CEPS SPECIAL REPORT
Thinking ahead for Europe

Does EU regulation hinder or stimulate innovation?

Jacques Pelkmans and Andrea Renda

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Abstract

'Does EU regulation hinder or stimulate innovation' is a frequently heard query in the EU, but there is little systematic analytical literature on the issue. Fragmented evidence or anecdotes dominate debates among EU regulatory decision-makers and in European business, insofar as there is a genuine debate at all. This CEPS Special Report 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 tend to 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 are complemented by seven case studies of EU regulation enabling and disabling innovation, two horizontal and five sectoral ones. The case studies are preceded by a broader contextual analysis of trends in EU regulation over the last three decades. These trends show the significant transformation of the nature as well as improvement of the quality of EU regulation, largely in the deepened internal market, which tend to have a favourable and lasting effect on the rate of innovation in the EU (other things being equal).

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 incorporating 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*.

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Introduction

As recalled on several occasions by the European Commission and other EU institutions, the EU's innovation performance has been (on average) rather sluggish over the past two decades.[1] The European Commissioner for research and innovation, 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] For at least two decades, the EU has been searching for better and new ways to improve and intensify innovation. It is remarkable that the most important day-to-day activity of the EU – regulation in the framework of the internal market and in common policies – and its effects on innovation have hardly been addressed in a systematic manner. The present CEPS Special Report attempts to begin to fill this major deficit. We ask the question whether EU regulation hinders or stimulates innovation in the EU. Of course, the ultimate purpose of the analysis is to help EU policy-makers, legislators and stakeholders to design EU regulation in such a way as to stimulate and not hinder innovation.

There is some awareness of the regulation and innovation issue, more often than not in the form of anecdotes or complaints from business. 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".[3] 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

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

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 '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.

1. 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.

1.1 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 an 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.

1.2 Regulation: Definition and main features

As explained in the previous section, regulation is one of the activities that governments can engage in and 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 the need to complete the Internal Market or to achieve Europe 2020 goals.

We distinguish between:[4]

- The **Agenda-Setting** phase of regulation: during this phase, the main preparatory documents (at EU level, Green Paper, White Paper, Communications) are prepared and adopted. This can include 'umbrella' regulations, e.g. framework regulations that are binding but 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 organisations 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.

[4] We rely on a simple conceptualisation 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).

1.2.1 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 organised groups establish themselves voluntarily to regulate and organise 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.[5]
- **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 organizations, or associations)".[6] 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.
- **Standardisation**. Another approach that can serve as an alternative to legislation, or partially replace detailed regulation, is the reference to European Standards. This, at the EU level, requires the involvement of the European Standards Organisations 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

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

[6] See the Interinstitutional Agreement on Better Lawmaking, Art. 18.

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.

1.3 Regulation and innovation: Mapping interactions

A review of the scholarly literature on the relationship between innovation and regulation 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.[7] Recent contributions (Stewart, 2010, Carlin and Soskice, 2006) differentiate clearly between the **incentive impact** and the **compliance cost** of regulations. Stewart also summarises 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.

