order to identify potential improvements.
- Similarly, **the impact of the stock of regulation on innovation should be a major part of the REFIT exercise** currently being carried out in various sectors. The same could be said for the **cumulative cost assessments** being performed in specific fields (steel, aluminium, Ceramics, Forest-based Industries) by DG Enterprise.

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Annex I – The Innovation Ecosystem

Capturing the evolution of innovation approaches is almost impossible, given the variety, diversity and heterogeneity of terminologies and the theoretical backgrounds that populate the world of innovation studies. Scholars very often distinguish between "industry-led" innovation and "other non-industrial" innovation, such as community-led innovation (e.g. open source software) and social innovation. Regulation can impact these latter types of innovation in very different ways.

The past years have marked a sea change in the way innovation occurs in various sectors. This is even more true for the ICT sector, where the intangible nature of most product and system components make it possible to obtain innovative products through collaborative efforts distributed throughout the globe. At least four major trends can be highlighted:

- ***From single-firm to systemic, to collaborative****.* Today, innovation is increasingly a collaborative, collective effort, rather than the product of a single brain in an R&D lab. Forms of collaboration give rise to new conglomerates governed mostly by weak property rules or even liability rules: the typical examples are "copyleft" rules in open-source software, and FRAND licensing agreements in patent pools and royalty-free cross-licensing agreements (Merges 1996).[24]
- ***From proprietary to modular, to granular****.* The modularity of products has been on the rise in recent decades, as testified by the pioneering work of Richard Langlois (1992).[25] Increasingly, modularity determines the need for collaboration between producers of complementors, and intellectual property is being (or should be) redesigned to facilitate these forms of cooperation.
- ***From supply-led innovation to co-innovation, to user innovation****.* The original paradigm of "technology push, demand pull" in innovation belongs to the history channel today. Co-innovation is becoming more widespread, especially in the IT world, but also in other technology-intensive sectors such as pharmaceuticals and biotech. In emerging economic sectors, especially in the digital environment, co-innovation is being replaced or complemented by user innovation, in which users take the lead in developing new solutions that match their industry needs.
- ***From closed to semi-open, to (almost fully) open****.* As collaboration and granularity become more widespread, product architectures also become less proprietary and are gradually replaced by semi-open and fully open models of production. For example, in modern broadband communications platforms such as those found on our smartphones and personal computers, proprietary models such as those adopted by Apple in the 1980s have been supplanted by semi-open models such as the one coordinated by Microsoft, which tried to maximise two-sided market effects by stimulating the widespread development of applications that would be Windows-compatible[26].

[24] FRAND stands for Fair, Reasonable and Non-Discriminatory. Cf. also Geradin (2006).

[25] Cf. also Chesbrough (2003, 2004).

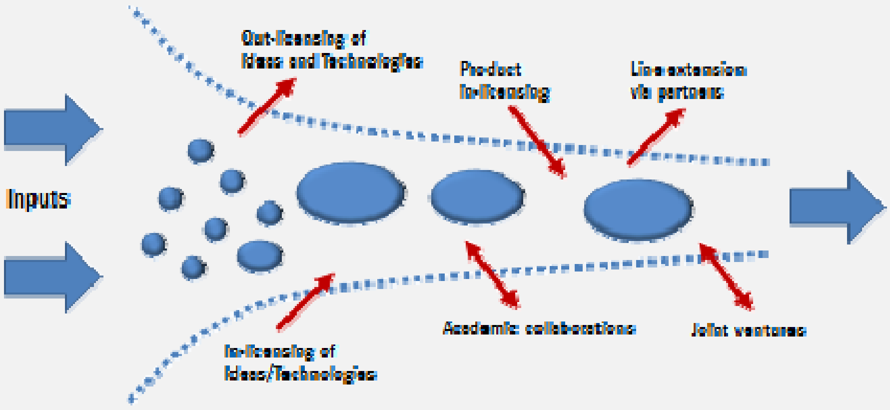
[26] Since then, more open models (partly) based on open-source software have become more important. However, especially in the Smartphone and mobile broadband sector the business models that prevail (e.g., Android and Apple's iOS) are still semi-open and not fully open[26]. This is due to two main reasons: the need to preserve control of the value chain and the need to reap revenues by the creation of modern platforms. As a matter of fact, a fully open and interoperable model in most cases does not guarantee any revenues to its creator, and basically belongs to the public domain.

BOX 1 – Open innovation

As recently reported also by the OECD (2008), "the organisation of innovative activities (technological as well as non-technological) across firm boundaries is clearly on the increase, with more balance between internal and external sources of innovation... Industries such as chemicals, pharmaceuticals and information and communication technology (ICT) typically show high levels of open innovation". Open innovation implies, *inter alia*, the use of internal and external R&D sources; openness to external business models, a variety of IP generators and collaborations (SMEs, academics, etc.), and a proactive IP asset management. This is leading to an increase in the number of companies collaborating in innovative activities. Figure 16 below shows the changing mode of innovation from traditional to "open".

Open innovation is paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as firms look to advance their technology (Chesbrough *et al.*, 2006). Open innovations are not only concerned with sourcing of external knowledge into the firm ("outside-in") but also with exploring new channels of revenue generation by granting usage rights (joint ventures, licensing or outright sale) of in-house developments to other firms ("inside-out"), "especially when the technology has future potential but is not part of the firm's core strategy" (OECD 2008). While the original perspective of innovation primarily focused on research and development of firms, open innovation has outgrown this narrow view and today integrates more and different streams and perspectives (Gassmann *et al.* 2010). One of these "new" streams contributing to open innovation and vice versa includes globalization of innovation and in this realm the context and aspects of frugal innovation (Tiwari and Herstann 2012).

Figure 4 – "Open" innovation



Source: Chesbrough (2003)

Main actors in the innovation ecosystem

An innovation ecosystem requires the simultaneous existence of several actors, each with a different role to play. In academic literature, the concept of a National Innovation System (NIS) emerged in the 1980s and is normally referred to as "the set of public and private actors involved in the exploitation and commercialization of new knowledge originating from the science and technology base and the interactions in between them"[27]. This concept has been operationalized by several academics including, among others, Porter and Stern (2002) and Archibugi *et al.* (2009), who develop indexes of national innovative capacity that rely heavily on the specific role played by each of the main actors that shape innovation patterns and success in a

[27] See the definition given by the European Commission, at the following link http://ec.europa.eu/enterprise/glossary/national-innovation-system_en.htm

given country. These actors are mostly large businesses and SMEs, university and research institutes, venture capitalists and business angels, and government.

Entrepreneurs

Given the intimate link between innovation and dynamic efficiency, innovation policy heavily relies on the actors that commit themselves to the discovery of new ways of producing existing goods or services, or entirely new products to place on the market or any other *locus* where exchange can take place. These individuals, in economic theory, are called "entrepreneurs". De Soto (2009: 8) defines entrepreneurship as the "typically human ability to recognize opportunities for profit which appear in the environment and to act accordingly to take advantage of them". Based on this definition, an entrepreneur might also not be the person that has developed an innovative idea, but an individual that is able to bring that idea to market in a successful way. In a recent publication the OECD (2010: 32) defined entrepreneurs as the principal actors in innovation, since they "bring about change in an economy by providing 'new combinations': new or improved goods, methods of production, markets, sources of supply of inputs, organization of an industry, or management processes within a firm". Entrepreneurs are defined as opportunity identifiers, risk takers, resource shifters and breakthrough innovators (Kirzner 1973, 1997). In other words, entrepreneurs are the engine of a national innovation system.

Large firms

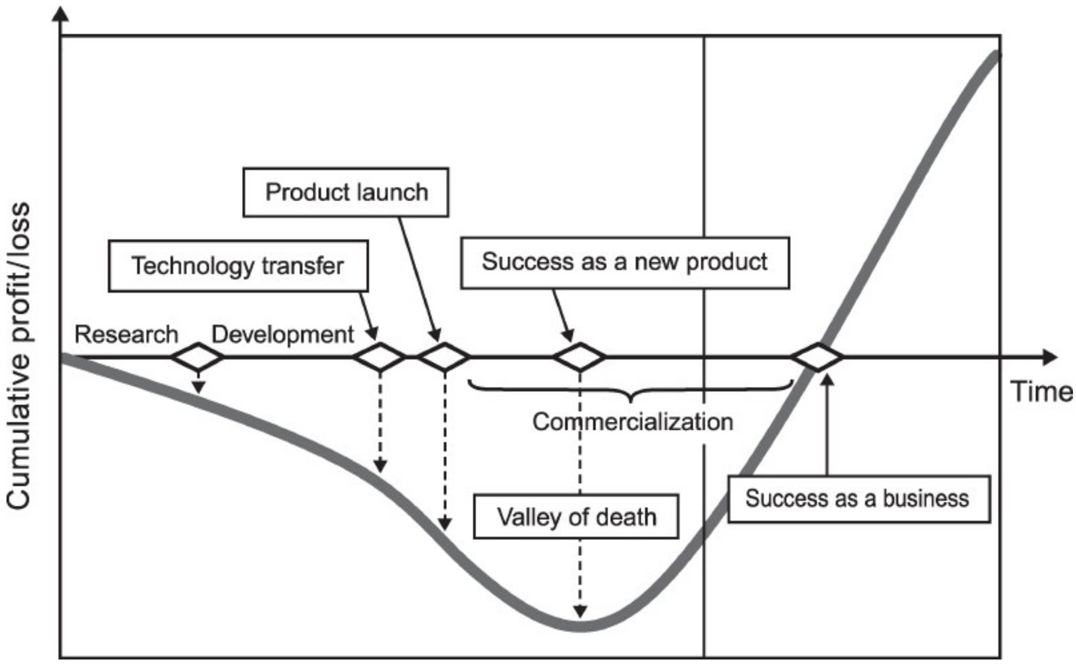
Large firms typically possess the resources needed to invest in R&D, and accordingly can invest in product and process innovation more easily than smaller firms, which typically depend on access to external sources of funding (see below). At the same time, in an open innovation environment large firms increasingly act as catalysts of innovative projects by selecting those smaller firms that have a high innovation potential: hence, in an open innovation environment, large firms mostly buy R&D from smaller firms (see Box 1 above). Large firms do not only have advantages over smaller firms, but also disadvantages: typically the latter are related to the rigidity of the large firm's administrative and hierarchical organization, as well as more "path dependency" due to the fact that the firm operates on a consolidated business model. Accordingly, in some markets partnerships between large and smaller firms are emerging (so-called "Gorilla-Gazelle" partnerships), which combine the financial endowment and consolidated market position of large firms with the superior agility and adaptability to change of (some) smaller firms.

Small firms

Given their superior flexibility and the reduced importance of economies of scale in the Internet age, SMEs are increasingly defined as the perfect candidates to play the role of entrepreneurs in a national innovation system. Scholars like William Baumol refer to a functional combination and coordination of large and small firms as the optimal environment in which innovation can flourish. To be sure, SMEs are universally acknowledged as the real engine of modern economies, where they represent the overwhelming majority of firms.

