European Commission

Assessing the Impacts of EU Regulatory Barriers on Innovation

Final Report

Research and Innovation

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E-mail RTD-A5-SUPPORT@ec.europa.eu
RTD-PUBLICATIONS@ec.europa.eu

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EUROPEAN COMMISSION

Assessing the Impacts of EU Regulatory Barriers on Innovation

Final report

Viola Peter, Julien Ravet, Laura Roman, Christien Enzing (Technopolis Group)
Maike Venjakob, Thomas Adisorn, Claus Seibt (Wuppertal Institute)
Mariana Dates (Optimity Advisors)

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Abstract

This report summarises the results of the study 'Assessing the impacts of EU regulatory barriers on innovation'. To obtain the necessary data, a European-wide survey was conducted in 2016. This study focused on four sectors: energy, food, health and water. Each of these four sectors addressed the innovation system and regulatory framework, alongside questions on challenges, innovation drivers and barriers. While regulatory barriers to innovation were identified for the whole economy as well as within the four sectoral studies, the overall impact of regulation on innovation is predominantly neutral to positive. The main regulatory barrier identified concerns 'conflicting regulation' rather than a single type of regulation. The study also found that compliance with regulation creates innovation, with a net gain of EUR 3-6 billion per year in additional innovation investments and in terms of employment a net gain of 120 000 additional jobs. Removing existing regulatory barriers could release up to EUR 4-8 billion on general innovation investment per year.

EXECUTIVE SUMMARY

Approach

The present study took account of the available descriptive and empirical literature and aimed to assess the economic effects of existing regulatory barriers and the potential effects when these are removed. The study was based on a combination of methods. First, a large survey of predominantly innovative companies in Europe, which enabled differentiation by industry, sector, country and company size, provided the basis for quantitative measures of the impact of regulation on innovation in terms of both R&D investments and jobs in innovation. Second, a thematic focus on four industries/sectors was required, namely energy, food, health and water. Case studies were established for these four sectors, and included identification of the relevant sectoral innovation system with its main actors, governance and regulation. The case studies were based on literature, desk research, data analysis and interviews. The above-mentioned survey also provided specific insights for these four sectors.

Economic analysis and results

The quantification of economic impacts was based on direct evidence collected via the survey. Complete responses were collected from just over 1300 stakeholders.

The main results of the study are as follows:

As regards the innovation profile of the **respondents**, 38 % have introduced product or process innovations in the last three years, while 78 % have introduced marketing or organisation innovations; 29 % have introduced both types of innovations while 13 % did not introduce any innovation during this period.

Varying perception of regulation

Through a principal component analysis (PCA), patterns of responses by country, sector and type of regulation were identified. Clear patterns can be summarised as follows:

- Regulatory factors act as **drivers** in Italy and Romania. In terms of sectors, the motor vehicles, furniture, jewellery, musical instruments, toys, repair and installation of machinery and equipment, water public administration, and administrative and support service activities also perceive regulation as a driver. In addition, respondents with marketing and organisational activities (only) are more likely to see regulation as a driver.
- A **neutral** effect tends to be asserted by respondents from the Czech Republic, Denmark, Finland, Germany, the Netherlands and the UK. In terms of sectors, the industries manufacturing computer, electronic and optical products mainly stated neutral effects.
- Results are rather polarised when it comes to two types of regulatory **barriers**, namely regulatory factors linked to market-related regulation and competition (competition law, procurement rules, and existence of private or public monopolies on the market), and other 'non-market' factors. Manufacturers of pharmaceuticals, chemicals, food and metal, as well as in the health and construction sectors associate barriers with product safety regulation, environmental protection and labelling. Water, the primary sector of consultancy services, and the chemical sector all perceive dedicated sectoral policies or sector-specific barriers.
- Those respondents considering market and competition regulation as hindering competition are most often found in public administration, management consultancy activities, information and communication, the primary sectors as well as transportation and storage. Respondents from Portugal and public institutions also associate with this type of barriers.

Economic benefits due to regulation

In terms of net economic effects, impacts on innovation investments and on jobs were calculated. Overall, most respondents were neutral about such impacts (43 %-47 %). However, when analysing the responses which mentioned either positive or negative impacts, there is clearly a **positive net impact from regulation** both in terms of innovation investments and employment. The net gain in regulation corresponds to approximately 1.8 % of additional EU innovation investments per year. In terms of employment, the total impact is close to 0.3 % of additional jobs. This corresponds **annually to EUR 3-6 billion of additional innovation investments** while the net gain in terms of employment amounts to **120 000 additional jobs** by innovative companies in Europe. When differentiating by size, large companies tend to report a lower gain than SMEs[1].

Respondents from Eastern and Baltic countries consistently report a positive economic impact from regulation compared to other countries. The analysis also indicated that size is correlated with a larger non-neutral impact: larger firms more consistently report either positive or negative impacts from regulation than SMEs.

Removing existing barriers: release of additional investments

However, regulation also hampers investments in innovation and jobs. Removing the barriers could release 2 %-4 % of innovation investments which equates to EUR 7-14 billion in general innovation investments until 2020. In addition, in terms of employment in innovation, an additional 2%-4% jobs could be created.

While the above summarises the overall effects, sector-specific differences were identified, as indicated below.

Table 1: Barriers, drivers or neutral; innovation impacts of regulations on selected and all sectors (1)

Regulatory factors	Energy	Food	Health	Water	All sectors
Competition law (incl. state aid rules)					
Conflicting requirements of different regulations					
Dedicated sectoral policies					
Environmental protection regulation					
Existence of private dominant positions in the sector					
Existence of state/semi-state dominant positions in sect					
Labelling					
Procurement rules					
Product safety regulation					
Standardisation					
Trade agreements					
Other factors					

Source: Technopolis Group
(1): Dark green: drive ; yellow: neutral; red: barrier. Orange: the responses were divided between neutral and barrier. Light green: the responses were divided between neutral and driver

Overall, a more positive, driving effect on innovation was attributed to environmental protection regulation, standardisation, and product safety regulation. A barrier to innovation was attributed to 'conflicting requirements of different legislation', although there are exceptions – respondents appear to be mainly neutral to labelling, competition law, trade agreements, procurement rules, or existing private and state/semi-state dominant positions in their sectors.

Lessons to be learnt

According to the survey responses, regulation has neutral effects for the majority of respondents. While barriers from regulation have been identified, its positive and driving role predominates.

[1] Definition of SME is based on number of employees being below 250 and maximum turnover of EUR 50 million per year (EU recommendation 2003/361). The balance sheet criterion of maximum EUR 43 million was not taken into account as this information was not collected in the survey.

Specific regulations can hamper innovation but they tend to hamper individual sectors. As Table 1 indicates, specific types of regulation have different impacts depending on the sector. Thus, in order to understand and address barriers, a sectoral analysis of the existing regulations is needed. This sectoral approach supports the European Commission's approach to test regulatory fitness of one or more relevant legislative acts and the single or cumulative impact on one or more industries (i.e. REFIT exercise).

One finding which is based on the qualitative part of the study strongly suggests that the impact of a regulation within a given sector can change over time. It depends, for example, if the industry is in a market-finding 'search' situation or is already in a saturated phase. While signals such as standards and labelling can be important drivers for the market-finding phase, they may be seen by newcomers as a burden in a later stage. Regulations are set as a stabilising factor in a very dynamic business world and appreciated for this function. Nevertheless, regulation can become outdated or irrelevant and thus become an unnecessary burden. This calls for flexibility clauses in the legislative design.

1. INTRODUCTION

1.1. Objective of the study

The main objectives of the study were to provide an economic analysis of the effects of EU regulatory barriers to innovation over the past 10 years, defined in terms of additional costs for innovations as a result of regulatory barriers, and lack of adequate response to the patterns of global demand. Missed investment opportunities in Europe and missed job opportunities were also to be covered. Furthermore, economic projections (until 2020, 2025 and 2030) were to be made in terms of additional investment, innovation potential, and job creation in Europe if regulatory barriers were to be removed in the following sectors: energy, food, health and water.

Thus, the study aimed to improve the understanding and economic evidence-base on the impacts of EU-level regulatory barriers on innovation.

1.1. Methodological approach

As a basis for the analysis, the study team designed a survey, aimed primarily at the private sector. At the same time, case studies on the four selected sectors were prepared through desk research, data analysis and interviews. The survey included generic questions which were addressed at industry as a whole. The main regulations identified for the selected sectors, as well as the barriers and drivers which were identified through the case study work, were integrated as sector-specific questions within the survey.

The four dedicated sectoral case studies provided a general scoping in terms of sector definition, identification of the main innovation actors, aspects of governance, the relevant EU-level regulation, innovation indicators, innovation leaders, and regulatory drivers and barriers. The case studies were then enriched with the findings and economic provisions based on the survey.

Since regulation does not only hamper but also fosters innovation to a large extent (see below), the survey addressed the issue neutrally by providing the respondents with the option to express what hampers and what fosters innovation. Details of the method and results are provided in a dedicated report, while the main results are summarised below in section 2 and in the annexes.

1.1. Key concepts

Measuring the impact of EU regulation barriers to innovation starts with an assumption, namely that regulation poses barriers. But is this really that clear? There is less literature about regulation and innovation than on regulation and costs. In fact, it may be better to start with a more neutral premise and to ask about the aims of regulation, in particular EU regulation.

The term regulation is used and defined in at least two senses. The OECD defines it as "*the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers*". (OECD 1997)

An overlap exists in the wording as regards the EU-level, which differentiates three types of formal and informal legal provisions, namely:

- **Legislative proposals**, such as regulations, directives and decisions;
- **Non-legislative initiatives**, which comprise a number of so-called 'soft' regulation such as 'recommendations', voluntary agreements (self-regulation or co-regulation), but also technical standards. It also includes all other instruments such as demand-side policies (taxes, subsidies, incentives, labelling schemes, etc.).
- **Implementing and delegated acts**; while implementation measures are set out in the form of implementing acts, delegated acts allow non-essential elements of the basic legislative act to be amended, supplemented or deleted. Since implementing acts are often technical measures, ultimately they have a significant impact on citizens and the private sector. They are used in a wide range of policy areas such as energy labelling or authorisation of certain types of food additives.