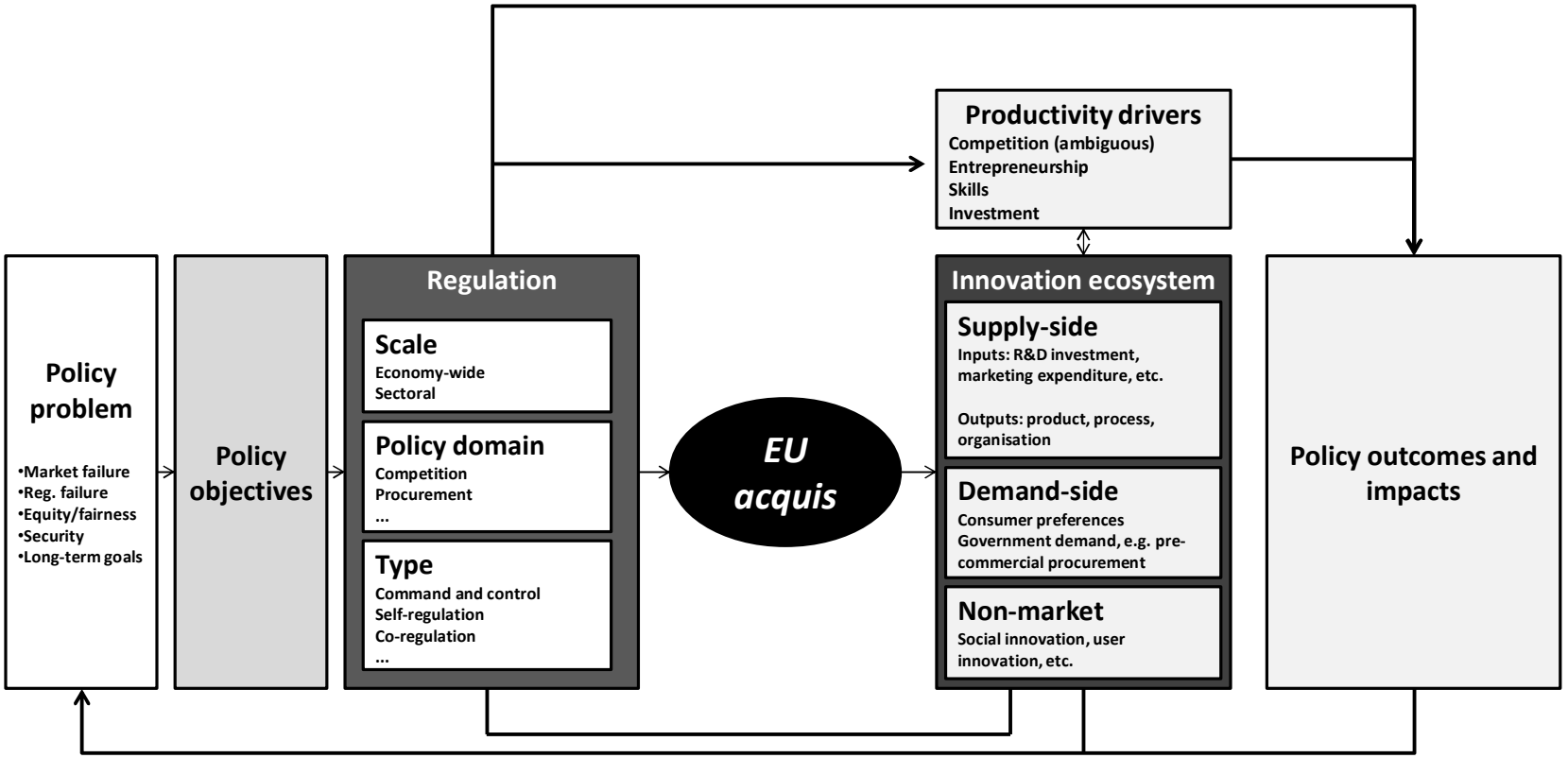
Another important factor is **uncertainty** on the content and scope of future (upcoming) policies. Policy uncertainty reportedly has a mixed effect on innovation, although often it will precipitate the effects of the innovation dimensions of the regulation itself, regardless of whether the regulation 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. 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 for 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).

[7] Ashford (2000).

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



Source: Authors' elaboration on BERR (2008).

1.3.1 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, standardisation, 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 **commercialisation** 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 authorisations, licenses, etc.

1.4 Key questions

1.4.1 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 recognised 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.

1.4.2 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 commercialisation. 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.

1.4.3 What categories of regulation can be distinguished according to its 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.

1.4.4 To what extent do 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 commercialisation, 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 of 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 of innovation, but only provided that the timing and stringency of the rules at hand are conducive to innovation incentives.

2. 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 commercialisation.
- ***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, while 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).[8]

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

- Rules 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.