Against this background, SMEs are targeted by specific policies for entrepreneurship and innovation all over the world. In order to fully unleash their potential, they need to be supported in the search for funds and in the establishment of valuable partnerships for the realisation of their ideas and the creation of new products in a market. This is why in most industrialised countries innovation policy reserves a key role for the provision of equity funds and borrowed capital to SMEs that wish to pursue high-risk, high-potential research and development activities aimed at the production of innovative products. Otherwise, SMEs risk remaining stuck in the "valley of death", i.e., the phase in which SMEs are still to fully exploit the potential of their innovative ideas, and yet financial markets cannot fully appraise the merit of those ideas, and accordingly are not willing to blindly finance any innovative project. Figure 13 below graphically illustrates this problem.

Figure 5 – The "valley of death"



Source: Granieri and Renda (2012)

SMEs can play a paramount role in the creation of innovation both in sectors in which innovation is essentially disruptive, as well as in sectors dominated by incremental, follow-on innovation. Regarding disruptive innovation, most often large firms lack the flexibility and adaptability needed for the development of entirely new products. Also, large firms that have consolidated positions in their markets normally have more to lose from a disruptive innovation, as they derive revenues from an already existing product. This is why SMEs are often better positioned for the development of high-risk, high-potential innovation, provided that they can convince financial markets of the viability of their projects. Christensen and Bower (1996) confirm that large firms are often likely to dismiss disruptive innovation exactly for these reasons.

In the case of incremental follow-on innovation, SMEs also have enormous and growing opportunities. In particular, SMEs can specialise in: a) the development of components of existing system goods; b) selling innovative services that rely on products that are widely used in the market; or c) developing applications for existing platforms (Gawer 2009). Moreover, in an age of open innovation, SMEs can easily become interconnected with the emerging world of intermediaries that facilitate the emergence of collaborative solutions (Brunswicker and Vanhaverbeke 2011).

There are several challenges faced by SMEs on the way to becoming real entrepreneurs. Besides the problem of funding and the valley of death, SMEs have problems in developing and attracting key innovation skills that allow them to control and manage innovation internally. Investing in human resources and skills also means helping SMEs achieve more absorptive capacity, defined as a firm's "ability to recognise the value of new information, assimilate it, and apply it to commercial ends" (Cohen and Levinthal, 1990). At the same time, SMEs often have difficulties in identifying potential partners for collaborative innovation, as well as opportunities to signal their skills and competences to potential business angels, incubators and open innovation accelerators.

Universities and research institutes

The role of universities in national and regional innovation systems has been widely researched in the literature on innovation[28]. Most often, the identified role of universities is that of institutions in charge of producing basic research and new knowledge, which will then be converted into applied research and new products. This is certainly a major impact of universities. However, in recent years, universities and research centres have increasingly played another role, that of facilitators of knowledge transfers, open innovation and co-innovation, up to the point that many of them have indeed become platforms and hubs in which innovation is created, coordinated, managed and steered towards societal needs[29]. In summary, the role of universities in modern innovation systems is intimately related to the concept of knowledge creation, transfer and management. This includes, of course, basic research: currently in the USA, universities perform 56% of all basic research, compared to 38% in 1960 (Atkinson and Stewart, 2011). At the same time, the need for universities to become more intimately commingled with the other actors of innovation within a broader eco-system has led to the development of the concept of "entrepreneurial university", which merges the concept of entrepreneur with that of traditionally more static institutions, such as universities, which are now called to enter the world of commercialization of innovation through emerging practices such as technology transfer (Clark 1998, 2004).

Venture capitalists and business angels

Entrepreneurs do not always possess the necessary funds to implement the ideas they have to successfully innovate. Venture capitalists can provide the necessary equity funding for SMEs, which in turn allows SMEs to leverage more borrowed capital and reach a sufficient endowment of capital to be able to effectively implement, promote and commercialize innovation. Venture capital can be defined as financial capital provided to early-stage, high-potential, high-risk, high-growth start-up companies. Venture capitalists must be entrepreneurs in the sense that they should be able to identify profit opportunities by looking at existing small enterprises and individual inventors who have ideas that can successfully reach the market. In the USA, venture capital accounts for a remarkable percentage of total wealth and growth. According to the National Venture Capital Association of the United States, 11% of private sector jobs come from venture-backed companies and venture-backed revenue accounts for 21% of US GDP.

Together with venture capitalists, a key role is also played by business angels (BAs), defined as "individuals, acting alone or in a formal or informal syndicate, who invest their own money directly in an unquoted business in which there is no family connection, and who, after making the investment, take an active involvement in the business, for example as an advisor or a member of the board of directors" (Maso and Harrison 2008). Importantly, business angels normally commit their own funds, whereas venture capitalists commit funds borrowed from other sources. Business angels are acknowledged as being the most important providers of venture capital

[28] For an introduction to the literature, cf. Kroll, H., E. Baier and T. Stahlecker (2012).

[29] Co-innovation is a termed used to indicate the joint creation of innovative products by more than one party, normally including producers and users/customers.

together with seed funds. Mason and Harrison (2008) observe that business angels face lower transaction costs compared to venture capitalists and are able to launch smaller investments. This causes the informal venture capital market to be the largest external source of early-stage risk capital, dwarfing the institutional venture capital market. OECD data confirm these trends: figure 14 shows the level of venture capital investment in the ICT sector across OECD countries.

Government

Governments are key actors in innovation. As is becoming increasingly clear, markets alone present imperfections, which make it difficult to reach socially optimal levels of innovation. These include, among other things, transaction costs, imperfections in the dissemination and sharing of key information related to innovative products and ideas, general imperfections in the "marketplace of ideas", imperfections in financial markets and rational biases in consumer demand. All these frictions and imperfections in markets determine the need for government intervention.

Moreover, over recent years it has become clear that governments can act in several ways to promote innovation.

- **Direct intervention**. This includes state aids and subsidies for innovation, and industrial policy to promote innovation in specific sectors of the economy (e.g., space policy, tourism policy) (Aghion et al. 2011).
- **Regulation**. Governments can intervene with legal rules to facilitate private bargaining over collaborative innovations. The paramount example of this form of intervention is intellectual property law and legislation on technology and knowledge transfer, but also standardisation policy that reduces transaction costs in the development of industrial innovation.
- **Supply-side policies in innovation**. They include: (a) public expenditure to support R&D through grants, tax incentives, public provision of equity funding and public venture capital; (b) the development of research infrastructures and institutions, from patent offices to university funding to investment in enabling technologies such as ICT technologies, and the provision of training, lifelong learning, and mobility programmes for researchers; (c) information and brokerage services such as the production of data and the development of patent databases and portals for innovating firms; and (d) networking measures such as the creation of science parks in collaboration with universities, the creation of incubators and open innovation accelerators, support for cluster policies, etc.
- **Demand-side policies**. They include the promotion of user-driven innovation, the use of pre-commercial procurement and green public procurement, support for private demand for innovative products, etc.
- **Infrastructure policies and digital agendas**. These facilitate the development of online collaborative partnerships for innovation as well as innovation hubs and platforms.

Annex II – Literature review on regulation and innovation

In this annex we briefly map the main contributions that have been provided by the academic literature and by the work of governments and international organizations to the understanding of the complex relationship between regulation and innovation. We start by mapping the general literature, applicable to a range of sectors or to the economy as a whole, and then we briefly explore sector-specific literature. With a *caveat*: the literature that discusses the growth-enhancing, innovation enhancing or entrepreneurship-inducing impacts of existing or future regulations is virtually endless: accordingly, we only provide a selection of those contributions that directly, and explicitly aim at mapping the interaction between the two phenomena, regulation and innovation.

The "porter Hypothesis"

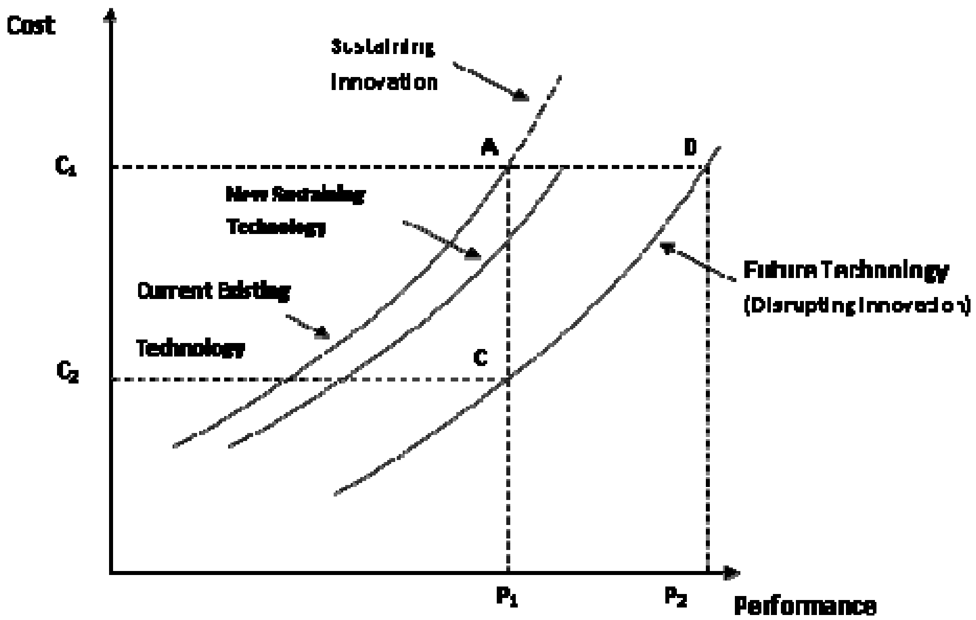
A key contribution in the literature has been provided, since the late 1970s, by Nicholas Ashford from the Massachusetts Institute of Technology. In particular, a number of MIT studies led by found that regulation could stimulate significant fundamental changes in product and process technology which benefited the industrial innovator, as well as improving health, safety and the environment, provided the regulations were stringent, focused, and properly structured (Ashford 1976; Ashford *et al.*, 1985; Ashford 2000). This work largely preceded what would later become known as **the "Porter Hypothesis"**. This implies that firms at the cutting edge of developing and implementing technology to reduce pollution would benefit economically by being first-movers to comply with regulation (Porter 1990, Porter and van den Linde 1995a and 1995b).

Ashford himself describes – with specific reference to environmental sustainability – the Porter Hypothesis as having both a weak and a strong form:

- The **"weak form"** is that regulation, properly designed, can cause the regulated entities to undertake innovations that not only reduce pollution -- which is a hallmark of production inefficiency -- but also save on materials, water, and energy costs, conferring what Porter calls 'innovation offsets' to the innovating firm. This occurs since the firm, at any point in time, is sub-optimal, and can achieve 'learning curve' advantages if it acts before its competitors.
- The **"strong form"** of the Porter Hypothesis (not explicitly discussed by Porter) was first proposed by Ashford and his colleagues at MIT after years of cross-country and US-based studies that showed that stringent regulation could cause dramatic changes in technology, often by new firms or entrants displacing the dominant technologies. The replacement of dominant technologies by new entrants, rather than incremental change by existing technology providers, has been the source of the most important radical innovations this century.

MIT research found paradoxically that the only government policy that affected innovation was in fact health, safety and environmental regulation, not strategies devised by government as a part of its industrial policy. Moreover, the effects of regulation on innovation turned out to be positive, not negative as expected by the conventional wisdom at that time. Stringent regulation could stimulate entirely new products and processes into the market by new entrants with the displacement of dominant technologies rather than the transformation of technologies by existing firms[30].