Regulation can also be understood in the sense of 'regulated markets' where specific regulations regulate competition, market entry or price, for example.

Regulations protect consumers, the environment, as well as employees and businesses. They are core institutions adding to the 'rules of the game' and thus provide stable, reliable conditions which are important for businesses and consumers alike. Nevertheless, regulations are accompanied by a number of administrative procedures – inspections, tests, registering – often simply called bureaucracy or, if they are perceived as excessive or lacking any real need, as 'red tape'. Given the increases in new products and processes, new technological and social challenges, the number of regulations increases. The growing number adds not only to the administrative procedures pile, but since regulations may have been drawn up at different times and without a good alignment to or amending existing ones, they can also create confusion, overlaps or conflicts. Often, companies' complaints about 'excessive regulation' are more about the administrative procedures rather than the regulation as such. For them, compliance to the administrative procedures is time consuming and labour intensive and thus a cost factor.

Regulations serve specific purposes – such as consumer or environmental protection – then the solution is not to remove them but to keep the corresponding administrative burden to the minimum. Many governments and public-sector entities seem to be 'obsessed with EU red tape'[2] and struggle with the challenge to cut red tape and reduce the number of regulations. Progress in this respect is supposed to unleash economic growth.

If aspects such as consumer protection or sustainability were not regulated at EU level, many if not most would require national legislation with the accompanying administrative procedures. It is often overlooked that these procedures serve wider information and monitoring purposes for the administration, enabling them to check that the legal obligation has been met. This is a precondition for enforcement. Interestingly, while many companies complain about 'excessive administration', they often point to countries where regulation is either not strictly implemented, monitored or enforced, as hampering overarching goals such as sustainability, as well as restricting the diffusion of innovation (see in particular sections 3.1 on energy and 3.4 on water).

The link between regulation and innovation is complex and any direct causality is hard to demonstrate. The various forms of regulation do not have a uniform impact on the innovation process. In fact, the impact varies considerably between new market entrants and incumbents, the degree of maturity of a technology, whether it is a process or product innovation, and at what stage in the value chain a firm and a product/process is situated. Thus, this complexity requires a rather differentiated approach in order to identify at which stage of the process the type of regulation that is more of a driver, a barrier or is neutral to innovation. Despite this heterogeneity, there would appear to be a limited number of stylised facts which were summarised by Stewart (2010) as follows: regulations that are most effective at stimulating innovation will tend to require compliance innovation and, at the same time, will minimise the compliance burden and mitigate the risks of producing failing or – in his words – "dud" inventions. The design of a regulation will determine whether it fosters incremental, radical, or failing innovations. Regulations have mainly three axes where regulators can make a difference via the degree of stringency, flexibility, and the level of information they contain.

1.2. Structure of the report

Section 2 provides key information about the survey before going into detailed findings at EU level. These include identifying those factors which matter (section 2.2), the economic effects on investments and jobs, investments outside the EU, and impacts on the market

Thus, the sectoral profiles provided (section 3) show the main differences between the sectors, the role of regulation in the sector as such, and as regards its innovation behaviour.

Based on the survey, a number of sector-specific regulatory drivers and barriers were identified. But what would be the effect of removing the barriers? Economic projections were made for the four sectors, revealing a substantial gain in investment in innovation.

The present report summarises the main findings from the survey and provides a synthesis for the four sectoral case studies. For these, as well as the survey and economic findings, dedicated reports are available[3].

[2] Renda, A. (2015): The cost of Europe: can better EU regulation lift the burden? accessible from: http://policy-network.net/pno_detail.aspx?ID=4854&title=The+cost+of+Europe%3a+can+better+EU+regulation+lift+the+burden%3f

2. EFFECTS OF REGULATION ON INNOVATION

2.1. Introduction

What are the quantified impacts of EU regulation on companies? This leading question was addressed within a Europe-wide survey to innovation stakeholders. It formulated regulation as both a potential driver and a barrier to innovation. Furthermore, a methodology was designed to quantify the importance of the economic effects of EU regulation on innovation (see Box 1)[4].

The quantification of economic impacts was based on direct evidence collected via the survey. Hence, the results reflect the perception of the regulatory environment from the perspective of EU stakeholders. Complete responses were collected from 1308 stakeholders (74 % of which were for-profit companies), with an extensive coverage in terms of countries, sectors, size, types of innovators and types of organisation (see Annex A.1).

The survey **questionnaire** aimed to yield indicators for all sectors at EU level. In addition, dedicated questions were included on sector-specific legislation for the four sectoral cases: food, energy, health and water. To achieve a high response rate, the questionnaire was designed to be as short as possible and to include quantified figures proposed in ranges. It included questions relating to both the negative and positive impact of regulation on innovation.

The target sample was created based on the following sources:

- Amadeus (by Bureau Van Dijk): used to identify companies with R&D and patenting activities
- Horizon 2020 participants
- Target stakeholders of DG RTD.

To maximise the number of respondents, about 50 000 e-mails were sent out inviting those contacted to complete the survey. Given a bounce rate of almost 30 %, 2013 responses were received, and 1308 stakeholders provided complete responses giving the data used as the basis for the calculations made. Of the 1308 complete responses received, 963 (74 %) were provided by for-profit companies. Other categories included non-for-profit private organisations (185 responses public institutions (96), academic institutions (40), and other stakeholders (24).

Efforts were made to encourage stakeholders across the four specific sectors to participate in the survey, which resulted in 196 complete responses from stakeholders in the health sector, 183 from the energy sector, 48 from the water sector and 45 from the food sector. The lower number of responses for water and food suggests the need to interpret the results related to these sectors carefully, especially where responses differ significantly. However, the number of responses is still sufficient to get a good insight into the impact of regulation in these sectors.

The survey respondents cover all EU countries. The countries most represented in terms of both number of respondents and innovation expenditure are Spain, Germany and Italy, followed by France, the Netherlands, the UK, Belgium, Austria, and Denmark. Contributions also came from 85 participants from non-EU countries, although their responses have not been taken into account in the calculations. Overall, Germany appears to have the highest expenditure on innovation activities (consistent with Eurostat statistics).

In order to relate the survey data to Eurostat data, respondents were also asked to identify their NACE Rev.2 sector (based on the list of all economic activities classified in 2-digit sectors and standard aggregates, as well as selected 3-digit sectors identified by top CIS*KIA coefficients[5]). Overall, responses collected from the survey cover all economic activities, except sector 19 (Manufacture of coke and refined petroleum products).

The distribution of for-profit companies across size categories indicates that 29 % of the companies employ less than 10 people, 32 % between 10 and 49 people, 18 % between 50 and 249, and 20 % employ more than 250 people (large companies).

Concerning the innovation profile of the respondents, of the 1308 who participated, 493 (38 %) have introduced product or process innovations in the last three years, while 1020 (78 %) have introduced marketing or organisation innovations. Furthermore, 377 (29 %) respondents have introduced both types of innovation while 172 (13 %) have not introduced any innovation. The

[4] The full methodology and survey results can be found in Task 1 study report.

[5] http://ec.europa.eu/research/innovation-union/pdf/cis-kia-coefficients.pdf#view=fit&pagemode=none

latter category also includes types of stakeholders that are not potential innovators but still wanted to provide input to the survey, such as industry associations. In comparison to business innovators in the CIS, respondents with non-technological (marketing/organisational) innovation are better represented, although stakeholders in all types of innovation represent a large share of the dataset.

Box 1: The methodology used to link regulation and innovation

The approach relies on **direct calculations of the link between regulation and innovation** based on survey data. Descriptive statistics and principal component analysis (PCA) of the responses provide straightforward measures to identify how regulatory factors act as barriers or drivers for their innovation activities. Quantified responses at the respondent level are also extrapolated at EU level, based on EU statistics from Eurostat.

To calculate the economic impact, the data taken into account are limited to those provided by companies in the survey (representing the majority of responses) as these can be linked to CIS data on business enterprises. Calculations are weighted by sector before aggregating them at the whole economy level. This allows the over/underrepresentation of respondents in a given sector to be addressed by either reducing or increasing their importance in the results. Sectors for which fewer than five respondents contributed to the survey were not extrapolated at EU level in terms of economic impact[6].

The reasons for relying on survey data are manifold:

- **Data limitations**: data on the relation between economic indicators on innovation and EU regulatory barriers are not part of standard reporting requirements and are not readily available in statistical databases at either the macro-level (Eurostat, OECD) or micro-level (Amadeus or other commercial databases, company balance sheets)[7].
- **Limitations of standard econometric methods**: indirect calculation using counterfactual analysis, for example, is not appropriate given the limitations on microeconomic data for EU actors and thus limitations to construct both treated and control groups of actors to infer a counterfactual situation (i.e. the situation that would have prevailed in the absence of regulatory barriers). Since the implementation year of a regulation is known, time-series analysis could be an option for the indirect calculation of the figures (e.g. through event study-related methodologies, time-series modelling). However, this type of approach does not optimally address regulatory barriers per se or expected issues, such as anticipated reactions to regulations, variability of the length of time windows (phase-in period), or overlapping regulations.
- **Company interviews too limited**: stakeholders such as companies tend to be able to make the link between regulation and innovation. Since the aim here is to cover the whole EU economy without limiting it to specific legislation, hundreds of interviews would be needed to cover all sectors, which is both time consuming and expensive.

On the contrary, conducting a large survey allows for sufficient data to be collected to give good coverage of stakeholders in Europe. Quality assessment of a large sample can be based on the distribution of responses and identification of outliers.

However, while the survey enabled indicators to be produced for all sectors at EU level, the methodology is not flawless. Results should be interpreted taking into account the following considerations:

- The information provided reflects the subjective perception of the stakeholders. Thus, a non-conforming perception of the regulatory impact or biased responses can occur. To minimise this effect, the survey adopted an *ex-ante* non-biased approach by considering both the positive and negative potential impacts of regulation.
- While large datasets are better to ensure the representativeness of the results, they do not allow for face-to-face validation of each figure with stakeholders. Hence, the consistency of quantitative responses needs to be assessed by examining the distribution of responses across respondents while ignoring outliers that could significantly impact the calculations.