2.1 Major enabling/constraining aspects of regulation

2.1.1 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, which 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 of the existing administrative burdens and drain of resources are embedded in required systems that guard against food-related diseases and maintain food quality.

Governments have attached growing importance to administrative burden reduction programmes in recent years. The Netherlands is a pioneer 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 analysed 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 important is singling out those pieces of legislation that are considered to hamper entrepreneurship most significantly, without creating substantial social benefits, and possibly designing 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 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.

2.1.2 *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 excessive 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, "Phase II", mandatory as of 1 January 2010, elicited an early reaction by 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.[9]

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.

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

[9] 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.

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.

2.1.3 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 crystallise 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 standardisation: the message is that standardisation should not occur too early, and also not too late, for stimulating and encouraging 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 in 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.

2.1.4 Flexibility

As already recalled, flexible, performance- or outcome-based regulation stimulates innovation more than purely prescriptive regulation does. 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 standardisation in the EU is a clear example of outcome-based standardisation, which can help innovation (this is discussed in section 3.1). Standards based on functional or performance-based technical specifications, rather than on purely prescriptive specifications, offer more room for innovative bidders to propose new products. 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.

2.1.5 Uncertainty

Like most of the other variables discussed in this section, uncertainty can act as a driver and 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."[10]

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

[10] Ashford et al. (1985: 426).

2.2 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 the freedom of 'innovators' 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 those of 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.

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 of 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).

Swann (2010) provided a comprehensive update of the state of the art in the economics of standardisation, reporting, on the basis of a detailed literature review, that several detailed econometric studies carried out for the UK, Germany, France, Canada and Australia established a clear connection at a macroeconomic level between standardisation in the economy, productivity growth and overall economic growth. Crucially, while it is commonly

believed that standards obstruct innovation, the evidence suggests a rather different story. Surveys of innovating firms find that standards are a source of information that helps their innovation activities. Moreover, while many say that regulations 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 contribute to: i) the exploitation of economies of scale; ii) the effective division of labour; iii) the building of competencies; iv) reducing barriers to entry; v) building network effects; vi) reducing transaction costs; and vii) increasing 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.

3. EU regulation and innovation: Trends and case studies

3.1 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 the 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), and a means for making 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 concerning 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).

3.2 Why regulation has become the EU's 'core business'

The 'hard core' of what the EU does is summed up in the term "internal market". It includes many 'common' policies employing EU regulation. Some such EU regulation is horizontal, but most of the regulatory *acquis* is sectoral. Based on the foundation of the 'four free movements' (goods, services, capital, labour)[11] and the right of establishment, which in and of 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) that would render the 'proper functioning'

[11] 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) that 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.

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, the EU's 'core business' is essentially the making, improving or removing 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 1,500 directives and nearly 2,000 EU regulations, many of them highly complicated.[12]

As the Monti report (Monti, 2010) reminded us, no fewer than 15 DGs of the Commission work routinely on internal market rules. Many of these directives and regulations have a sectoral slant and frequently these are likely to have a direct impact on incentives to engage in innovative activities and 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 standardisation bodies via mandates or other means. Some 3,000 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 be aware of rules on (national and regional) public procurement and EU rules on competition in the broad sense.[13]

3.3 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 of 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 and regulatory impact assessments. Where regulation interferes with market mechanisms 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 effectively and swiftly nip in the bud anti-competitive conduct against new entrants. This was accompanied by a gradual but consistent move to privatise numerous companies.