Figure 6 – The "porter Hypothesis"



Source: Ashford (2000)

With regard to regulation, what seems to matter is not only the stringency, mode (specification versus performance), timing, uncertainty, focus (inputs versus product versus process) of the regulation, and the existence of complementary economic incentives -- but also the inherent innovativeness (usually in new entrants) or lack of it (usually the regulated firms) (Ashford and Heaton 1983, Ashford *et al.* 1985). The importance of new entrants is missing in the analysis offered by Porter. In order for innovation to occur, the firm (or government itself) must have the **willingness**, **opportunity/motivation**, and **capability or capacity to innovate** (Ashford, 2000). These three factors affect each other, of course, but each is determined by more fundamental factors.

More specifically:

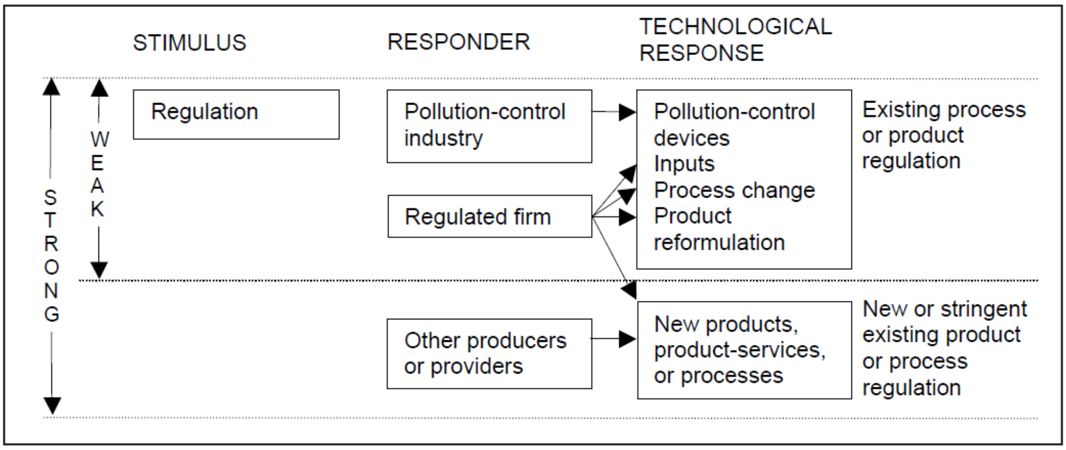
- The **willingness** factor is determined by:
    - attitudes towards changes in production in general,
    - an understanding of the problem,
    - knowledge of possible options and solutions, and

[30] One of several vivid examples is the displacement of Monsanto's PCBs in transformers and capacitors by an entirely different dielectric fluid pioneered by Dow Silicone. Regulation can thus encourage disrupting innovations by giving more influence to new 'value networks' or 'customer bases' in which demands for improvements in both environmental quality and social cohesion are more sharply defined and articulated. Of course, industries that would fear disrupting new entrants would not be expected to welcome this regulation. This explains in part their resistance to regulation and their propensity to try to capture regulatory regimes, surreptitiously or through direct negotiation (Caldart and Ashford 1999).

  - o ability to evaluate alternatives.
- **Opportunity and motivation** involve both supply-side and demand-side factors.
  - o On the supply side, consciousness of existing technological gaps could prompt firms to change their technology, as could the opportunity for cost savings. Regulatory requirements could also define the changes that would be necessary to remain in the market.
  - o On the demand side, factors that can push firms towards technological change include opportunities for cost savings or expansion of sales, public demand for more environmentally-sound, eco-efficient, and safer industry, products and services, and worker demands and pressures arising from industrial relations concerns.
- Capability or capacity can be enhanced by
  - o An understanding of the problem,
  - o Knowledge of possible options and solutions,
  - o Ability to evaluate alternatives,
  - o Resident/available skills and capabilities to innovate, and
  - o Access to, and interaction with, outsiders.

More recently, Ashford and Hall (2011) developed a comprehensive visual representation of the major factors that govern the relationship between regulation and innovation, distinguishing between the weak and the strong versions of the Porter hypothesis. As shown in Figure 4 below (specifically designed for environmental legislation), the difference between the two approaches mostly rests in one factor – the interaction of the firm with outsiders.

Figure 7 - A model for regulation-induced technological change for weak (Porter) and strong (Ashford/MIT) forms of the regulation-induced innovation hypothesis



Source: Ashford and Hall (2011)

BOX 2: Market structure and innovation: an external querelle

In this box we briefly explore a very important issue in the economics literature: the relationship between competition and innovation. This is a relevant aspect of public policy, as it can lead to different conclusions about how competition policy hampers or stimulates innovation, as well as whether antitrust law (and all the ex ante regulation that is based on its principles, such as the e-communications framework discussed below) should treat concentrated market structures as a danger for innovation and dynamic efficiency.

The debate on market structure and innovation is among the most researched issues in economics, especially due to the long-lasting debate between two of the most prominent economists of the past century, Joseph Schumpeter and Kenneth Arrow, who had completely opposite views of the best market conditions that would contribute to stimulating innovation. According to Schumpeter, "[t]he introduction of new methods of production and new commodities is hardly conceivable with perfect – and perfectly prompt – competition from the start. And this means that the bulk of what we call economic progress is incompatible with it. As a matter of fact, perfect competition is and always has been temporarily suspended whenever anything new is being introduced – automatically or by measures devised for the purpose – even in otherwise perfectly competitive conditions". On the other hand, Kenneth Arrow focused on a different view of dynamic efficiency, by looking at the incentive, for market players, to achieve superior levels of productive efficiency (mostly reductions in unit costs of existing products) over time, which would allow them to beat rivals in reasonably competitive environments. Every time inventors can appropriate part of the social benefit of the invention they introduce, their private incentive will be aligned with the public interest. Since this is more likely to happen under competitive conditions, given the pressure exerted from rivals, more competition also means more innovation.

More recently, the work of Philippe Aghion and various co-authors has shed more light on the potentially beneficial impact of competition on innovation and growth. These include: (a) a "Darwinian effect" or "innovate to survive", generated by intensified product market competition that forces managers to speed up the adoption of new technologies in order to avoid loss of control rights due to bankruptcy*;* (b) a "neck-and-neck competition" effect, especially observed when innovation is incremental and forms compete to overtake one another in a constant competitive race; and (c) a "mobility effect" that emerges when skilled workers are able to easily switch to new production lines.

Also, the work of David Teece (1986) has shed a different light on the dynamics of innovation. Rather than adopting a "market structure" approach, like Schumpeter, Arrow and Aghion, Teece focuses on a contracting, "Williamsonian" approach to innovation policy. In particular, he considers that most innovative products have to be integrated in a nexus of complementary products to really unleash their full potential. Thus the modularity of modern products and the possibility of integrating innovation into existing system goods becomes one of the essential drivers of product innovation in a given economy.

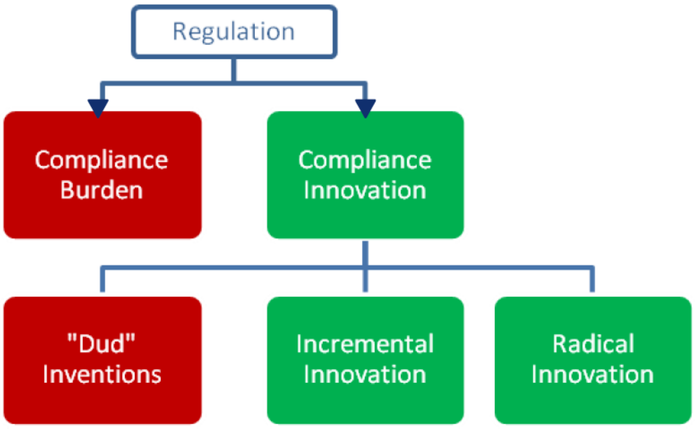
As is easily observed, the debate over the preconditions for innovation has important policy implications: if a policymaker is confident that a more competitive market structure is conducive to more dynamic efficiency and innovation, then competition policy will become an important ingredient of innovation policy. To the contrary, if monopoly or oligopoly are thought to be optimal market conditions for long-term dynamic efficiency, then innovation policy will fall outside the remit of competition policy, and will potentially clash with it at times. Finally, if policymakers believe that the intellectual property regime and the role of the state as facilitator of the introduction of incremental innovation in existing system goods are the key pillars of innovation policy, then industrial policy and a pro-active innovation policy becomes the key mission of modern government.

Subsequent research on the Porter Hypothesis

A paper commissioned in 2010 by the Institute of Medicine to Luke Stewart of the ITIF summarizes a substantial amount of the research performed in various sectors on the Porter hypothesis and related research streams. Stewart distinguishes between incremental and radical innovation, as well as between economic and social regulation. More specifically, economic regulation affects market conditions and includes *i.a.* price controls, market entry conditions, production obligations, the regulation of contract terms, and most regulations governing the finance industry. Social regulation is the imposition of requirements on firms to protect the welfare of society or the environment. Examples include environmental controls, health and safety regulations (so-called "lifesaving regulation"). In Stewart's approach, largely based on the previous literature, the impact of regulation on innovation depends on the balance between the costs (compliance burdens) and the benefits (compliance innovation) generated by the regulation in terms of innovative activity.

Interestingly, Stewart (2010) distinguishes between **compliance innovation** and **circumventive innovation**. The latter innovation can be realised when the scope of the regulation is rather narrow and an innovation allows companies to escape the exposure of the regulation. Compliance innovations have to be achieved when the coverage of the regulation is rather broad and the resulting product or process innovations remain consequently within the scope of the regulation. Similarly, Carlin and Soskice (2006) differentiate clearly between the **incentive impact** and the **compliance cost** of regulations. They determine an equilibrium rate of technological progress and consequently innovation endogenously. Starting from the Solow growth model, a negative relationship between the rate of labour productivity enhancing technological progress or innovation – analogously to an increasing population or labour force – and the equilibrium capital intensity can be derived. This relation is called the "**Solow relation**". In contrast, the "**Schumpeter relation**" assumes that with increasing capital intensity more resources are available for investments in research and development, which allows fostering innovation.

Figure 8 – Innovation burdens and benefits in terms of radical and incremental innovation



Source: Stewart (2010)

However, it must be observed that in studies related to the Porter hypothesis the approach to the analysis of compliance burdens is not very detailed. As a matter of fact, it must be observed that not all the burdens imposed by legislation would necessarily result in a reduction of innovative activity: the key assumption is that all resources devoted to compliance with regulations are subtracted from innovative activity: such assumption – which led some authors (e.g. Kox 2005) and many governments to claim that a reduction of red tape would automatically result in a significant increase of GDP – is very heavily contested in the literature and has no empirical backing to date.