[6] Following this criteria, two services sectors were excluded from the calculations of the economic impact: I - Accommodation and food service activities and K - Financial and insurance activities.

[7] Responses to a question in the Eurostat CIS survey about "high cost of meeting government regulations or legal requirements" provide a complementary insight on the topic which was examined in intermediate steps of the analysis but are not sufficient to produce the economic figures for this study.

Results from the computations should be interpreted as illustrative of the magnitude of the regulatory impact. The economic indicators show an initial comprehensive picture of the quantified impact of regulation on innovation in Europe.

The complexity of the relationship between regulation and innovation emanates from the fact that changes in the regulatory framework do not always trigger changes in innovation in an immediate and direct way. Such changes in innovation will sometimes occur in the course of indirect changes in competition, skills, investment or entrepreneurial activities. A direct measure based on feedback from innovators regarding the impact of regulation on innovation may provide a partial picture of the overall long-term effects.

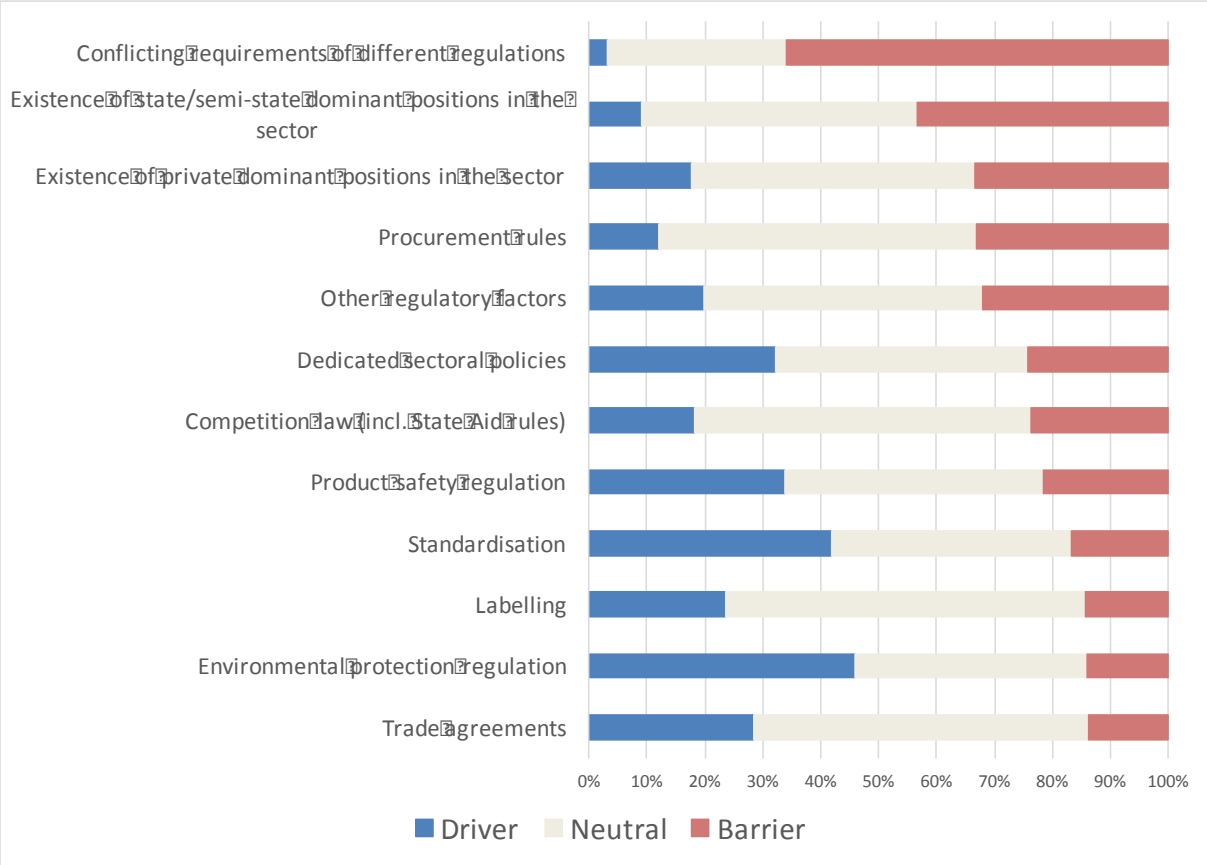
2.2. Regulation and innovation: what factors matter?

The 12 regulatory factors presented in the questionnaire as potential barriers to or drivers for innovation were based on a previous study (European Commission, 2014). These factors cover the potential regulatory impact at all stages of the innovation cycle, from the early phase of decision to innovate to the commercialisation of the innovation. Development phases may be influenced by *general rules* across sectors (e.g. procurement rules, competition rules), *by supply- and demand-side innovation specific regulation* (e.g. standardisation), and by *sector-specific rules*, imposing a certain degree of regulation stringency which has an overall impact on the business environment, as well as uncertainty, risk, or the potential market size that are essential to any innovation decision. Commercialisation of innovations will mostly be affected by general rules (e.g. product safety regulation, trade regulations) or sector-specific rules related to administrative processes for launching new products (Pelkmans and Renda, 2014).

General trends can be identified based on frequencies. Figure 1 indicates a more positive effect with regard to factors that most often act as drivers to innovation. These are related to environmental protection regulation, standardisation, and product safety regulation. To a certain extent, this result is in line with Blind (2012), who stated (when referring to the Porter hypothesis) that a few social regulations have actually resulted in the development of new markets, more specifically when stringent social regulation aims to address societal challenges by means of disruptive and radical innovations. Moreover, according to Ashford (2000), a "strong form" of the Porter hypothesis referring in particular to environmental regulation illustrates that stringent regulation can dramatically stimulate innovation via the replacement of dominant technologies by new firms or entrants.

On the other hand, a barrier to innovation was attributed to 'conflicting requirements of different legislation'. Respondents appear mainly neutral to labelling, competition law, trade agreements, procurement rules, or existing private and state/semi-state dominant positions in their sectors. For each factor, detailed results by category of respondents are presented in Annex A.1 .

Figure 1: Regulatory factors: barrier to or driver for innovation activities(1)



Source: Technopolis Group; Data: own survey

(1): Based on the question "Do you consider that the following elements act as barriers or drivers to innovation activities in your sector?"

While Figure 1 shows regulatory factors separately, it is to be expected that responses for some factors are correlated with other factors and that certain respondents consistently report barriers or drivers for all factors. To get a better understanding of the overall patterns, a PCA was conducted to analyse observations that are described by several inter-correlated quantitative variables. Results from this analysis help to identify different response patterns among this set of respondents:

- Categories of respondents that appear to be associated most with the perception of regulatory factors acting as **drivers** are those from Italy and Romania. In terms of sectors, they represent motor vehicles, furniture, jewellery, musical instruments, toys, repair and installation of machinery and equipment, water public administration, and administrative and support service activities. In addition, respondents with marketing and organisational activities (only) are more prone to seeing regulation as a driver.
- The dimensions related mostly to the **neutrality** of factors are mainly the country dimension (Czech Republic, Denmark, Finland, Germany, the Netherlands, and the UK) groups and also the sector manufacture of computer, electronic and optical products.
- Results are rather polarised when it comes to two types of regulatory barriers, namely the **regulatory factors related to market and competition** (competition law, procurement rules, and existence of private or public monopolies on the market), and other ("non-market") factors. Results show that specific sectors are consistently reporting barriers relating to non-market regulatory factors, namely food, beverage and tobacco manufacturing, chemicals, pharmaceuticals, motor vehicles and furniture, jewellery, musical instruments, toys and repair and installation of machinery and equipment. German respondents were also more closely associated with the perception of barriers related to non-market regulatory factors. Those respondents considering market and competition regulation as hindering competition are most often found in public administration, management consultancy activities, information and communication, the primary sectors as well as transportation and storage. Respondents from Portugal and public institutions are also associated with this type of barrier.

- The chemical, pharmaceutical, food, metal, construction and health sectors are mainly associated with larger numbers of respondents reporting **barriers** from product safety regulation, environmental protection regulation and labelling. Water, primary sector, consultancy services and the chemical sector seem to be associated more with barriers from dedicated sectoral policies or sector-specific barriers.

Based on the PCA, the sectoral dimension appears to matter most in terms of the differentiated perception of regulatory impact.

2.3. The impact of regulation: net economic effects

The net economic effects were calculated to estimate the impacts of regulation. The survey asked about impacts on innovation investments and on jobs. Overall, most respondents were neutral about the impacts (43-47 %). However, when analysing the responses which mentioned either positive or negative impacts, regulation clearly has a positive net impact both in terms of innovation investments and employment. This is true for business companies as well as for other types of respondent. This result suggests that regulation incurs a **net gain** on innovators in Europe. However, the descriptive results illustrate both sides of regulation impact with respect to innovation: regulation acts (more) as stimulating but also (less) as a hindrance for innovation. A slight limitation of this result is the fact that the survey mainly addressed innovators, which might create an upward bias in positive responses. Nevertheless, this potential bias is not expected to impact the differentiation of results among stakeholders.