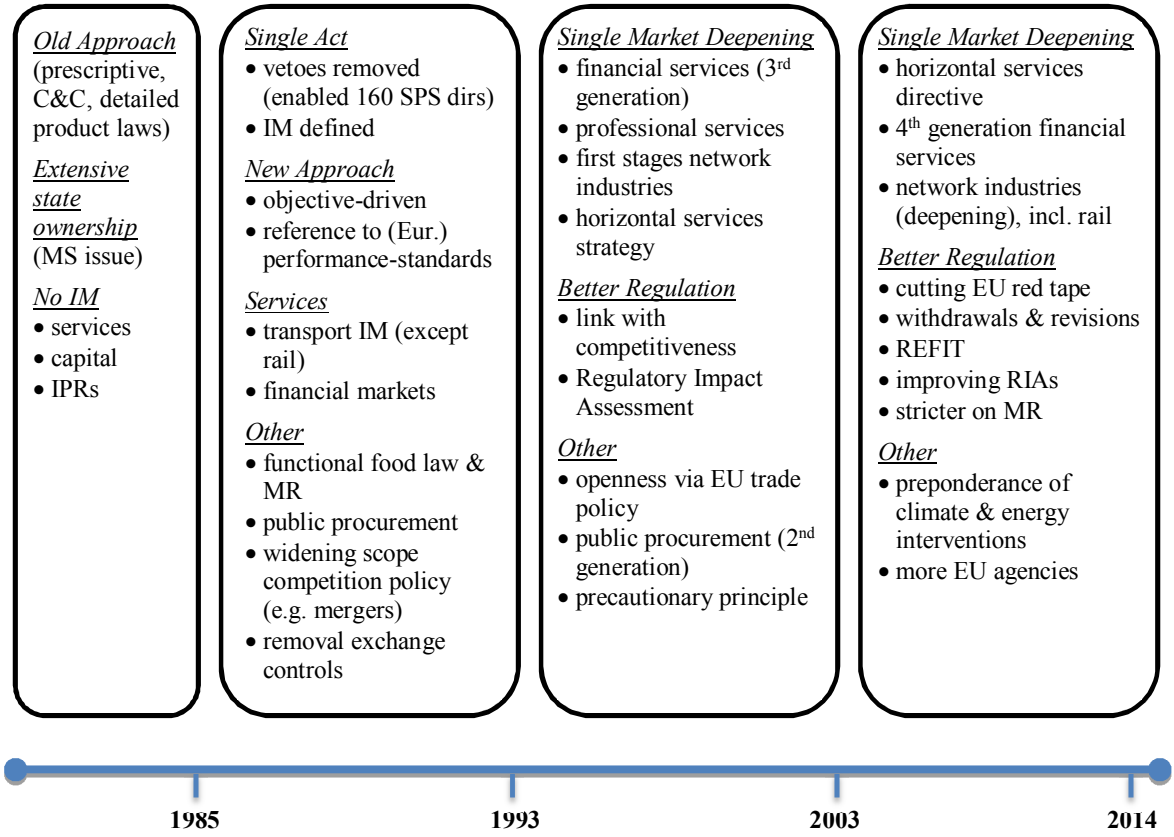
Figure 2 below summarises the trend in EU regulation over four periods since the early 1980s: the days before the Single European Act of 1985 with still many rigidities and countless obstacles in the internal market; between 1985 and 1993 when the famous EC1992 programme was successfully pursued; between 1993 and 2003 when competitiveness became increasingly linked to EU regulation, leading among other things to EU regulatory impact assessment; and from 2004 until today, with "Better Regulation" and impact assessment dominating most EU regulation. After 1993, the deepening of the internal market continued, even in areas formerly considered too sensitive, e.g. many services and network industries. It is not an exaggeration to say that these trends have radically transformed the EU regulatory landscape, which now features far more market-friendly, better conceived and better justified EU regulation, whilst

[12] Not counting many decisions (to specific addressees) and recommendations.

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

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 favourably relative to the innovation climate in the EU. But as we shall see in subsection 3.5 on sectoral cases, there are exceptions to this favourability, typically related to the (too loose) application of the precautionary principle: these tend to hinder or cripple innovation more often than not.