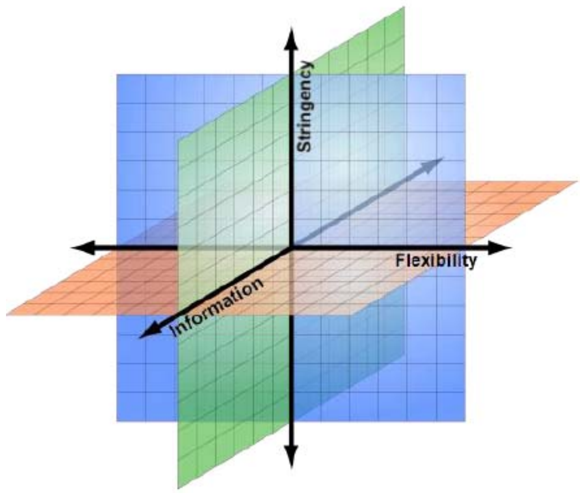
Stewart also summarizes previous literature in defining three main dimensions that affect the impact of regulation on innovation:

- **Flexibility** describes the number of implementation paths firms have available for compliance.
- **Information** measures whether a regulation promotes more or less complete information in the market.
- **Stringency** measures the degree to which a regulation requires compliance innovation and imposes a compliance burden on a firm, industry or market.

Each dimension plays a large role in determining the impact of regulation on innovation. Greater flexibility and more complete information generally aid innovation; with stringency, there is a trade-off between the compliance burden and the type of innovation desired, as more radical innovation will generally come at a higher cost.

Another important factor is **uncertainty** on the content and scope of future (upcoming) policies. Policy uncertainty reportedly has a mixed effect on innovation, although often it will precipitate the effects of the innovation dimensions of the regulation itself, regardless of whether the regulation is eventually enacted or not. For example, if firms expect a change in the stringency of a regulation to require compliance innovation, then policy uncertainty may spur innovation prior to the regulation being enacted. Likewise, the compliance burden may affect firms prior to enactment if, in anticipation, they begin diverting resources toward compliance. That said, this behaviour assumes that the degree of policy uncertainty is not so large as to discourage business decision making entirely. If policy uncertainty is high and the optimal decisions with and without the regulation are contradictory, then firms may suspend investment in innovation until a policy uncertainty is reduced to a more comfortable level (Ishii and Yan, 2004).

Figure 9 - The three dimensions of innovation



Source: Stewart (2010)

Regulation and innovation: research commissioned by the UK government and NESTA

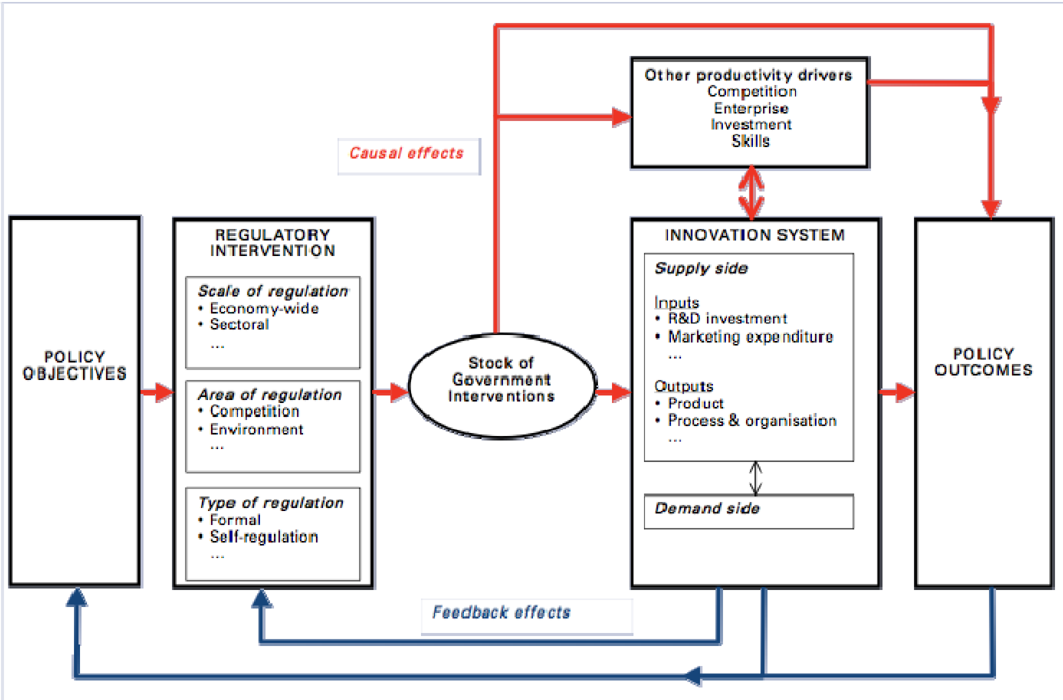
The UK government has been perhaps the most active in stimulating research and a thorough reflection on the relationship between regulation and innovation over the past few years. In particular, a research paper published by the BERR in 2008 explored the main relationships and interactions between regulation and innovation and develops a conceptual model to map the relationship between regulation and innovation as reported in figure 5 below. In the figure, the relationship starts with the definition of the policy objective and proceeds with the decision to use the regulatory framework (rather than taxes or public spending) to achieve it. Intervention through the regulatory framework may take three forms: the introduction of a new regulation; revisions to current regulation; or the removal of an existing regulation (i.e. de-regulation.) These interventions may apply across the whole economy or to specific sectors and relate to different areas of policy (e.g. consumer protection, competition, intellectual property). They may also involve amendments to formal rules and requirements or entail the use of alternatives such as self-regulation (e.g. voluntary codes of conduct). All these different changes in the regulatory framework, in turn, alter the total stock of government policies (regulatory, tax and spending policies) and also the scale and nature of the interactions between them.

Regulatory interventions may affect both the supply-side and demand-side of the innovation system. On the supply-side, regulatory interventions may affect business behaviour and decisions resulting in changes in innovation inputs (e.g. R&D investment, marketing expenditure) and outputs (e.g. products, processes and organisational structures). On the demand-side, regulatory interventions may alter user preferences for particular technologies and products and services leading to changes in the pace and direction of innovation.

Changes in the innovation system may, in turn, affect policy outcomes. Alone, or through the other four productivity drivers (i.e. competition, skills, investment and enterprise), innovation may have an effect on economic objectives such as productivity or social and environmental objectives such as improved health and safety or better environmental quality.

Finally, the development of new technologies, products and business practices may give rise to new markets and markets failures which require modifications, where appropriate, to the current regulatory framework and, in some cases, the introduction of new rules where none were previously necessary. By incorporating 'feedback effects' as a feature, the conceptual model captures the dynamic aspect of the relationship between regulation and innovation.

Figure 10 – BERR's model of the relationship between regulation and innovation



Source: BERR (2008)

As highlighted by BERR (2008), the relationship between innovation and regulation is:

- **Complex**: regulation can alter the incentives as well as the risks of innovation but also the costs and benefits associated with the innovation process.
- **Multidimensional**: both the supply side and the demand side of the innovation system are affected by regulation.
- **Ambiguous**: e.g. a certain type of regulation may be regarded as pro-competitive and thereby be expected to encourage innovation, but modern economics has converged on the view that there is a U-shaped relationship between competition and innovation. Hence, the impact of regulation on innovation must be appraised on a case-by-case basis: there are examples of successful innovation in an initially non-competitive environment triggered by early-stage standardization (e.g., the GSM standard for 2G telephony); and also innovation made possible by regulatory exemptions from the application of EU anti-trust rules (e.g. common platforms for a new type of cars in a single factory for three competing brands, Volkswagen Sharan, Seat Alhambra and Ford Galaxy).
- **Dynamic and two-way:** technological change and/or other factors may transform sectors or markets such that prevailing regulation has to be transformed as well, one prominent example being telecoms, now e-Communications. Entire economic sectors can be transformed *because of* regulatory reform, a prominent example being passenger air transport, which saw the emergence of entirely new business models (and airport organisation) that would have been impossible under EU regulation before the late 1980s.

The paper concludes that policies should be forward-looking, flexible and innovative and evidence-based.

More recently, in a paper commissioned by NESTA, Blind (2012) specifically analyses the impact of economic, social and institutional regulation on innovation. The latter includes *i.a.* employment protection legislation, immigration laws, bankruptcy laws and legislation on intellectual property rights. Interestingly, Blind (2012) adopts the same cost-benefit approach to innovation by exploring the compliance costs and the innovation incentive effects of specific types of economic, social and institutional regulations. Also, the four main factors (stringency, timing, flexibility and regulatory uncertainty) are used as a general framework. Table 1 below summarizes some of the results of the analysis contained in Blind (2012).

Table 2 – Type of regulation and impact: available empirical evidence

Type of regulation	Compliance cost or negative incentive effects	Positive incentive effect	Empirical evidence
Competition enhancing and securing regulation	Reduces rents for innovators Prohibits R&D cooperation	Increases and secures incentives to invest in innovation	Ambivalent
Antitrust regulation	Dominant (innovative) companies have limited incentives to invest further in R&D	Allows competitors to enter the market and put pressure on dominant companies	Only anecdotal evidence
Merger & acquisitions	M&A restrictions limit takeover pressure and incentive to innovate	M&A allows efficient takeover of innovative companies M&A restrictions protect management from short term market pressures	Ambivalent (U-shape)
Market entry regulation	Prohibits market entry of probably innovative newcomers	Reduces competition for incumbents, e.g. for infant industries	Only indirect evidence of entry pushing innovation in technology advanced sectors
Price regulation	Price caps reduce innovation incentives	Minimum prices secure minimum turnovers and decrease risks; completely free prices allow monopoly pricing	Not available
Regulation of natural monopolies and public enterprises	High price pressure and low gains allow no investments into R&D in case of marginal cost pricing	Incentives to achieve progress in productivity in case of rate of return regulation	Positive in case of deregulation

Source: Blind (2012)

Standards and innovation

Apart from the literature based on the Porter hypothesis and on the compliance burdens and incentives effects of regulation, it is worth mentioning briefly another important stream of literature, which refers to a specific form of regulation, *i.e.* standardization. As clarified by BERR (2008), Standards serve a number of functions including:

- **Performance/outcome** – standards can define desired performance criteria or desired 'outcomes', enabling products or services to achieve the desired effects without restricting 'innovators' freedom to design their products and services
- **Measurement** – standards can convey technical information in a transparent and consistent manner enabling innovators to benchmark the performance of their products/services and processes and compare it against their competitors.
- **Compatibility/interface** – standards can help innovators work to ensure that new products, services and technologies are compatible with existing ones thereby promoting open and competitive markets.
- **Quality** – standards can communicate to consumers that new products, services and technologies meet socially desired minimum levels of quality and safety (e.g. health and safety and environmental standards).
- **Variance reduction** – standards can promote conformity between products, services and technologies brought to market thereby enabling producers to exploit economies of scale and enabling users to have confidence in their choice of product.