Table 2: Impact of regulation on innovation investments and jobs (1)

	Negative impact	No impact	Positive impact	No response	Total
Impact on innovation investments					
For-profit company	83 9 %	432 45 %	294 31 %	154 16 %	963 100 %
Other type of respondent	27 8 %	150 43 %	71 21 %	97 28 %	345 100 %
Impact on jobs					
For-profit company	80 8 %	452 47 %	308 32 %	123 13 %	963 100 %
Other type of respondent	33 10 %	152 44 %	86 25 %	74 21 %	345 100 %

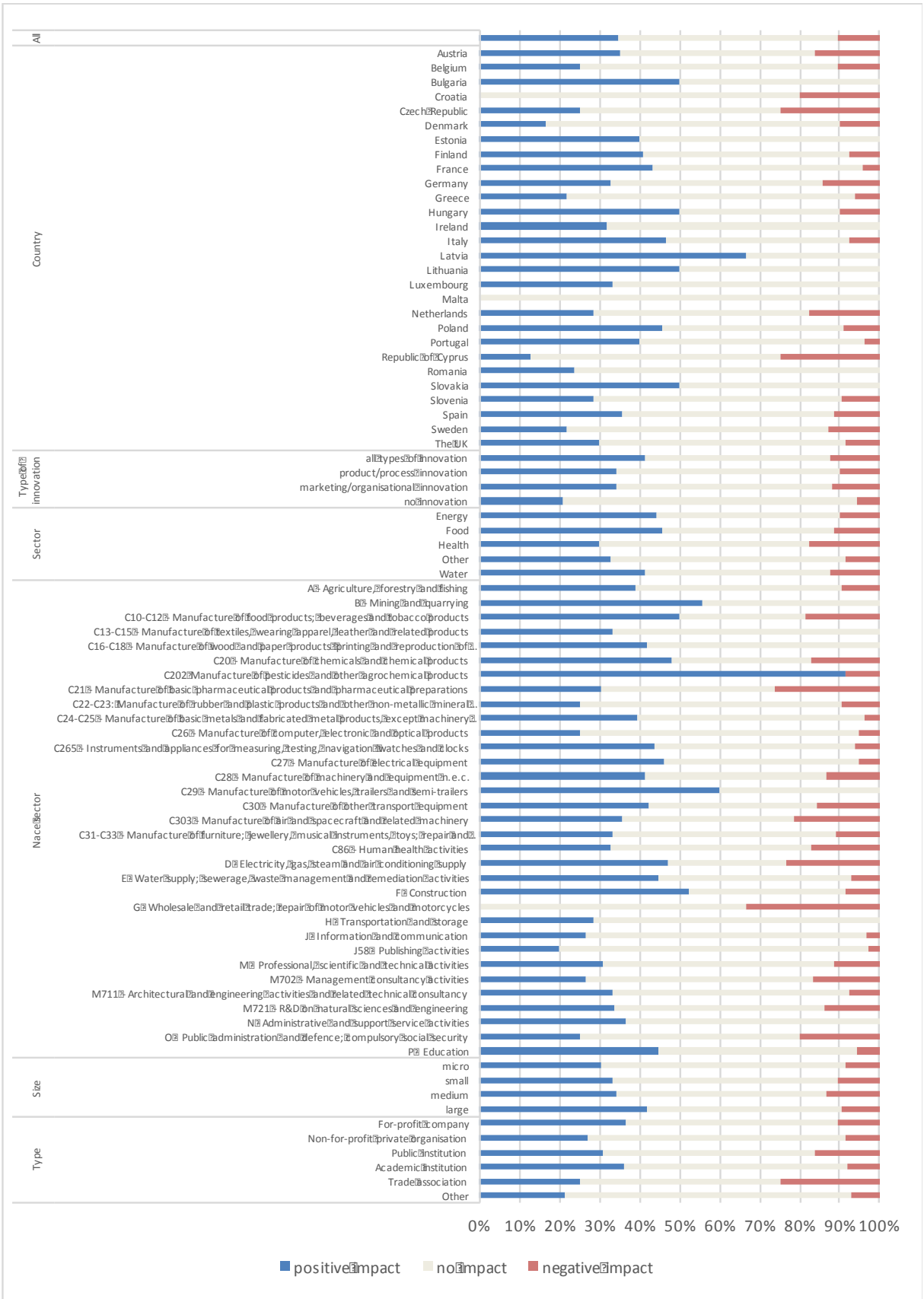
Source: Technopolis Group, Data: own survey

(1): For-profit company vs other type of respondent, absolute number of responses and shares

Figure 2 and Figure 3 illustrate how respondents provided positive, neutral or negative responses concerning the question of innovation expenditure, and jobs. The tables include country, type of innovation, sector, as well as size and type of company. Observations include:

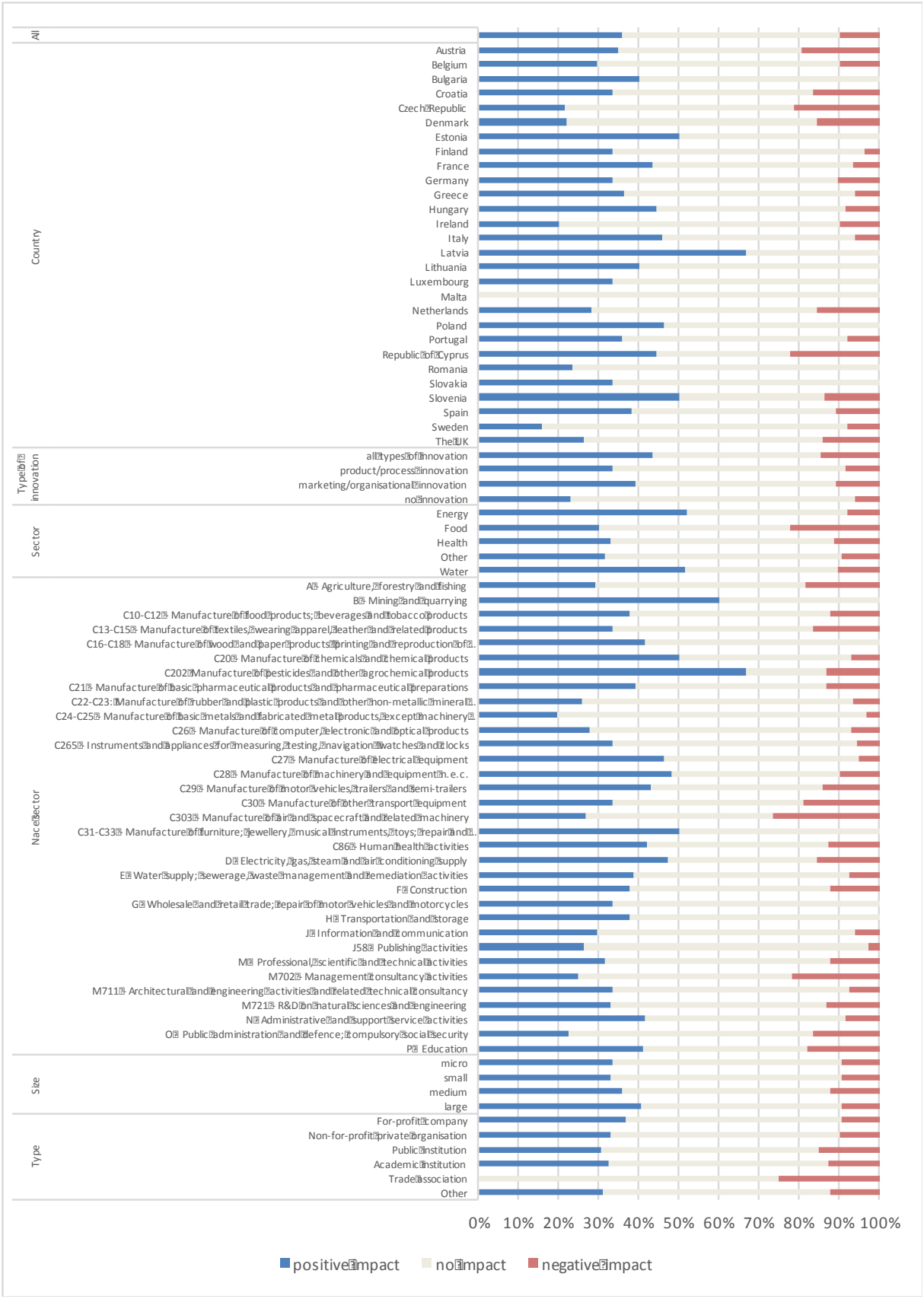
- Respondents from Eastern and Baltic countries (Latvia, Bulgaria, Lithuania, Slovakia, Hungary and Poland) seem to report more consistently a positive economic impact from regulation than other countries;
- Among the four chosen sectoral studies, the health sector appears to encounter more negative economic impacts than the others;
- Size is correlated with a larger non-neutral impact: larger firms more consistently report either a positive or negative impact from regulation. For-profit companies exhibit the highest rates of positive economic impact.

Figure 2: Impact of regulation on innovation investment – by type of respondent



Source: Technopolis Group, Data: own survey

Figure 3 Impact of regulation on jobs – by type of respondent



Source: Technopolis Group, Data: own survey

The quantification of the net gain due to regulation can be done in relative terms (as a percentage) at the survey level and in absolute terms (in euros) at the EU level.

According to the survey data, in relative terms, the **net gain from regulation** corresponds to approximately 1.8 % of additional EU innovation investments per year. In terms of employment, the total impact is close to 0.3 % of additional jobs.

In absolute terms, these figures correspond to **EUR 6 billion a year of additional innovation investments** by innovative companies if we consider a broad definition of this kind of investment (i.e. investments in R&D, machinery, equipment, software, external knowledge, 'other' innovation activities – design, training, etc.). Limiting the definition to intramural R&D investments (which are part of innovation investments) represents EUR 3 billion a year of additional R&D investments. The net gain in terms of employment amounts to **120 000 additional jobs** in innovative companies in Europe. When differentiating by size, large companies tend to report a lower gain than SMEs[8].

2.3.1. Missed investment and job opportunities as a result of regulatory barriers

However, according to the survey responses, regulation is also a barrier which hampers investments in innovation and jobs. Regarding **quantification of the impact of barriers**, results are rather high and estimated as being 2-4 % of innovation investments. Thus, if the perceived existing barriers are addressed in total, an additional EUR 7-14 billion per year could be released on general innovation investment (based on all types of innovation investments[9] in CIS2012 reported by innovation companies). The quantified impact of regulatory barriers on jobs is also estimated as being approximately 2-4 % of total jobs. In terms of the number of jobs, this represents 1-2 million additional jobs compared to the current situation.

These figures on missed investments and jobs can be seen as **potential maximum benefits** of addressing existing regulatory barriers, if other factors remain unchanged.