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 gradually moved from a rather political approach to harmonising the national regulations at member state 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 has favoured innovation, while resulting in 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 the 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. The same spirit has often been generated in the European Parliament since it obtained near-complete co-legislative powers (between the Single Act and Lisbon, in steps).
- Third, the thinking about 'good' EU market regulation received a major boost with mutual recognition and the "New Approach" initiated in 1985.[14] The central idea underlying the New Approach, inspired by the mutual recognition doctrine of the Court of European Justice (CJEU), is that, when risks are not too serious, EU regulation can be 'light' – that is, consist of a mere agreement on objectives (concerning, say, health, safety, etc.), plus some procedural issues – and the technical specifications detailed in European standards. This can be done only 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 rethink in other areas of EU regulation, first in goods and later in services. 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 has been controlled by a semi-independent Impact Assessment Board since 2007 and this has had a healthy effect.[15]

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 with minimal (or no) specification of how these targets ought to be met (hence,

[14] 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 and 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.

[15] See Fristch et al. (2013).

allowing innovative approaches based on entrepreneurial choices) or by establishing cap-and-trade systems, e.g. for CO_2, with similar entrepreneurial discretion.

3.4 Horizontal legislation: case studies

3.4.1 Case study: Refusal to deal in competition law and e-communications regulation

A good example of a general rule that can affect the overall incentive 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 CJEU 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 in recent years. In addition, in the European Commission's April 2004 decision against Microsoft, the "exceptional and cumulative set of circumstances" test was partly rejected by the Commission, but it 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.

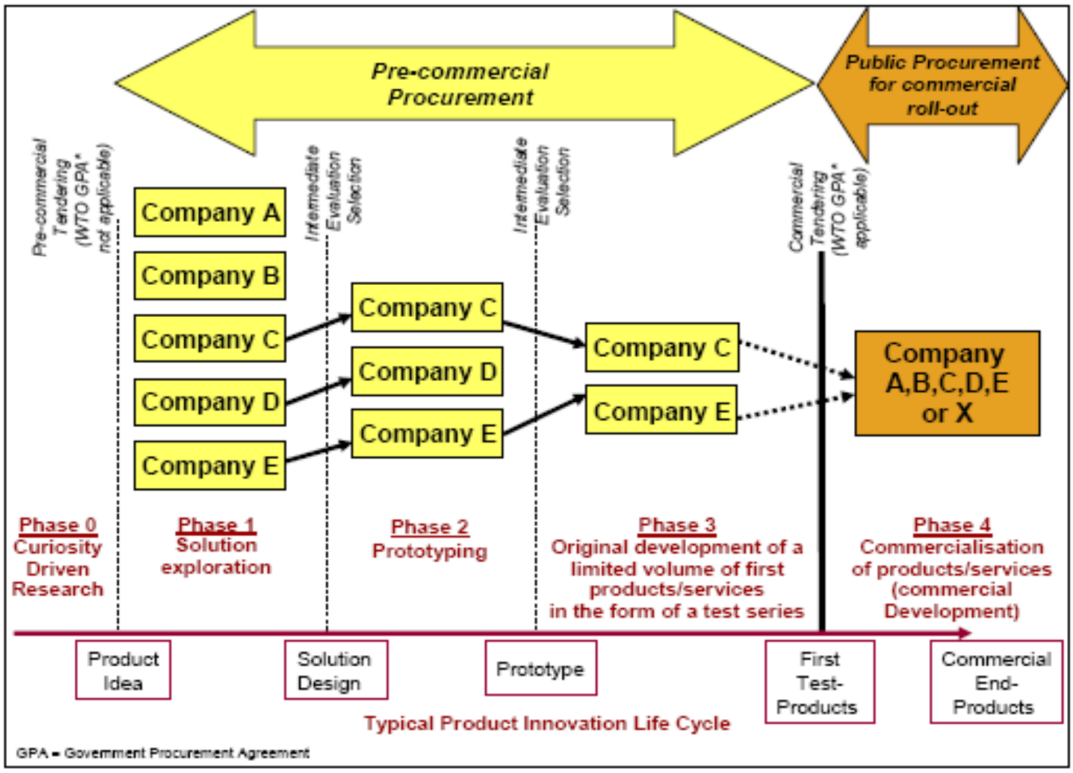
What remains to be fully ascertained is whether a rather rigid application of the rule in both antitrust and ex ante regulation could lead to a weakening of incentives to innovate. In principle, first inventors should be discouraged by a rule that allows competitors to access the winning rival's own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

3.4.2 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 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 acknowledged 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.
- Public procurers' lack of knowledge of 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 potential 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 LMI's long-term goals are: to remove obstacles preventing European enterprises from entering new and quickly growing global markets; to facilitate faster uptake of new products, services and technologies; and to bridge the gap between the generation of new products, services and technologies and the success of those innovations on the market.