An early contribution on the impact of standards on innovation is that of Swann (2000), which concludes that:

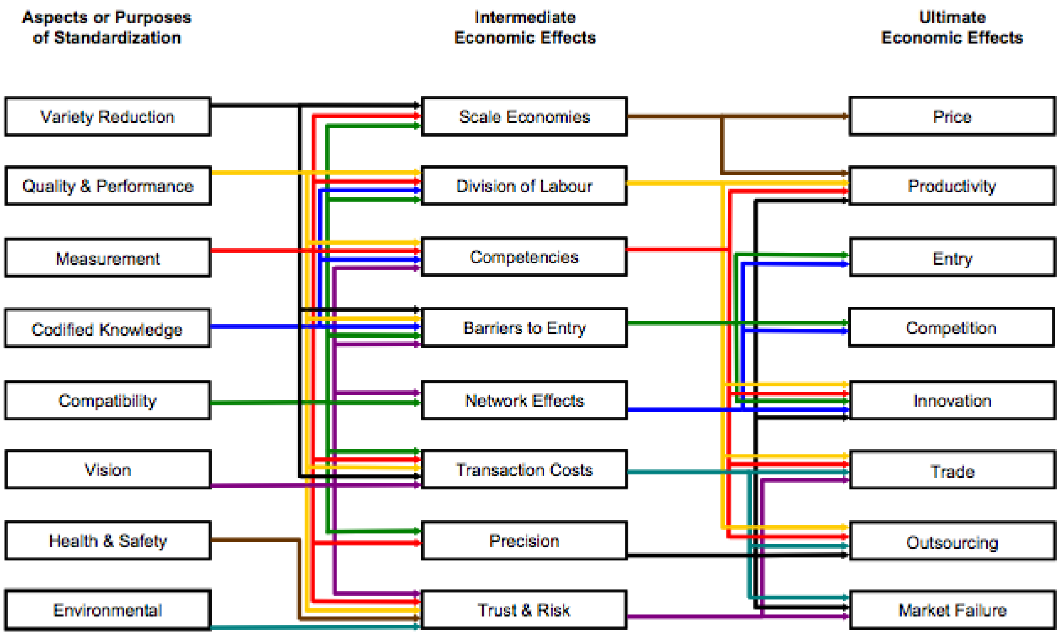
- Standardization helps to build focus, cohesion and critical mass in the emerging stages of technologies and markets;
- Standards for measurements and tests help innovative companies to demonstrate to the customer that their innovative products possess the features they claim to have, but also acceptable levels of risks for health, safety and the environment;
- Standards codify and diffuse state of the art in science and technology and best practice;
- Open standardization processes and standards enable a competition between and within technologies and contribute therefore to innovation-led growth.

In 2006, Standards Australia published a comprehensive overview of the impact of standard on the Australian economy, finding that there is apparently a positive relationship between economy-wide total factor productivity and the "stock of standards", either when this is kept as a separate variable, or combined with a stock of R&D variable.

In 2010, Swann (2010) provided a comprehensive update of the state of the art in the economics of standardization, and reports, on the basis of a detailed literature review, that several detailed econometric studies carried out for the UK, Germany, France, Canada and Australia have established a clear connection at a macroeconomic level between standardization in the economy, productivity growth and overall economic growth. Importantly, while it is commonly believed that standards obstruct innovation, the evidence suggests a rather different story. Surveys of innovating firms find many enterprises say that standards are a source of information that helps their innovation activities. Moreover, while many say that regulations do also constrain their innovation activities, these constraints do not necessarily prevent innovation. Moreover, these 'informing' and 'constraining' effects tend to occur together. In addition, standards can help: (i) the exploitation of economies of scale; (ii) the effective division of labour; (iii) the building of competencies; (iv) to reduce barriers to entry; (v) to build network effects; (vi) to reduce transaction costs; and (vii) to increase trust between trading partners.

The report then presents a schematic model of the beneficial (and dysfunctional) effects of standards, reported in figure 9 below. The model recognises eight different purposes or aspects of standardisation: variety reduction; quality and performance; measurement standards; codified knowledge; compatibility and interoperability; vision; health and safety; environmental. The model recognises that these aspects of standardisation can impact on eight intermediate economic variables: scale economies; division of labour; competencies; barriers to entry; network effects; transaction costs; precision; trust and risk. And finally, the model recognises that these intermediate variables can impact on eight ultimate economic variables, of policy interest: price; productivity; entry; competition; innovation; trade; outsourcing; market failure.

Figure 11 – Model on the economic effects of standardization



Source: Swann (2010)

Recently, Blind (2013), in its paper for NESTA, shows the positive and negative impacts often correlated with different types of standards.

Table 3 – Standards and innovation: positive and negative effects

	Positive Effects on Innovation	Negative Effects on Innovation
Compatibility / Interoperability	• Network externalities • Avoiding lock-in old technologies • Increasing variety of system products • Efficiency in supply chains	• Monopoly power • Lock in in old technologies in case of strong network externalities
Minimum Quality/ Safety	• Avoiding adverse selection • Creating trust • Reducing transaction costs	• Raising rival's costs
Variety Reduction	• Economies of scale • Critical mass in emerging technologies and industries	• Reducing choice • Market concentration • Premature selection of technologies
Information	• Providing codified knowledge	

Source: Blind (2013)

The impact of regulation on entrepreneurship

Another fundamental aspect of the impact of regulation and innovation is the extent to which regulatory interventions can affect entrepreneurship. Djankov *et al.* (2005, 2006a, 2006b) investigate the role of a broad set of macro and micro variables on entrepreneurship in Russia, China, and Brazil, empirical. Other papers that make the link between regulatory constraints (mostly product market regulation) and entrepreneurship are Alesina *et al.* (2005), Bassanini and Ernst (2002), Bayoumi *et al.* (2004), Blanchard and Wolfers (2000), Fiori *et al.* (2007), Nicoletti and Scarpetta (2003). Another stream of research focuses on the regulation of product and labour market and contract enforcement, and includes Ciccone and Papaioannou (2006), Klapper *et al.* (2006), Guiso and Schivardi (2006), and Ardagna and Lusardi (2008). The latter investigate international differences in entrepreneurship and find that regulation plays a critical role, particularly for those individuals who become entrepreneurs to pursue a business opportunity. The individual characteristics that are impacted most by regulation are those measuring working status, social network, business skills, and attitudes toward risk.

Other papers focus specifically on entry regulations, *i.e.* regulations that make it more costly for operators to effectively enter a new market. Klapper *et al.* (2006) find a consistent negative effect of costly regulations on firm entry, especially focusing on sectors in which entry is suppose to be high. Rostam-Afschar (2010) studies the initial causal evidence of the effect of a policy reform in Germany. Dixon *et al.* (2006) show evidence of the disproportionate impact of compliance burdens on smaller businesses and reflect on consequences for entrepreneurship.

EU policy and innovation: besides innovation policy

As already mentioned in the introduction to this report, very little has been written on the impact on innovation and entrepreneurship of EU legislation, besides those legal rules that are directly devoted to innovation (e.g. the Innovation Union flagship initiative). One recent exception is the paper by Battaglia, Larouche and Negrinotti (2011), which even question whether the EU can be said to have an innovation policy. The authors observe that "It is remarkable that, in major policy initiatives where innovation plays a central role, such as the Lisbon Agenda and its successor Europe

2020, little attention is paid to those areas of the law which influence the incentives to innovate, namely competition law, intellectual property law, sector-specific regulation (especially electronic communications regulation) and standardization (hereinafter 'EU economic law')". The authors observe, in particular, the inconsistency between EU innovation policy and the underlying rationale of European Commission decisions in the pharmaceutical sector, which seem to dance to a completely different drummer.

More generally, as confirmed by Larouche and Schinkel (2013), it seems that competition policy should be handled by the European Commission in a way that is innovation-compatible, and should therefore place a greater emphasis on long-term dynamic efficiency rather than short-term static efficiency effects of market outcomes (see our case study below, Section 3.1.1).

Annex III – Case Studies

Refusal to deal in competition law and e-communications regulation

A good example of a general rule that can affect the overall incentives to engage in innovation is found in the field of antitrust law. One of the most frequently cited is the approach to 'refusal to deal', *i.e.* a case of exclusionary abuse of dominance, as such regulated by Article 102 TFEU. The significance of this example is even greater since this specific rule has had a profound impact on *ex ante* regulatory regimes such as the one for electronic communications in force in Europe since 2003 (Renda, 2010; Pelkmans and Renda, 2011).

The European Court of Justice has clarified on several occasions the cumulative conditions that have to be met before compulsory third party access to networks can be enforced under community competition law. This has been done in a stream of cases that goes from *Commercial Solvents* to *Tiercé Ladbroke*, *Bronner, Magill* and *IMS health*. These conditions include the following:

- the refusal relates to a product or service that is objectively necessary to be able to compete effectively on a downstream market,
- the refusal is likely to lead to the elimination of effective competition on the downstream market, and
- the refusal is likely to lead to consumer harm.
- The refusal is not objectively justified.

The Commission Guidance document on the treatment of exclusionary abuses under article 82 EC Treaty (now 102 TFEU), published in December 2008, clarifies at §75 that

> *"The existence of … an obligation [to supply] — even for a fair remuneration — may undermine undertakings' incentives to invest and innovate and, thereby, possibly harm consumers. The knowledge that they may have a duty to supply against their will may lead dominant undertakings — or undertakings who anticipate that they may become dominant — not to invest, or to invest less, in the activity in question. Also, competitors may be tempted to free ride on investments made by the dominant undertaking instead of investing themselves. Neither of these consequences would, in the long run, be in the interest of consumers."*

The delicate balance struck by the CJEU ruling on refusal to deal has been shaken a few times over the past years. The refusal to supply has long been under the spotlight also due to the important differences existing between the US and the EU approaches in this field, as emerged mostly in *Microsoft*, *Trinko*, and *linkLine*. The underlying theme is mostly related to the EU's reliance on the so-called "essential facilities" doctrine, which in the US has always been downplayed by the Supreme Court as, if anything, an "elaboration of lower courts"[31]. In addition, in the European Commission's decision against Microsoft of April 2004, the "exceptional and cumulative set of circumstances" has been partly rejected by the Commission, which had failed to prove that the four circumstances were met in the case at hand, but decided to condemn Microsoft anyway. This situation created a serious problem of legal certainty within the EU: the set of circumstances under which antitrust rules could lead to the imposition of mandatory third-party access to the dominant firm's own assets was now

[31] As in *Trinko*. See Renda (2010).

uncertain, and as such unpredictable. The Court of First Instance decision on the same case in September 2007, and the already mentioned guidance paper on the treatment of exclusionary abuses under article 82 (now 102 TFEU) partly solved the problem.

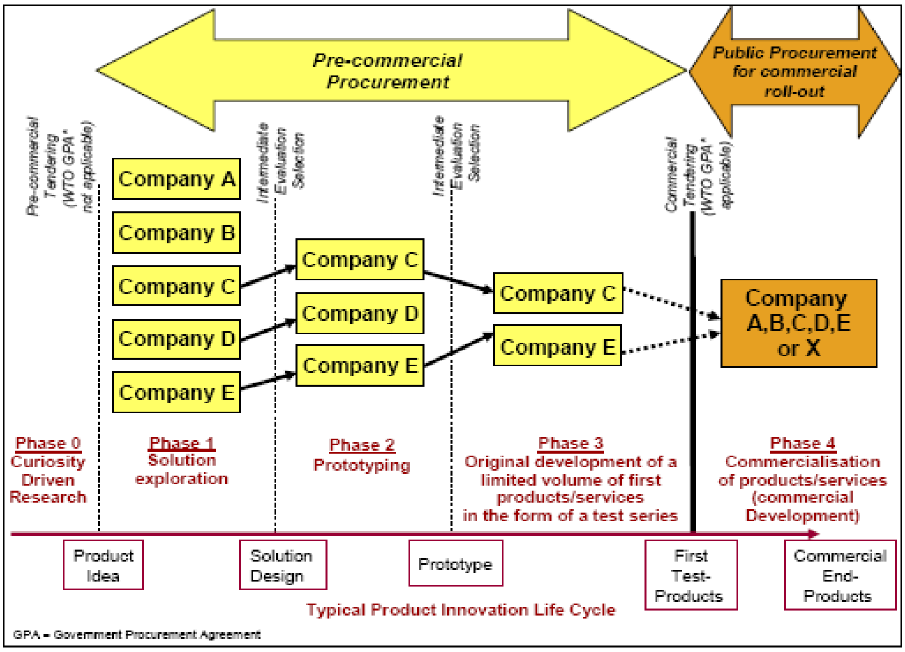
What remains to be fully ascertained is whether a rather rigid application of the rule in both antitrust and ex ante regulation could lead to a weakening of incentives to innovate. In principle, first inventors should be discouraged by a rule that allows competitors to access the winning rival's own assets. At the same time, however, incremental innovation could be facilitated by the application of an essential facilities rule.