2.3.2. Innovation investments outside the EU

Does existing regulation in the EU foster innovation investment outside the EU? This is a rather difficult but politically important question. It is challenging to come up with a complete picture for this indicator. In order to estimate the effect, those companies reporting innovation investments outside the EU were analysed. They represent 25 % of the total turnover of the companies in the survey sample. The total amount of innovation investments outside the EU is estimated to be close to 1 % of innovation investments in the EU. After extrapolation, this total represents 1 % of innovation investments in EU. Thus, due to the EU regulatory environment, it is estimated that about EUR 3 billion of innovation investments (using the broad definition) are made annually outside rather than inside the EU. If we limit the definition to R&D investments, this corresponds to EUR 1.5 billion per year.

2.3.3. Impact on market shares on world markets

It can also be assumed that regulations impact on world market shares. Survey data show that the majority of companies report no impact (these companies represent 83 % of the turnover of the sample). For those citing an effect, companies representing 14 % of the sample turnover reported a negative effect and those accounting for 3 % of the sample turnover reported a positive one. Hence, negative effects on world markets appear to dominate over positive effects. Reasons for companies to report losses of global markets shares can be explained by a potential loss of competitiveness with respect to non-EU competitors when EU regulation incurs high compliance costs on them. On the other hand, when regulation encourages innovation activities, it is expected that firms will strengthen their position on international markets. However, this latter effect on market shares is not an immediate one. By extrapolating the figures observed in the survey, loss of non-EU market shares caused by EU regulation correspond to 0.3 % of the turnover of innovative companies, which amounts to approximately EUR 70 billion euros in turnover each year.

2.4. Economic projections

The figures presented in section 2.3.1 about missed investments and jobs can be seen as the **potential maximum benefits** from addressing existing regulatory barriers, with other factors remaining unchanged. Depending on the effectiveness of the actions and efforts made to address regulatory barriers, the benefits can vary significantly. By considering a scenario whereby a progressive removal of regulatory barriers is observed by 2030, the projections for additional innovation investment and jobs in innovative activities range from EUR 4-8 billion of additional

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[8] Definition of SME based on number of employees being below 250 and maximum turnover of EUR 50 million per year (*EU recommendation 2003/361*). The balance sheet criterion of a maximum of EUR 43 million was not taken into account as this information was not collected in the survey.

[9] Investments in R&D, machinery, equipment, software, external knowledge, 'other' innovation activities – design, training, etc.

innovation investment on average per year and between 70 000 and 140 000 jobs created annually..

Table 3: Projections of economic impact of removing regulatory barriers by 2030

	Additional innovation investments (EUR billion)		Jobs created (thousands)	
	Low estimate	High estimate	Low estimate	High estimate
average per year	4	8	71	143
2016-2020	7	13	95	190
2021-2025	19	36	333	667
2026-2030	30	58	571	1142
2016-2030	56	107	1000	2000

Source: Technopolis Group; Data: own survey and Eurostat/CIS2012.

Note: low and high estimates based respectively on the impacts of 2 % and 4 % calculated previously

2.5. Conclusions on the quantification of impacts

In order to produce quantified measures of the impact of regulation on innovation, the approach used in this section considers a spectrum larger than regulatory barriers simply by covering both the undesired and desired effects of regulation. Therefore, regulation is examined as a source of both potential drivers and barriers to innovation. The process of quantifying economic impacts relied strongly on the direct evidence collected via a survey addressed to innovators.

The two sides of regulation: barriers to and drivers for innovation

Overall, survey data shows that EU regulation is not only seen as a source of barriers to innovation: while conflicting requirements of different legislation seem to be a particular problem, many respondents consider that EU regulation drives innovation activities. Here, environmental protection regulation, standardisation, and product safety regulation were specifically mentioned.

The study attempted to identify patterns related to different dimensions (such as sector, country, size, type of innovation activities, type of organisation) and confirms **that 'sector' is clearly the dimension that matters the most**. For example, the automotive industry, the water sector and administrative sectors clearly acknowledged that regulation plays a positive role for innovation.

The analysis also identified two separate patterns in reporting regulatory barriers, namely market-related barriers and non-market barriers. Several industries are confronted with marked-related regulation such as competition and procurement rules (for example, the consultancy sector, ICT sector and primary sector) while other stakeholders are confronted with non-market regulation, such as:

- manufacturing of pharmaceuticals, chemicals, food and metal, as well as health and construction sectors are associated with barriers related to product safety regulation, environmental protection and labelling;
- water, primary sector, consultancy services and the chemical sector are associated more with barriers from dedicated sectoral policies or sector-specific barriers.

This result strongly suggests that regulation should be addressed in a highly differentiating way: one type of regulation may be perceived as a barrier in one sector while it works as a driver in others. Thus, when one sector complains about one specific regulation or 'a regulative burden' as such, it is likely to be sector-specific rather than generally true.

The net perceived impact of EU regulation is slightly positive

By combining survey data and statistics from Eurostat (CIS), companies' results show that regulation has a **net positive impact on innovation investments** (about 2 % per year, which corresponds to an extra EUR 6 billion annually, if we use a broad definition of innovation investments, and an extra EUR 3 billion per year if we only consider intramural R&D investments). For **employment,** there is also a slightly positive figure of 0.3 % or 120 000 additional jobs from innovative companies, meaning that negative impacts are compensated for by the positive impacts of regulation. Although this result acknowledges that there are barriers due to regulation, it clearly illustrates once again that the both sides of regulation are also as a stimulus for innovation. However, it is worth bearing in mind that most survey respondents are involved in innovation activities, which might create a slightly upward bias in positive responses.

Addressing existing regulatory barriers can leverage net positive impacts on innovation activities

The negative impact of regulatory barriers in terms of missed investments and job opportunities could also be addressed and turned into maximum potential gains. Removing existing regulatory barriers can leverage 2-4 % of additional investments. The potential gain depends on the effectiveness of actions taken and efforts made (based on identifying specific barriers and ways to address them). If we consider a scenario based on a progressive removal of barriers with its maximum potential reached by 2030, this corresponds to a yearly average of EUR 4-8 billion of additional innovation investment, and the creation of between 70 000 and 140 000 additional jobs annually.

3. SECTORIAL ANALYSES

3.1. The energy sector

3.1.1. Introduction

The aim of performing a sectorial analysis in the energy sector was to better understand the EU legal and regulatory framework and to assess the economic effects of the specific regulatory framework in this sector with regard to innovation.

To achieve this objective, a broader scoping exercise was performed, including a delineation of the sector (NACE 1 or 2-digit level which limits the scope to energy user sectors), identification of core actors and their roles and functions in the innovation system, as well as main regulatory governance aspects and framework conditions.

In addition, energy-sector-related results are presented from the survey (see section 2), as well as innovation impact analysis on case studies (Renewable Energy Directive, Energy Labelling and Ecodesign Directive).

3.1.2. Snapshot of recent EU legislative/regulatory initiatives in the energy sector

In 2007, an energy chapter was embedded in the primary European Union law. Prior to that, the EU had already passed energy-related legislation in the 1990s, with two Directives on the internal market for electricity and gas. These provided the basis for efficiency gains, price reductions and increased competitiveness.

Today, EU legislation on energy issues is rather comprehensive. It covers at least six interrelated 'fields' (see Figure 4), and clearly indicate the extended scope of the energy sector – within the energy value chain – where regulations apply to the production, transmission, distribution of energy as much as to its use in the form of individual goods and services. This key characteristic points to the limitations of a sectoral analysis. Figure 4 below provides a limited overview of some key legislative acts; other legislative areas also affect the energy sector.

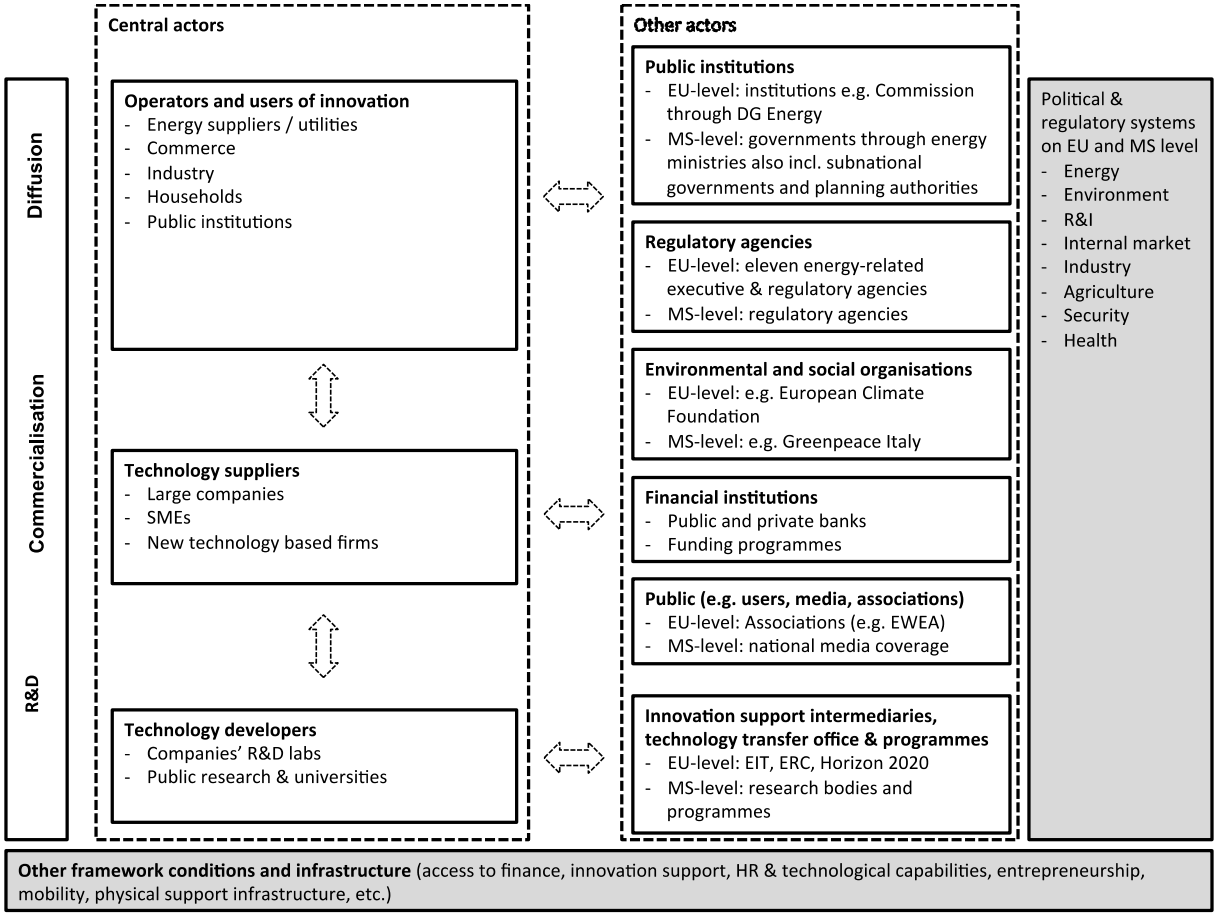
Figure 4: Examples of key energy legislation