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 application. 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 EU-28 in order to produce even greater impacts.

It is also of interest that the new public procurement Directive 2014/24 comprises several improvements with a view to fostering innovative solutions. Thus there are now more possibilities for additional flexibility in choosing a procurement procedure that provides for negotiations, which is 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.

3.5 Sectoral regulation: Case studies

3.5.1 Case study: Energy efficiency regulation for equipment and cars and innovation[16]

An instructive example of the positive interaction between EU regulation and innovation 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 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 that reduce consumer expenses for energy.

However, since the early 1990s many OECD and other countries have added 'hard' energy targets by means of specific energy limits for many types of equipment[17] 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

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

[17] 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.

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 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 establishing a new classification of energy use per appliance underlying the colour labelling system).

The enormous success of energy efficiency regulation for appliances 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 and only relatively marginal improvement of energy performance. But this did not happen, quite the contrary: "…all products examined have experienced a decline in real prices between 10% to 45%, while energy efficiency increased by 10% to 60%…"[18] These gains have been accomplished without a decline in service. Only top products fell in price very slightly, but that turned out to be caused by other, e.g. luxury or 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 was 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 many 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 outdoor construction or gardening equipment from generating too much noise, noise limits were regulated in Directive 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 product's lifetime (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 and hurting competitiveness in export markets. The EU has never dared to push

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

for lower noise targets and find out through practical experience whether such hard requirements would induce more radical innovation.

3.5.2 Case study: Innovation via European standards. GSM and smart meters[19]

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 presented. One is the European 2G digital mobile telephony standard GSM, the other is about 'smart meters'. The rationale for presenting these two 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 replicate in 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, one should not merely concentrate on the technical standardisation itself, even though this was impressive. It is the 'standard adoption strategy' that 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 enacted directives on frequencies, on competition in telecoms terminals (such as handsets) and on mutual recognition of conformity of telecoms terminals, in addition to a recommendation and, later, a Commission mandate for ETSI to take over the technical standard 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 3G, 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 first movers 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 (around) 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 simultaneously

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

with telecoms liberalisation in the EU, 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. 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 if scale and cost reduction are 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 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 standard ideas was reported. By the end of 2012, in a second report, 56 standards were defined or ready for a vote. The coordination group is expected to stay active until 2020 for new applications and links with smart grids in particular.

3.5.3 Case study: The End-of-life Vehicles Directive[20]

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 (the last in 2013), aim to reduce 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, 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 industries as they might have conflicting interests and these have to be internalised, or of 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, for a typical car, some 75% of its weight consists of ferrous and non-ferrous (especially aluminium) metals and 25% of rubber, fluids, plastics and other materials. The quantitative targets are: the reuse and recycling of 80% of the car weight in 2006, up to 85% by 2015; reuse and recovery of at least 85% in 2006 and 95% in 2015. In 2011, of the 14 million deregistered cars in the EU, the number of ELVs was probably 7.8 million.

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

The remainder are either exported legally or illegally to third countries or simply kept in private garages.

The ELV Directive has had and still has a significant impact on innovation in the car and car-related industries. Already in 2000 Zoboli, Barbiroli and Leone listed 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 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 and 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 that of the EU. 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 (copper, palladium) whose price is expected to rise significantly before 2030, which amounts to a powerful incentive to develop new technologies. Moreover, electric vehicles, ideally, should not have permanent magnets.

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.