The strategic use of public procurement

One of the most widely acknowledged forms of demand-side innovation policy is the use of public procurement in support of innovation, and in particular of the "competitive dialogue" as well as the so-called "pre-commercial procurement". The latter guarantees significant demand for new products and services

Figure 3 below shows a representative scheme for pre-commercial procurement and public procurement for commercial roll-out of innovative products, as interpreted by the European Commission. As shown in the figure, procurement can be launched even at very early stages of innovation, such as the development of product ideas and the elaboration of solution designs; but also at the prototype phase and successive launch phases of innovative products up to the development and procurement of commercial end products.

Figure 12 - Pre-commercial procurement: a European Commission scheme



It is widely acknowledge that public procurement is insufficiently used to stimulate innovation in Europe for many reasons, including the following:

- Wrong incentives. Procurers tend to favour low cost, low risk, and "off the shelf" solutions even when there are longer term benefits to the public service provider in testing and procuring new technologies and solutions. Moreover, there is a first mover problem as no individual procurer is willing to take the additional cost and risk (financial, operational, political) of being the first one to purchase a new technology or innovation, while all procurers would benefit from someone else going first.

- Lack of knowledge and capabilities of public procurers on what new technologies and innovations are, or could be, available in the markets – in particular for developments outside their regions/ countries. This is compounded by the lack of dialogue between procurers and supplier companies and because such companies have no clear signals of future demand on which to base innovative investments.
- No strategy that links public procurement with public policy objectives (e.g. health, environment, transport) and Research, Development and Innovation (R&D&I) support initiatives (typically grant funded). Public procurement should articulate the demands for better public services into commercial propositions and procurers and the public services they support should be able to benefit from new technologies and innovations developed under public R&D and innovation programmes.
- Fragmentation in demand with individual procurements too small for companies to make innovative investments, and no mechanisms to allow the pooling of risk and resources across countries.
- SMEs cannot cope with public procurement at the first stage, more often they act as subcontractors. This hampers the access of public authorities to the innovative potentials of SMEs, while SMEs are important creators of innovations and innovative solutions.

In 2006 the European Commission launched the "Lead Market Initiative" (LMI) as a first attempt to engage in demand-side innovation policy. The long-term goals of the Lead Market Initiative were clearly stated in the May 2008 Competitiveness Council conclusions: to remove obstacles to enable European enterprises to enter new and fast growing global markets; to facilitate a faster uptake of new products, services and technologies; and to fill the gap between the generation of new products, services and technologies and the success of those innovations on the market that need to be bridged.

Six lead markets were chosen: sustainable construction, technical textiles for intelligent personal protective clothing and equipment, bio-based products, recycling, eHealth and renewable energy. These markets are highly innovative, and provide solutions of broader strategic, societal, environmental and economic challenges. Also, these markets have a strong technological and industrial base in Europe and they depend more than other markets on the creation of favourable framework conditions through public policy measures. Under the LMI three public procurement networks became operational in September 2009: the SCI network (Sustainable Construction and Innovation network), the LCB/Healthcare and Enprotex (protective textiles).

The impact in the six lead markets were compiled in an evaluation report published in 2011. The conclusion was that the approach was successful to date, but it requires a more consistent application through the EU28 in order to produce even better impacts.

It is also of interest that the new public procurement directive 2014/24 comprises several improvements with a view to foster innovative solutions. Thus, there are now more possibilities for additional flexibility to choose a procurement procedure which provides for negotiations, relevant for authorities having difficulty in predefining full technical solutions for complex contracts. If the market does not offer ready-made solutions, contracting authorities can establish a long-term partnership for the development and subsequent purchase of a new innovative product or service.

Energy efficiency regulation for equipment and cars and innovation[32]

An instructive example of the positive interaction between EU regulation and innovation, also dynamically over time, is found in energy efficiency regulation of household equipment, other small (e.g. office) equipment and cars. The general purpose of this category of EU regulation is to reduce energy consumption for a given use of equipment or of cars, in the light of the overall EU climate strategy aiming to cut greenhouse gas emissions. An associated EU benefit of such regulation is the positive effect on energy security, given the expected increase in the EU import dependence for oil and gas in the coming period. Three regulatory instruments are of importance: consumer-friendly colour labels, mandatory energy limits and credible compliance. Labelling's first purpose is to inform the consumer before or at the moment of purchasing the equipment or the car. For labelling to be effective, one needs to avoid technical or specialist jargon, better still, to find ways to generate immediate awareness of the core of the issue to be conveyed to consumers. Whereas, for example, nutritional labelling has struggled for many years with incomprehensible jargon and too much text which most consumers do not understand and/or takes too much time at the moment of purchase, colour labelling has proved to be a most effective (regulatory) innovation which consumers understand right-away. The subsequent question is whether labelling can also incentivise consumers to buy 'greener' products, after understanding the range of choices between offerings of cars or of equipment in terms of energy efficiency. This depends on two critical factors: one is the energy use over the life time (or the period over which the consumer uses the car or the equipment), the other is the purchase price. As long as the latter is not (much) higher than prices for less green products, it is rational for consumers to opt for green products, as the energy bill over some years will be lower (other things equal), unless the consumer has other motives in his preference function (e.g. luxury; higher performance, etc.). In this form, colour labels can thus function as incentive regulation: incentive for consumers to buy greener products and incentives for suppliers to innovate and satisfy the incipient demand for greener products which reduce consumer expenses for energy.

However, ever since the early 1990s, many OECD countries (and meanwhile other ones as well) have added 'hard' energy targets by means of specific energy limits for many types of equipment [33] and for personal cars. This would seem to be 'command-and-control' regulation, but that is only correct with respect to the energy limit. In fact it has been employed in a fairly sophisticated, incentivising manner in combination with colour labels, also over time. The colour label preceded the introduction of 'hard' targets. For the producers, the function of the colour label in the case of home appliances was to allow them some time to adapt their offerings and make them greener – a direct stimulus of innovation – before the hard energy limits became mandatory. Consumers were given time to get accustomed to colour labels, too, and – in combination with information on how much savings (say, in KWh) a green appliance would yield per year – were incentivised by pecuniary motives. However, the EU was convinced that the interaction between industrial innovation and incentivised purchasing behaviour was too weak, perhaps because the energy savings were too small in the first place. More radical innovation was required if the demanding energy efficiency objectives of the Union were to be achieved. More radical meant that the least efficient appliances on offer would have to leave the market. Once ambitious compulsory targets were set, the colour labels appeared to be identical but, in fact, only referred to appliances still allowed on the market. The EU's first energy labelling directive was enacted in 1992 (92/75). Later revisions have tightened the mandatory

[32] This case is based on Ellis (2007); Pelkmans *et al.* (2014), and informal sources and interviews.

[33] For home appliances and office equipment, these targets are called 'MEPS', minimum energy performance standards. Strictly, this is a misnomer as standards are, by definition, voluntary.

targets considerably and the industry has responded with successive innovations in order to comply or even stay ahead of new constraints. In July 2014 the European Commission hopes to publish yet another review of energy labelling and efficiency targets. It is telling that the problem nowadays has transformed: almost all appliances have reached what originally was the A status on the labels (green colour), thereby significantly reducing the incentivising effect and information clarity for consumers. For example, washing machines now range from 'A 'to 'A+++', which confuses consumers. Leading producers already announce that they may soon reach four or five 'plusses' for the A status. This is a powerful indicator of the steady innovation having taken place ever since colour labels and hard targets (MEPS) have been introduced and tightened over time. At the same time, the colour labels will have to be revised in order to maintain the same effectiveness as before (possibly, by a new classification of energy use per appliance underlying the colour labelling system).

The enormous success of energy efficiency regulation for appliances, also with consumers, is mainly due to the unexpected outcome of the interaction between regulation and innovation. Some 25 years ago it was widely feared that compulsory energy efficiency targets, leading to greater energy savings than the market had generated in response to colour label incentives for consumers, would lead to rising costs and prices, for a relatively marginal improvement of energy performance. But this did not happen, quite the contrary: "…all products examined have experienced a decline in real prices of between 10 % to 45 %, while energy efficiency increased by 10 % to 60 % …"[34]. These gains have been accomplished without a decline in service. Only top products reduced in price very little but that turned out to be caused by other (e.g. luxury; high quality) features.

Comparing this happy 'win-win' of lower prices and better energy performance with cars and e.g. (noisy) outdoor equipment can help one to understand better the interaction between EU regulation and product innovation. For personal cars, a similar energy colour label has been introduced, be it that it indicates CO_2 emission levels or (for diesel cars) particles, both closely related to fuel consumption, as a function of the type of engine and the weight of the vehicle. This was and still is combined with gradually stricter energy (CO_2) performance requirements[35]. Major difference with appliances consist in (i) the greater significance of price and even income elasticities of demand given that the purchase of a car implies a relatively large expenditure for households; (ii) the range of offerings per brand is far wider. Altogether, this generated greater urgency for innovation for larger and high-performance cars than for very small cars. In turn, this split between large and small cars led to a much greater threat to corporate strategy for brands being relatively successful in selling larger and more luxury cars, than for companies concentrating on smaller cars. Fierce lobbying influenced the EU regulation initially adopted in such a way that larger cars remained at first relatively less affected. Eventually, however, tightening of the emission requirements forced companies to focus on disruptive rather than mere incremental innovation, by focusing on new types of engines (e.g. on hydrogen directly or with fuel cells, or hybrids; electric vehicles; use of natural gas or LPG although this technique is hardly new) whilst radically improving the performance of diesel engines (some 25 % of the car fleet uses diesel in Europe). Disruptive innovation of car engines is hindered by a chicken-and-egg problem, in that hydrogen or electric (or, for that matter, LPG) cannot be sold before widespread and costly infrastructure is available, but investment in such infrastructure is held back by the slow emergence of consumer-friendly features of such new technologies. What is comparable with appliances is that the real prices of personal cars, with much more

[34] M. Ellis (2007, p. 13). The OECD /IEA report covers data collection from the late 1980s to 2005.

[35] Of course, for cars, other aspects play a role as well, for instance, fuel requirements (no lead; higher octane, etc.), requirements for tyres and the obligation of catalytic converters.

features and greater safety than decades ago thanks to permanent and successful innovation, have not changed since the early 1980s.