Main field of energy legislation	Examples of legislative acts
Internal energy market	Electricity Directive (2009/72/EC); Gas Directive (2009/73/EC)
Energy supply security	Directive 2009/119/EC imposing an obligation on Member States to maintain minimum stocks of crude oil and/or petroleum products
Conventional energy	Directive 2009/31/EC on the geological storage of carbon dioxide
Nuclear energy	Council Directive 2009/71/Euratom for nuclear safety; Council Directive 2011/70/Euratom on radioactive waste
Renewable energy	Renewable Energy Directive (2009/28EC); Fuel Quality Directive (2009/30/EC)
Energy efficiency	Labelling Directive (2010/30/EU); Energy Performance of Buildings Directive (2010/31/EU); Energy Efficiency Directive (2012/27/EU and COM(2016) 761 final)

3.1.3. Snapshot of the energy sector innovation system

The central actors in the energy sector innovation system are grouped by their main roles and functions along the research and innovation value chain – R&D performers, and actors in commercialisation and market diffusion. In terms of R&D performers, a distinction can be made between private- and public-sector research institutions. Technology suppliers (either with or without in-house R&D activities), can make use of research outcomes and develop mainly product or process innovations. Finally, system operators and end-users take up these innovations and co-decide which will be successful on the market (see Figure 5).

Figure 5: Energy innovation system (actor landscape)



Source: own illustration based on Technopolis Group 2013

In terms of statistical classifications, the 'energy sector' is a rather narrowly defined industry sector, covering mainly energy producing and distribution industries. The relevant NACE class is NACE D35 *Electricity, gas, steam and air conditioning supply* which is also the basis for the available statistical data.[10] However, energy-related aspects in a sectoral perspective can be found in a number of manufacturing or service industries. During the last decade, many new technologies were invented and deployed, for example in the field of unconventional gas, solar, photovoltaic, biofuels or LED lightning.

While the energy sector is a relatively concentrated industry sector, in many EU Member States[11] the energy-producing or -providing firms rely to a considerable extend on technology suppliers from non-core energy industries. For example, there are suppliers of specialised components (e.g. solar cell materials or gear components for wind turbines) who may possibly sell a large part of their production to the energy-producing industry while the rest is sold to other industries. In this respect, the energy innovation system depends on a variety of sub-sectors[12] as well as other versatile industries (coating, components, mechanics, etc.).

To measure the innovation activities in the energy sector, it is possible either to count the patents of companies in NACE D35, or to apply a product-based approach using the international patent classification (IPC) system. In line with a study published by the OECD (2004) Buru et al. (2013, p. 33) argue that "*[w]hile the energy sector is not among the most strongly documented patent-intensive industry branches, low-carbon-energy technologies encompass many different fields of*

[10] D35 includes three sub-classes with Electric power generation, transmission and distribution (D351), Manufacture of gas; distribution of gaseous fuels through mains (D352), and Steam and air conditioning supply (D353). For some statistical data, sector E - Water supply; sewerage, waste management and remediation activities is aggregated with E as one economic activity. For the underlying report on the energy sector, the use of available statistical data based on NACE D35 was included to provide an overview. However, the survey and a patent analysis strongly confirmed the limitations using a NACE-based sectoral approach to delineate the sector and its innovation activities, or, put it differently, much of 'energy' related innovation is happening in other industry sectors. See also the Health sector, were a similar discrepancy can be noted.

[11] EC (2014)

[12] Borup, Mads et al. (2013)

advanced technologies and technological knowledge: e.g. biotechnology for producing biofuels and chemistry for carbon-capture technologies to new materials." Thus, the latter approach is not only more all-encompassing – if it is agreed that not only NACE D35 companies are the sources of energy-related innovations – but it is also more practical since the patent classification allows innovations to be measured on a component basis.

Given the strong political will to have a better overview of environmental patents (in a very broad sense), the European Patent Office (EPO) has created a new sub-class that brings together all patents under the label of "Climate change mitigation technologies" (IPC Y02).

A study by the United Nations Environment Programme (UNEP) and the EPO on CCMT patents indicates a rising number of European inventions in this area. Around two-thirds of the patents are considered to be of high value – they were filed at more than one patent office (UNEP & EPO 2015). Overall, the number of European CCMT patents increased fivefold (from 1700 in 1995 to 9000 in 2011, indicating an average annual growth of 11 %); a similar trend was identified globally (from 11 000 in 1995 to 51 000 in 2011; average annual growth 10 %).

Since 2005, patenting activities in the CCMT area have accelerated significantly. Given the lead-time from the company–internal innovation process until a patent is filed, this can be linked to factors which happened in 2002-2003. This was before the EU-level energy strategies were developed although, at that time, creation of the European Emissions Trading System was discussed. Once again, this sent a clear signal to industries that new markets would be created and innovative products and processes would soon be in demand. However, other regulatory instruments, such as renewable energy or energy efficiency policies at the national level, also have contributed to an increase in CCMT inventions.

What is subsumed under the industry classification and commonly addressed as the 'energy industry' is neither a synonym for the 'energy sector', nor the source of innovation 'in the energy field'. Similarly, the relevant NACE class is not the only sector addressed by energy-related regulation. However, the first Directives on gas and electricity have helped to liberalise these highly regulated (in the sense of their governance) markets. Current legislation addresses all kinds of 'climate change mitigation technologies' (CCMT) – ranging from conventional energy producers, to renewable energies, addressing users – industry and ultimately households. Thus an industrial delineation of the sector based on NACE D35 – which enables a number of key indicators – is not directly compatible with those industries where innovation occurs. This can be seen when analysing the main innovating companies for CCMT – only a few 'core' D35 firms can be found among the leading patenting firms. Energy-relevant innovation takes place mainly in sectors that are 'users' (or consumers) of energy such as transport or manufacturing.

3.1.4. Regulatory impacts on the energy sectoral innovation system

Energy sector regulation is strongly driven by environmental and climate regulation in particular in the two areas: 1) renewable energy and decarbonisation; and 2) energy efficiency, in which 80 % of the survey respondents in the field of 'energy' perceived EU regulation as a driver for innovation. Safety regulations are another relevant area, mainly inducing innovation barriers in the energy sector. The 'non-uniformity' of electrical equipment regulations across EU Member States is reported as a barrier to innovation. Thirdly, economic regulation is seen as crucial for innovation in the energy sector's network industries like electricity supply and transmission. Network industries tend to monopolise their activities to increase their territorial rent, which provokes barriers preventing new entrants from accessing markets and competing with the incumbents.

Economic studies on barriers to and drivers for innovation in the climate/environmental and energy context are providing mixed evidence as to whether regulations trigger or hamper innovation (Roediger-Schluga 2004, Ambec & Cohen 2011). Porter and Van der Linde (1995) initiated the discussion with their finding that environmental regulation led to increases in innovation and technological change[13]. Regulatory stringency has an overall positive impact on patenting, although this impact is seen as negative for large companies (Rubim de Pinho Accioli Doria 2010). Environmental regulations in the automobile sector (i.e. emission-control technologies) have stimulated innovations in the US automotive sector mainly in the early phases of technological change (Lee et al. 2004, 2007). A number of studies suggest mixed results in terms of regulation and the development of new environmental technologies (e.g. Jaffe 1995. Jaffe et al. 2003). According to this research, it depends on the energy applications (Johnstone et al. 2010) and the period of time: under a medium- and long-term horizon, regulations have a positive impact on

[13] The examples provided by Porter and Van der Linde are the Clean Air Act in California in 1990 and the Montreal Agreement to ban ozone-depleting substances, for example, in cooling equipment, which was a major driver for innovation and created new market segments in the industrial cooling sector

environmental innovation (Popp et al. 2007). The rather diverse findings suggest that different regulations have different short-term or long-term effects on specific products, technologies, markets – and companies. While a regulation can be a driver for an established large company, it can simultaneously be a barrier for a new, small firm to enter the market and the competition.

From a climate and environmental policy point of view, legally binding regulations in the energy sector are crucial to protect natural heritage, sustain the common good against individual economic interests, and to guarantee just conflict-resolution procedures among different societal stakeholders. However, this type of regulatory approach is expected to cause administrative burdens for all actor groups involved, and thus companies also hesitating to invest in research and innovation.

To this already ambiguous picture on drivers for and barriers to innovation, the survey provided a large number of individual remarks about the impact of regulation. Within the survey, the main drivers for and barriers to innovation in the energy sector were identified as follows:

Figure 6: Drivers and barriers in the energy sector

Reported mainly as drivers	Reported mainly as barriers
• dedicated sectoral policies • environmental protection regulation • labelling • product safety regulation • standardisation and norms • trade agreements	• non-uniformity, conflicting requirements • private and state/semi-state dominant positions territorial monopolies • *procurement regulation*[14]

Source: Technopolis Group, Data: own survey

Overall, EU energy legislation is seen mainly as a ***driver*** for innovation in the sector – around 50 % of the respondents agree as regards energy supply security and the further uptake of internal energy markets. With regard to economic progress in the energy efficiency and renewable energy sector, 80 % of the respondents think that EU regulation/ legislation is a driver for innovation. The share of respondents who estimate regulation as a driver for energy and environmental innovation is 10 percentage points higher in the energy sector than in the other three analysed sectors. One interviewee noted that even though EU legislation and other initiatives (including the 20-20-20 targets) originally contributed to innovation in the energy sector, more recent issues/events undermine these previous positive framework conditions. However, the interviewee did not find these challenges at EU level but rather at Member-State level, which includes, amongst others, unstable framework conditions or insufficient policy implementation in Member States. Hence, it can be concluded that regulation at individual Member-State level is affecting innovation activities, which may have a negative impact on the EU region in general.