3.5.4 Case study: How EU chemicals regulation hinders innovation[21]

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 assigned to member state 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, at 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

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

requirements for all existing and new substances alike. While this removes the discrimination against new substances from before REACH's implementation, 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 by ranking groups of substances by degree of risk, as known from the literature, or by testing or according to experience over a long period. Direct testing costs and the indirect costs of substitution of risky substances by other – possibly new – ones would only pertain to the relatively limited groups of substances where there is uncertainty about risks.

The other feature of REACH, owing to 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.

In 2014 several interim reports of REACH are available and they confirm these fears. R&D expenditure has shifted away from planned projects and towards technical compliance activities; compliance costs for SMEs divert resources that cannot be spent on any R&D; extra costs reduce profits considerably in some cases; and much uncertainty throttles new product initiatives. The incentive structure under REACH is adverse for companies, since the costs of testing, finding substitutes and value-chain compliance are all upfront for as many as 11 years, whereas the societal benefits are most uncertain and not expected to be realised until 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, third countries would adopt a REACH-like approach (which is only slightly the case for Korea and possibly partially for China).

3.5.5 Case study: EU biotech regulation as a penalty on innovation[22]

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 echoing consumer aversion have embraced the 'precautionary principle' as the respectable route to restricting or prohibiting 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 genetically modified organisms (GMOs) and for crop protection. GMOs have significant and proven societal benefits. Worldwide, many millions of farmers experience greater certainty and less poverty due to GMOs' capacity to protect their harvests. This is certainly true in large quantities for developing countries' farmers growing cotton (80%) and soybeans (70%). Given the reality of reduced land, water and fertiliser resources, it is essential that more food be produced sustainably worldwide. 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

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

Amflora and transferred that activity to the US. The maize is cultivated practically only in Spain; no other EU country accepts it and NGOs discredit the cultivation or the company behind it. 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 fewer 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 to justify suspicions that GMOs thus far allowed in non-EU OECD countries are a risk to society.

The EU biotech industry is not dead, far from it; it is doing well to avoid specialisation in GMO or 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 was bypassed, damaging the prospects for a relatively new and successful product, and perhaps discouraging the industry from pursuing others.

4. Conclusions and policy recommendations

This short paper has shown that the interaction between regulation and innovation is complex, multifaceted, 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 of innovation and entrepreneurship, but at times regulation can and does disable innovation**. 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 commercialisation.
- **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 commercialisation, 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* demonstrates both 'positive' and 'negative' examples**. Our case studies span from the early adoption of standards that largely stimulated innovation, e.g. the GSM, to cases of overly excessive regulatory burdens, e.g. chemicals. This suggests that, in the revision of the *acquis* in various sectors (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 (now under consultation) will be a valuable opportunity to strengthen the analysis of the balance between innovation-enhancing and innovation-constraining effects of the various alternative policy options scrutinised 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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- Maintain the highest standards of academic excellence and unqualified independence
- Act as a forum for discussion among all stakeholders in the European policy process, and
- Provide a regular flow of authoritative publications offering policy analysis and recommendations,

Assets

- Multidisciplinary, multinational & multicultural research team of knowledgeable analysts,
- Participation in several research networks, comprising other highly reputable research institutes from throughout Europe, to complement and consolidate CEPS' research expertise and to extend its outreach,
- An extensive membership base of some 132 Corporate Members and 118 Institutional Members, which provide expertise and practical experience and act as a sounding board for the feasibility of CEPS policy proposals.

Programme Structure

In-house Research Programmes

Economic and Social Welfare Policies
Financial Institutions and Markets
Energy and Climate Change
EU Foreign, Security and Neighbourhood Policy
Justice and Home Affairs
Politics and Institutions
Regulatory Affairs
Agricultural and Rural Policy

Independent Research Institutes managed by CEPS

European Capital Markets Institute (ECMI)
European Credit Research Institute (ECRI)

Research Networks organised by CEPS

European Climate Platform (ECP)
European Network for Better Regulation (ENBR)
European Network of Economic Policy Research Institutes (ENEPRI)
European Policy Institutes Network (EPIN)