The case of noisy outdoor equipment is also instructive for another reason. In order to prevent building or gardening equipment used outdoor to cause too much noise annoyance, noise limits have been regulated in dir. 2000/14 for 22 types of equipment, including a noise label based on technical jargon. In discussions to revise the directive, the introduction of a colour label was suggested. However, the market failure here is that the purchaser may produce annoyance but hardly suffers from it; it is other persons in 'the' environment who may experience this annoyance. A user-friendly colour label to incentivise purchasers to buy low-noise equipment would not work, because there is no pecuniary incentive whatsoever: no lower taxation (for cars) and no savings over the life time (appliances). This implies that the only effective regulatory option would seem to be to lower the noise limits of regulated outdoor equipment. However, lower noise is regarded as a costly issue for producers, due to the fact that engine heat and emission requirements may well cause a trade-off, leading to higher prices. These higher prices are sensitive since outdoor equipment is hardly regulated in other parts of the world and EU industry is a major exporter, in sharp contrast with cars and appliances where all OECD countries and many developing countries have introduced regulation. Another difference is that both for appliances and cars, "less" is always better for consumers: less expenditure on energy or tax and less burden for the climate. Hence, the pressure for ever lower energy targets or emissions. But in outdoor noise, there is a (weak) rationale of banning the noisiest equipment, but this rational reduces rapidly with tighter targets, until noise levels hardly cause any annoyance anymore. Altogether, the interaction between EU regulation and innovation cannot easily be expected to be so powerful. For all these reasons, the EU has never dared to push for the experiment of lower noise targets, and finding out by practical experience whether such hard requirement would induce more radical innovation. At the risk of damaging the competitiveness of the EU outdoor equipment industry, when small improvement in noise performance turns out to increase costs of equipment sharply.

Innovation via European standards. GSM and smart meters[36]

Standards can sometimes inhibit innovation, especially when compatibility or interoperability is essential. But (European) standards can also be used explicitly to pursue innovation. Two such cases will be very briefly set out. One is the European 2G digital mobile telephony standard GSM, the other is about 'smart meters', reflecting a conscious strategy by the EU (led by the European Commission) to develop a longer term EU standardisation agenda for smart meters, linked to the EU's smart grids strategy, which blends traditional and innovative elements. The rationale for setting out two standards examples is that it is next to impossible to generalise about European standards. Often Commission mandates might seem to refer to 'a'standard to be developed but in fact lead to a 'family' of standards (from less than ten in toys to nearly 800, now, for machines). The GSM case is about a single standard, but a highly complex one (the first version being over 6000 pages, combining very distinct technologies), whereas the smart meters programme is leading to a long series of harmonised but traditional standards together with many new standards reflecting innovation.

GSM is known as a successful example of a European standard stimulating a breakthrough (disruptive) technology in mobile at the time, with a highly positive (though temporary) impact on the EU mobile equipment industry's competitiveness. In

[36] The two instances in this case are based on Pelkmans (2001); Bekkers *et al.* (2002); CEN/CENELEC/ETSI (2011, 2012); and European Commission (2011).

terms of the economic literature on network compatibility standards, it is a cooperative industry-wide standardisation strategy but with explicit direct as well as indirect government intervention at national and EU level. It is in many ways a unique experience, very hard to be repeated for other areas (indeed, in HDTV during the late 1980s an EU attempt to replicate a similar strategy failed hopelessly). The efforts undertaken by the 15 telecoms operators and the equipment industry were enormous – the GSM association has always claimed that the costs of bringing GSM to the market (in late 1992, after ten years of frantic activity) was ten times that of the Apollo programme of sending astronauts to the moon. It was also unique because the initiative and much of the first R & D investments were made by telecoms monopolies (13 out of 15 also state-owned) which had the technical infrastructure and the funds to focus on the technology without much fear of competition (at the outset) and without an initial threat of competing technologies (as they controlled what would be allowed to connect to their networks). GSM is a comprehensive 2 G standard, not just for the airface (as the 2G standards in the US were) but also for the base stations and some other features; this near-exhaustive specification made it much easier to pre-empt deviations during the ten-year long steeple-chase towards the introduction in the market. It is open, non-proprietary, interoperable and offers high systems capacity (compared to analogue), high voice capacity and some other sophisticated functions. In order to appreciate the innovation aspect well, one should not merely concentrate on the technical standardisation itself, even though this was impressive. It is the 'standard adoption strategy' which rendered GSM so special, with various pre-commitment mechanisms agreed and intensified over time. There was a Memorandum of Understanding between telecoms operators with detailed principles of joint pro-competitive procurement, cross-border roaming and planning. The EU level enacted directives on frequencies, on competition in telecoms terminals (like handsets) and on mutual recognition of conformity of telecoms terminals, besides a recommendation and, later, a Commission mandate to ETSI taking over the technical standards issues. There were drawbacks, too, but these did not hold back innovation; on the contrary they may have helped innovation to be so successful (but with costs and risks). One drawback is that the non-proprietary GSM turned out to be less open than foreseen, due to a kind of patent pool with free cross-licensing only for those few companies having patented (some 140) 'essential technologies' for GSM. As a result, companies with markets in analogue had almost no chance to join effectively; neither could the Japanese equipment suppliers get in. Another drawback was that a few cheap and very simple applications of digital mobile were suppressed on purpose in order not to dilute the expensive drive to mass market introduction. The only one which slipped through was the UK approval of PCNs (personal communication networks) at higher frequency, first regarded as a setback. A third drawback turned out to be the lock-in effect for 3 G, for which the CDMA airface (from Qualcomm) is better suited than the TDMA one underlying GSM. As a result, the UMTS underlying 3G has become unnecessarily complicated due to forced compromises. The longer run consequence has been very costly for EU equipment suppliers as their initial competitive advantage melted away with new competitors, and even further with newer software applications (e.g. Android) and 4G. In June 2014 EU and Korean companies decided to try to be a first mover on 5G. Nevertheless, there is no doubt about the phenomenal success of GSM in and outside Europe and the positive effects on EU manufacturers' competitiveness. Also the telecoms companies, mostly privatised by (say) 2000, benefitted due to mass consumption of services, new business models (e.g. pre-pay) and excessive roaming charges long after the set-up costs had been recouped. Because GSM was introduced simultaneous with telecoms liberalisation in the EU, also the consumer could benefit not only from the highly popular new technology, but also from far lower services tariffs except for roaming.

A smart meter is an electronic device that records consumption of electricity (or gas or water) and communicates this information to the supplier of electricity very regularly; however, modern smart meters enable two-way communication between the meter and the central system. The drive behind modern smart meters is explained by energy savings (i.e. efficiency). There is no doubt that this is true for energy suppliers; some doubt is lingering whether the tiny savings for consumers outweigh the extra costs of installing them, but of course the proper comparison is between consumer savings over a long period and the one-time fixed costs of installation. They are new digital generations of electricity meters (possibly with variants for gas and water). Smart meters is no longer merely about metrology, as they are capable of helping to foster efficient use of electricity (e.g. by differential pricing during the day) and are therefore one of the targets of the Energy Services directive 2006/32, called 'intelligent metering systems'. No less than 80% of electricity consumers ought to have such a meter by 2020. However, it was quickly understood that such meters better be standardised in the EU for scale and cost reduction to be realised. Some 110 different standards were found to exist in the Member States in 2009; there were battery and mains-powered meters and distinct national architectures. Therefore, in order not to inhibit technological developments, a common 'toolbox' of standards has been defined which do facilitate metering deployments. The two critical technological areas in this field are communication (e.g. the use of pagers, mobile phones, satellite, licensed radio, use of powerlines; different networks may be involved including even Wi-Fi; numerous smart meters apply Open Smart Grid Protocol from ETSI, again a family of specifications, but there are other as well) and information technology (e.g. powerline communications for smart meter systems ought to be standardised; note, for instance, that there was a Google.org Power Meter between 2009 and 2011 when it was retired). There is a strong innovation drive behind the programme, in that the entire Advanced Metering Architecture and not just the meters are covered, permitting explicit links with smart grids and eMobility standardisation, two highly dynamic areas. In addition, all kinds of potential applications became feasible based on the digital communication with the network operator. This in turn led to much more radical thinking about what are now called 'smart grids', of which smart meters would be only one component. European standardisation therefore had to focus on communications in smart metering systems if one were to support emerging software and hardware architecture and related (new) standards. Commission mandate M/441 of 2009 to CEN/CENELEC/ETSI is about these challenges. In a technical report on a functional reference architecture (2011), the functional entities and interfaces are identified that communications standards of smart meters should and could address. In the second phase harmonised standards for such functionalities (in fact, innovations) are now being developed. In so doing, a stream of standards enabling or facilitating all kinds of innovations are programmed and new applications and interfaces are discovered. The links with a later Commission mandate M/490 of 2011 on smart grids infuse yet another element of dynamism since smart grids require a wave of innovative standards based on the SGAM (smart grid architecture model, designed by Siemens at first) for many years to come.

In the 2011 report a first list of existing standards and 37 suggested new standards ideas is reported. By the end of 2012, in a second report, 56 standards have been defined or are up for voting. The coordination group is expected to stay active until 2020 for new applications and links with smart grids in particular.

The End-of-life Vehicles Directive[37]

The End-of-Life vehicles directive 2000/53, and subsequent (comitology) regulations (e.g. in 2003) and Decisions on regular updates of technical Annex II (last in 2013) aim at reduction of waste arising from end-of-life vehicles (ELV) for cars and light commercial vehicles. The six targets more specifically should (i) constrain or prevent the use of heavy metals (forbidden are cadmium, lead, mercury and hexavalent chromium), (ii) ensure the collection of vehicles at suitable treatment facilities, (iii) ensure 'de-pollution' (i.e. not in waste/landfills) of fluids and specific components, (iv) ensure coding and/or information on parts and components, (v) ensure information for consumers and treatment organisations, and (vi) achieve reuse, recycling and recovery performance targets.

There are four stakeholders: the producer, the recycling industry, the last holder and the authorities (mainly, the Member States); however, the leading principle involved is EPR, extended producer responsibility. ELV is product related waste regulation and therefore subordinate to general EU waste regulation. Although the ELV directive sets minimum requirements and Member States can go further, the EU approach has become more stringent over time, thereby gradually limiting the discretion of Member States. This is coherent with the design stage of cars which is of course oriented to the entire European market, if not the world market. An ELV can no longer be part of the second-hand car market for technical or economic reasons, but it may still have economic value for the parts/components collectors, recyclers and/or shredders (of the car hulk). This implies that 'regulation' may take the form of a voluntary agreement, if enforceable, possibly between different industries as they might have conflicting interests and these have to be internalised, or a compulsory rule. However, to a considerable degree, ELVs can be dealt with by markets themselves, if subject to strict environmental rules for dismantling, recycling and waste disposal (in the US there is no ELV regulation but the EPA maintains strict monitoring of the environmental aspects), because of the value in ELVs. The EU has clearly opted for targets going (gradually) beyond what a market-based approach might be expected to achieve.

To have a rough idea of the ELV process, cars (in terms of weight) are made for some 75 % or so from ferrous and non-ferrous (esp. aluminium) metals and 25 % from materials such as tires, fluids, plastics and other materials. Annex 1 of the ELV directive obliges treatment facilities to go first for 'de-pollution': to drain the ELV from all fluids and to remove components which are marked as hazardous (like mercury; explosive ones such as seatbelt tensioners or airbags). Subsequently, removal is mandated of e.g. catalytic converters, tires, glass, metals like copper, aluminium, magnesium and large plastics. The quantitative targets are: reuse and recycling of 80 % of the car weight in 2006, up to 85 % by 2015; reuse and recovery at least 85 % on 2006 and 95 % in 2015. In 2011 the number of ELVs in the EU was probably 7.8 million, of the 14 million deregistered cars. The remainder is either exported legally or illegally to third countries or simply kept in private garages for a while.