More than 30 % of the respondents estimate the existence of dominating individual companies as a **barrier** to innovation. This indicates that the lack of competition induced by a high sectoral concentration negatively affects innovation capacities within the energy sector. The same is true for market dominance by a public or public-private company: about half of the respondents see this as a barrier. Again, compared to the other sectors, this share is about 10 percentage points above the other sectors, indicating that dominating positions or quasi monopolies in network sectors are an important factor in this sector.

Labelling is mainly seen as a **neutral** factor: more than 90 % of the respondents were either neutral or positive about it. Procurement regulations were mainly reported as neutral, although about 30 % identified them as a barrier to innovation.

The survey also asked energy sector respondents about their views in open questions. In total, 90 organisations from 23 EU countries provided answers, with the majority of the responses coming from private-sector companies (66).

In terms of '**What other specific EU legal/regulatory instruments hamper innovation in your sector?**' the answers can be roughly grouped under the following headings:

- Specific legal/regulatory instruments regarding energy issues at the EU level

Here, the answers were very diverse, with most organisations reporting a specific instrument regarding their own sub-sectors. For example, an Italian non-for-profit organisation claimed

[14] With regard to public procurement rules, European state aid regulation is frequently reported by firms as a barrier to innovation, in particular at the national level. European state aid regulation does not allow for particular public investments within research and innovation funding programmes

there are no EU-harmonised regulations for hydrogen infrastructure, specific safety distances and safety roles; a Belgium for-profit company reported that the Industrial Emissions Directive does not provide a definition for "industrial scale" thereby generating potentially lengthy permitting procedures for the installation of small- to medium-scale electrolysers.

- Design of EU legal/regulatory instruments

Most answers focused on the design of the instruments. For example, a French for-profit company indicated that uncertainty over regulatory developments or the fear of upcoming very intrusive regulations might slow their interest in innovations. An Italian for-profit company claimed that regulations are not updated with the most recent state of the art.

- Differences at Member-State level

Differences at Member-State level were also addressed. Here, a German energy and water provider identified differences in legislation concerning the introduction of smart metering in the EU as a barrier for innovation. A Spanish energy service company complained that some countries do not have stable energy market frameworks. A British, a Spanish and a Swedish for-profit company each reported problems in general with national interpretation/transposition of EU regulations.

- Financial issues

Financial issues were mentioned, too: while a British for-profit company reported a lack of quick finance, a German for-profit company quoted the tax policy on investment in venture capital and the lack of financing for start-ups. A Belgium non-for-profit organisation mentioned the limited accumulation possibilities of state aid for R&D with H2020 funding which may have led to decisions not to invest in innovation.

When asked '**Does a non-uniform implementation of EU regulations in Member States impede innovation?**' most of respondents agree (31 positive answers vs. 15 negative answers, plus 12 undecided or unclear answers). Most of those agreeing also provided a short explanation or example.

Examples in the building sector include the statement of an Austrian applied research and consulting company: "The transposition of the EPBD is very different in Member States and does not result in the expected impact in some countries. It allows national governments to divert and continue business as usual instead of using the chance for innovation". Two French for-profit companies reported different local laws and different objectives regarding nearly zero-energy buildings (NZEB), as well as different building codes and thermal performance standards that are often used by incumbents to protect positions as barriers to innovation.

Smart metering is also given as an example, as there are heterogeneous devices and standards per country; energy providers which are preventing the deployment of faster and cheaper software solutions at the large scale, as one French for-profit company put it.

Energy efficiency regulation is given as another example. A German for-profit company remarked that the market for energy-efficiency products in combined heat and power CHP, for example, is still driven by the national funding policy. Here the EU is still divided in national markets with different product needs.

One example on renewable energies comes from a Spanish for-profit company, reporting that the complex regulatory framework, including the EU, Member States, regional and municipal regulations, provides a barrier (either perceived or real) to innovation in the power sector. This company mentioned its own experiences in developing different offshore wind projects in the UK, Germany and France.

Uniform implementation in the Member States is considered essential for fair competition. A non-uniform implementation of EU regulations may not only be problematic for the commercialisation of products but the differences in the organisation and operation of the various national markets impedes the introduction of managerial or process innovation at the European level.

Asked '**Do specific gaps exist that would need to be covered by EU legal/regulatory instruments in your sector ?**' 49 answers were received. While only two for-profit companies from the UK and Italy stated that the energy sector is well regulated and that no more legal or regulatory instruments are required, all other answers identified gaps. These can be roughly summarised into the following categories:

- Gaps in transposition/implementation at Member-State level

Several Spanish organisations mention this issue: one Spanish energy services company stated that the EU should reduce the time to implement the Energy Directive in each country and that the same regulatory instruments should be applied at the same time. A Spanish public institution asked for more control on Member States' correct and timely transposition.

- Gaps in standardisation and definitions

Here, a French for-profit company asked for a single NZEB definition for all European countries. A Spanish for-profit company commented that a EU standard for condensing biomass boilers is missing.

- Gaps in the design of EU legal/regulatory instruments, general issues

A French for-profit company stated that the actions around energy (support, financing, etc.) are too focused on resources and on hardware/facilities and that a lot could be accomplished with software, big data, apps, etc. – with lower costs. A Greek for-profit company suggested less regulation and more voluntary agreements.

- Gaps in the energy system, energy infrastructure

Three answers deal with this category: a Spanish for-profit company stated that a regulation about the end-use of storage and renewables would be useful. A Belgium for-profit company remarked that hydrogen technologies would create links between the power, gas, mobility and industry sectors, which are currently all regulated individually. EU regulations addressing the whole EU energy system are needed to address synergies between these sectors and remove cross-sectorial barriers. Energy storage and power-to-X activities should be regulated at energy-system level. A Danish for-profit company remarked that transportation of electricity between countries is still missing.

- Gaps in market organisation

A French for-profit company said that more competition in the energy retail market would foster innovation in the offers made to end-users. A Finnish for-profit company pursued the same direction: roles and responsibilities for aggregators need to be clarified urgently to enable the growth of demand response. A regulator link between energy efficiency legislation and energy management for buildings is needed which allows demand-side flexibility to enter the market and support the balancing of renewables.

Other aspects can be identified, such as financial issues; however, they tend to touch on system-level changes and not necessarily on specific issues. To summarise, the remarks and suggestions are rather diverse and show subjective perspectives, reflecting situations at regional or country-specific level. It all depends on the country of origin, the technological focus, and on the specific market to which the answering organisation is referring.

Another factor to take into account is that many of the barriers are seen in new energy areas, where they are regulations that have not been fully set yet, or where the market/technology development is too fast to react in time on a regulatory basis. Examples are smart metering, hydrogen infrastructure, the storage of renewable energies, or demand response.

However, some issues seem to be of general importance for reducing the barriers to innovation since they were mentioned several times in all three open questions:

- harmonisation in implementing EU legal provisions;
- EU-wide standardisation and common definitions are necessary;
- fair competition for all with similar framework conditions.

According to the survey responses, EU regulatory policy in the energy sector is perceived as a driver for innovation rather than a barrier. This was particularly true for regulatory action addressing the renewable energy and climate change mitigation technology sector as well as regulatory action addressing energy efficiency. EU regulation/legislation in these areas was seen as a driver for innovation by 80 % of the respondents. The two case studies summarised in the box below aimed to better understand these perceptions and to analyse impacts of EU regulation on innovation in more detail.

Box 2: Energy regulation examples

The expansion of renewable energy technologies positively affects, for instance, energy security and the creation of green jobs. The **Renewable Energy Directive (RED)** can be considered as a major European policy initiative in the field of renewable energies. The RED includes several articles influencing innovation in renewable energies. For example, by acknowledging that innovation does not only comprise the invention of a product but also its market diffusion and commercialisation, the RED fosters market creation for renewable energy technologies by establishing national renewable energy expansion targets for Member States (Art. 3 of the RED). However, targets may also serve as comfort zones for some states which have already achieved their targets.

With respect to the specific area of renewable energy source for transport, including biofuels and bioliquids, there is a relatively high level of administrative burden for all actors. This is mainly the result of developing a chain of custody safeguarding that feedstock used for producing biofuel products complies with sustainability criteria. Suppliers of respective biofuels, which are active in more than one country, are also burdened by "differing (reporting) requirements"[15] that must be met in various Member States and are not yet harmonised across the EU.

Hence, while the RED paves the way for innovation in the EU, some issues deserve better regulatory adjustment in order to reduce the administrative burden, while several refer to the Member-State level where differences in policy and regulation hamper faster market diffusion.

The **Ecodesign** and **Energy Labelling Directives** are key policy framework instruments to increase energy efficiency. The core aim of the Ecodesign Directive is to guide manufacturers towards reducing their products' energy consumption and to considering their ecological impacts as early as the product design and engineering phase. The Energy Labelling Directive aims to help consumers to choose energy-efficient products.

The setting of mandatory requirements for ecodesign and labelling at the EU level brings environmental and monetary benefits to both end-users and industry. The 2015 Impact Assessment gave an approximate annual impact by 2030 of 552 TWh primary energy savings, EUR 10-30 billion in consumer savings, and additional commercial revenue of EUR 34 billion[16]. Because of the common, harmonised and predictable regulatory framework for environmental issues, costs are reduced for manufacturers. Financial and commercial risks and the uncertainty of innovation are also lowered and European industry can better compete with lower-cost countries on higher-value-added products[17]. In practice, this has been confirmed by industrial stakeholders (e.g. for tyres).