ELV has had and still has a significant impact on innovation in the car and car-related industries. Already in 2000 Zoboli, Barbiroli & Leone list the following ten innovative developments*:* (i) creation of special technical competences in car manufacturing companies*;* (ii) creation of dismantling and recovery/recycling networks (contracted by car companies) with incremental innovation*;* (iii) advances in design for dismantling*;* (iv) advances in design for recycling*;* (v) adoption of life-cycle strategies*;* (vi) material regime simplification in cars*;* (vii) material competition and substitution*;* (viii) advances in automotive plastic recycling*;* (ix) research and development in innovative recovery technologies for ASR [= automobile shredding

[37] This case is based on Zoboli *et al.* (2000); European Parliament (2010); and Sakai *et al.* (2014).

residue], the most problematic element in ELV techniques*;* (x) cooperative research at the industrial level. This list shows that innovation takes place at the very beginning of the life cycle of cars, namely at the design & planning stage, followed by manufacturing as a result, and at the very end of the cycle, ELV treatment. These processes – both company-specific and systemic (helped by knowledge externalities inside and outside industrial networks) - are characterised by gradual achievements, uncertainty in various degrees and learning form experience. Three innovation paths may be distinguished: the 'material creation path' (e.g. for plastics), the 'energy market creation' path, especially. For energy recovery of ASR, and the 'radical substitution' path (reducing composite and advanced materials when not suitable for recycling). In Europe and Asia, regulation or even the threat of it is strongly shaping the whole innovation process. The end targets, especially the EU second stage, are probably going to be met by many Member States in 2015 and this is undoubtedly a major accomplishment. Nevertheless, the regulatory and incentive complexities are too detailed to be analysed for a short case like this, but two examples can be given. One is the principle of 'free take back' for last owners to producers, but one should not forget that many ELVs still have value*;* hence, there may be opportunity costs for last owners and they may seek other solutions. Another consists of the standard on car recyclability based on car weight: the same rate of recyclability can be achieved with different mixes, design and car conceptions.

The greatest difficulty is presented by targeting a higher recycling rate for ASR (which otherwise ends up in landfills). Japan has recently reduced the share that can go to landfills to 1 % - 2 %, lower than the EU at the moment. This requires still more advanced techniques to recover materials from the ASR and to make progress with 'detoxification' of ASRs; also, more exhaustive dismantling (which might be costly) would decrease the recycling costs of ASR. Two ASR problems having received recent attention are the increased computerisation of cars and the increased use of plastics. On the other hand, ASRs also contain rare earth compounds like dysprosium, as well as materials the price of which is expected to go up strongly before 2030 (copper, palladium), which amounts to a powerful incentive to develop new technologies. Moreover, electric vehicles should not have permanent magnets, ideally.

Altogether, ELV regulatory regimes are a powerful stimulant of innovation, beyond what market incentives combined with environmental rules, may achieve. Innovation has taken place and is still vigorously undertaken both at the very beginning of the life cycle of a car and at the very end of ELV treatment, and these processes also influence one another directly and via regulatory specifications.

How EU chemicals regulation hinders innovation[38]

One of the objectives of the REACH regulation 1907/2006 was to promote innovation in the EU chemical industry, a world leader in fine chemicals. Unlike bulk chemicals, competitiveness in fine chemicals depends on strong and sustained innovation capacity throughout the chemical value chain, especially for 'integrators' and 'formulators' but also for entirely new chemical substances by (usually) the large chemical companies upstream. REACH has been introduced for several reasons related to better risk management, but equally because the post-1981 regulatory environment of chemicals generated an anti-innovation bias. One among several reasons for this bias consisted of the burden of proof which was assigned to Member States' authorities when assessing a new chemical substance and allowing it on the market, whereas 30 000 existing chemical substances (registered in or before 1981) were allowed on the market without testing (subject to exceptions for known

[38] This case is based on the following sources: Eurostat (2012); CSES (2012); European Commission (2013); Pelkmans *et al.* (2013); and RPA (2012).

hazardous substances, and safeguards). The burden of proof of no harm to safety and health (and increasingly, the environment) was costly to governments, and this put a severe brake on the market introduction of new chemicals. In the longer run, this posed a threat of undermining the incentive to innovate as the basis for competitiveness.

However, on first sight, the design of REACH does not seem a priori to be pro-innovation. Essentially, this is due to two features. One is the imposition of fairly heavy testing requirements for all existing and new substances alike. While this removes the discrimination against new substances from before REACH, it brings with it an enormous burden for existing substances, irrespective of risk, a cost to be entirely borne by producers. Many existing chemicals are known for decades and no negative effects are known for workers and consumers. In other cases, such effects are well known and the value-added of new testing is often doubtful. It would have been rational, and in keeping with 'better regulation' principles, if testing requirements had been risk-based. One way to do this is making a ranking of groups of substances with decreasing degrees of risks, as known from the literature, testing or experience over a long period. In such an approach, the very high risk group would pose no problem precisely because it is well-known and is often already restricted in use or even banned. A large group with no reported risks over a long period would also pose no problem. As this group would easily comprise more than half of all substances, if not close to 80 %, dependent on how risk averse the classification would be, one could have continued to allow these on the market, with a monitoring obligation. Direct testing costs and the indirect costs of substitution of risky substances by other ones – possibly new ones -, including costs of reducing competitiveness purely on the quality of intermediate goods often consisting of 30 – 60 substances with subtle quality properties for a purpose (like specialty paints), would only fall on the relatively limited groups of substances where there is uncertainty about risks.

The other feature of REACH, caused by its ambitious precautionary approach of 'no data, no market' (access), is that this entire process of testing before being allowed on the market, takes no less than 11 years. Most laboratory capacity in Europe is bound to be occupied by the massive testing required, which reduces the capacity to test really new substances arising from innovation, but also risks anti-competitive behaviour (tacit collusion by keeping prices uniformly high). In companies, and in particular SMEs as formulators /integrators and for numerous firms further downstream as users of substances or intermediate products in almost any goods sector, all this leads to higher costs and lingering uncertainty for a long period (from 2008 through 2018). REACH obligations to communicate intensely over the value-chain render this quite demanding.

By 2014 several interim reports of REACH are available and they confirm these fears. The Commission REACH review of 2013, based on extensive field work by CSES, found that some 40 % of chemical companies shifted their R & D towards health, safety and environmental protection which they would not have done otherwise; some 5 % of firms undertook a fundamental re-appraisal of their R & D investment. Compliance costs have caused a serious and sustained diversion of resources away from innovation, for verification of literature, working in consortia [SIEFs], etc. In Pelkmans, Schrefler & Gubbels (2013) on SMEs under REACH, the diversion of R & D resources is reported to be strong and the uncertainty for 2018 (when substances of smaller output volumes, largely supplied by some 27 000 SMEs as intermediate chemical goods producers, are up for submission to ECHA, the chemical Agency) is great. The incentive structure under REACH is adverse for companies, since the costs of testing, finding substitutes as well as value-chain compliance costs are all upfront for many years, whereas the societal benefits are (a) most uncertain (see also RPA, 2012 and Eurostat, 2012) and (b) at best expected years after 2018 or much later still. There is also the risk of losing competitiveness vis-à-vis competitors in the rest of the world, except if, and to the extent that, 3rd countries would adopt a REACH-like approach (which is only weakly the case for Korea, possibly China partially).

EU biotech regulation as a penalty on innovation[39]

Two of the core principles of 'better regulation' are that regulation should be science and evidence based, and that risks – not hazard properties – of a substance or good should be the focus of health, safety and environmental benefits for society. Risks combine hazards with exposure, whereas hazards only say little or nothing about risk in numerous cases. Hazard-based approaches therefore lead to overregulation, possibly heavily so. In turn, risks should be established by globally respected rigorous science and evidence based risk assessment methods. Any other method or, worse, political conjectures or consumer aversion/preferences, are arbitrary and can imply major restrictions for innovative products or even for innovation as such in specific submarkets. Since 'better regulation' principles are increasingly accepted as rational and least-cost in the EU by all stakeholders, those advancing political conjectures or echo consumer aversion have embraced the 'precautionary principle' as the respectable route to restrict or prohibit new products or initiatives, even when little or no hard scientific evidence is available.

This is the predicament of two submarkets of biotechnology in Europe, namely for GMOs and for crop-protection. Also in the case of growth hormones for cows, profound consumer aversion was the single reason for a ban in 1986, not a risk assessment, later imposed by the WTO (an assessment which could only find weak and inconclusive evidence in one of six hormones at stake). Whereas in the case of growth hormones, one can question whether there really are societal benefits (even if risks are spurious or absent), this is certainly not the case for GMOs. Worldwide, many millions of farmers have greater certainty and less poverty due to GMOs protecting their harvests better. This is certainly true in large quantities for developing countries' farmers growing cotton (80 %) and soy-beans (70 %). It is essential that more food be produced sustainably worldwide, with less land, less water available and fewer fertilisers. In EU regulation as well as in debates in the two bodies co-legislating the rules, these formidable benefits seem to play no role. The upshot in the EU is that only two new GMO products have been allowed to be cultivated: NK603 GM maize and the Amflora potato. In both instances, endless political struggles, rather than the consistently positive risk assessment from the EU Food Agency EFSA, determined the fate of these products, causing many years of delays and uncertainty. In 2012, after having waited for more than 13 years, BASF gave up on Amflora and migrated that activity to the US. The maize is practically only cultivated in Spain, no other EU country accepts it or NGOs discredit the cultivation or the company. As a result, the EU has hardly been able to innovate in this area, a growth sector in the rest of the world. As Cantley & Lex (2011) note correctly: "When investments…. are made or withheld, these choices are not easily reversed. Especially in the EU we have seen a hysteresis effect – past errors leave scars and laws which constrain future choices". In the EU, GMO regulation and selective crop protection rules have blocked innovation for many years and undermined competitiveness by restricting choices severely. From a regulatory point of view, the restrictiveness of GMO regulation brings no benefit to European society whilst damaging the biotech industry, even though there is no scientific empirical evidence of any risk. The state of denial is so bad in the EU that no less than 23 national academies of science in the EU felt compelled to write a report (Planting the future) in June 2013, stressing that there is nothing in the scholarly literature giving a reason to suspect societal risks for GMOs so far allowed in non-EU

[39] This case is based on the following sources: European Academies Science Advisory Council (2013); European Commission (2009); Cantley and Lex (2011); Alemanno (2013).

OECD countries. This report was written after more than 25 years of intensive research all over the world and after many years of consumption of food, including GMO based ingredients, by billions of persons in most countries of the world.

The EU biotech industry is not dead, far from it, it is doing well by avoiding specialising in GMO or selected other crop-protection products. But even that is not without dangers. Recently, a very controversial decision to temporarily ban a (much used) neonicotinoids pesticide because of a suspected connection to the decline of Europe's bee population – again, under the precautionary principle – although several other reasons are at least as likely to have caused this decline, show that science-based risk assessment is by-passed, with damaging results for a relatively new and successful product, and with unknown discouragement effects for the industry.