The study states that "*the Ecodesign and Labelling Directives" have the potential not only to deliver energy savings and reduce environmental burden*[18] *but also to positively impact the innovation activities and competitiveness of the manufacturers of the regulated product family*"[19]. In a more general statement, it added that in some technology areas the regulations seem to have stimulated innovation, but not in other areas. The impacts often depend on how ambitious the requirements are. This is also reflected in the number of products that are removed from the market when a more ambitious regulation is adopted. Thus, this clearly has a higher innovation impact.

Braungardt et al. stated that: "*The innovation activities that are induced by ecodesign and labelling are found in the later stages of the innovation process and are typically incremental. The policy measures are not likely to have an impact on the technological development of radical innovations, however, they do have the potential to support the accelerated market uptake of such technologies* "[20]. The Ecodesign and Labelling Directives had and still have the potential to positively influence the innovation activities of affected industries. Labelling supports the market pull for high-efficiency end products and therefore indirectly influences innovation activities. Ecodesign regulations remove poor-performing products from the market.

15 Kampmann, B. et al. (2015)
16 EC (2015)
17 ibid
18 In addition, social burden as a burden on public health is, for example, reduced with the reduction of particular matters
19 Braungardt, S. et al. (2014)
20 ibid

3.1.5. Economic impact and projections

Projections in this section are based on the methodology detailed in chapter 2.4. The idea is to use the information provided by respondents on the perceived impact of regulation on their activities, which they identified via quantified ranges (in percentages of their innovation investments and jobs). Estimates are produced by relating this impact with their responses on the role played by regulatory factors (i.e. driver, barrier, neutral factor). The rationale behind this exercise is to estimate the difference in the quantified impact of regulation between a respondent who identifies a given factor as a barrier and a 'similar' (in the econometric sense) respondent who does not consider the factor as a barrier. The approach does not assume that regulation has an overall net negative impact, but that this impact can be either less positive or more negative due to regulatory barriers. The impact, observed in relative terms (i.e. percentages) at the level of the survey respondents, can be extrapolated to EU figures using CIS data in order to get absolute figures. For the purpose of the projections, data from CIS until 2030 were estimated (based either on estimated future growth rates calculated by CEDEFOP for employment or on recent trends for innovation investments) as a baseline scenario from which the impact in absolute value of addressing barriers has been calculated.

The estimated impact of addressing barriers for companies in the energy sector is an annual rise in innovation expenditure of 1.8 % to 5.1 %. The number of jobs in innovation activities is estimated at 2.9-4 % higher compared to the situation with barriers. The potential impact of addressing regulatory barriers on innovation expenditure is summarised in Table 4.[21]

Table 4: Economic projections for the energy sector (EUR billion)

	Direct full impact from 2017		Progressive impact over 15 years	
	Low estimate	High estimate	Low estimate	High estimate
Annual average	0.5	1.4	0.3	0.8
Total 2016-2020	1.9	5.4	0.3	1
Total 2021-2025	2.5	7.4	1.3	3.7
Total 2026-2030	2.8	8.1	2.4	7
Total 2016-2030	7.2	20.9	4	11.7

Source: Technopolis Group

Note: Direct full impact: the percentages above are directly applied for each year after 2017-2030. Progressive impact: the percentage of impact in 2016+n is the percentage above multiplied by n/14 (linear progression)

In the table, total figures represent the sum of annual increases in innovation expenditure when addressing barriers over the period. Addressing regulatory barriers may facilitate about EUR 4-20 billion in innovation expenditure over 2016-2030, if all barriers are removed by 2030.

By 2030, the total potential impact on employment in innovative firms over the period would be close to 75 000 jobs. This is achieved by estimating the number of jobs in innovative companies in 2030 and calculating the difference compared to the situation without barriers. This total difference can be averaged annually, as shown in Table 5 below[22].

Table 5: Impact projections for jobs in the energy sector

	Progressive impact over 15 years	
	Low estimate	High estimate
Annual average	3638	4989
Total 2016-2020	5197	7126
Total 2021-2025	18 189	24 943
Total 2026-2030	31 181	42 759
Total 2016-2030	54 566	74 828

Source: Technopolis Group

[21] Please note that this study uses EUR 23 088 099 thousands in 2012 as the initial number for innovation expenditure (sum of different types of innovation expenditure, incl. R&D, from CIS). For this exercise, the evolution of annual innovation expenditure for the sector has been estimated over 2016-2030

[22] Please note that this study uses 1 986 972 jobs in 2012 as the initial number of jobs in innovative companies (from CIS)

Table 6 presents the number of respondents answering the survey question: 'Based on your perceived barriers/drivers to innovation, please estimate how innovation has impacted over the past three years the following indicators'. The answers suggest a positive net impact from regulation:

Table 6: Perceived impacts on the energy sector (in absolute and relative terms)

Energy	Negative impact	No impact	Positive impact
Innovation expenditure	15 (10 %)	69 (46 %)	66 (44 %)
Jobs in innovation activities	9 (6 %)	59 (42 %)	71 (51 %)
Other jobs	6 (4 %)	96 (62 %)	54 (35 %)

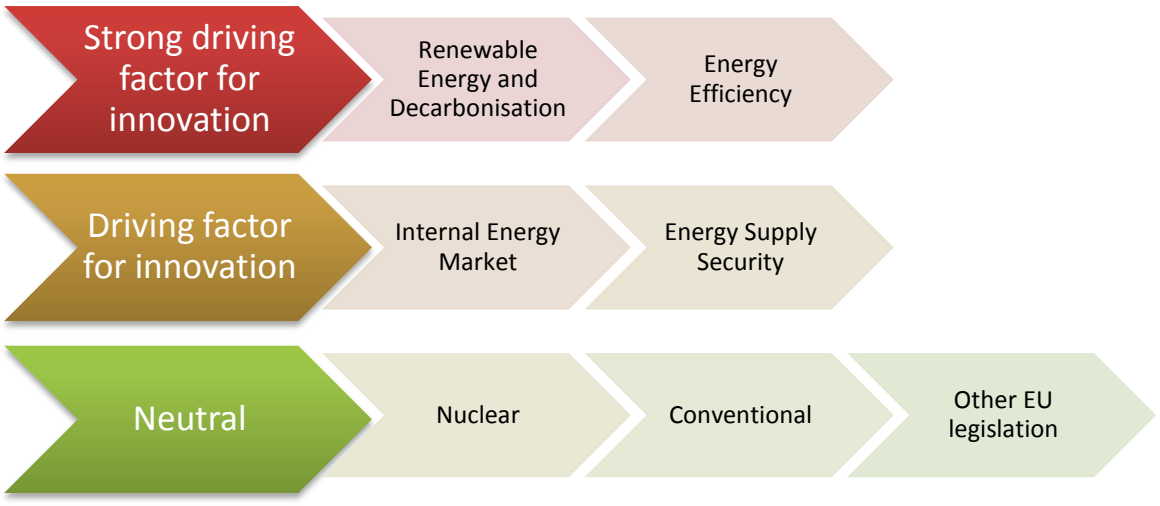
Source: Technopolis Group

3.1.6. Conclusions

The impacts of regulation on innovation concerning the energy sector can be generally regarded as positive. Most survey respondents and further interviewees reiterated this. Nevertheless, given the broadness and diversity of the energy fields, some fields 'benefit' from regulation more than others as summarised in Figure 7. According to 80% of the survey respondents, energy sector regulation is strongly driving renewable energy, decarbonisation, and energy efficiency. Linked to the effects of regulation are a number of aspects such as a timely update with the most recent state of the art but also the lack of regulation which is seen in particular in new and upcoming energy areas or where the market/technology development is too fast to react in time on a regulatory basis.

While EU regulation as such is seen mainly as a driver, a perceived barrier to innovation is a non-harmonised implementation of EU legal provisions in the various MS. EU-wide standardisation and common definitions are necessary and their lack prevents fair competition for all with similar framework conditions.

Figure 7: Energy fields and their impacts on innovation



Source: Technopolis Group

Case studies in the Renewable Energy Directive and in the Ecodesign and Labelling Directives also indicate their positive impacts on innovation. They conclude that a positive impact on innovation is typically found in the later stages of the innovation process (product diffusion). However, in some cases, there is also an impact on the earlier stages (process innovation) e.g. through the regulation on pumps within the framework of the Ecodesign Directive.

A caveat of the analysis is linked to the broadness of the field. 'Energy' merits to be broken down into fields and to be individually addressed. This will enable more detailed analysis, insights and understanding of the impacts of individual regulatory bundles. Tackling the broad field only provides more general insights which may not be fully equally applicable to all sub fields. In addition, the perceptions about regulations change with the stage of the value chain and the products' and processes' level of maturity. Thus, in the energy field, a differentiated and somewhat regular analysis is needed to assess regulations and their changing impacts on innovation.

3.2. The food sector

3.2.1. Introduction

In recent years, the food industry[23] has been confronted with several challenges, including government regulations, that have had an impact on the sector's innovation activities, and consequently on its competitive performance. To better understand the impact of the EU's legal and regulatory framework on the food sector, a survey and interviews were held with representatives of the European food sector. Quantitative methods were used to assess the economic effects of this framework as regards innovation. Together with the results of analytical work done in previous studies on this subject, the following is a short summary of the regulatory framework and mapping of the actor landscape involved in the regulatory governance, a snapshot of the food sectoral innovation system, an assessment of how the regulatory framework has triggered or hampered innovation in the food sector, an economic analysis of the effects of investment in innovative solutions during the period 2013-2015, and economic projections for additional investment, innovation potential and job creation in Europe. In the last section, the main conclusions on the impact of regulation on innovation in the food sector are summarised.

3.2.2. Snapshot of recent regulatory initiatives in the food sector

Regulatory governance in the sector

Several actors play an important role in the development and implementation of legislation in the food sector at the EU level. The main ones are the European Commission (EC), the European Parliament (EP) and the Council of the European Union. Furthermore, Member State governments and parliaments also play an important role since they contribute to policymaking through the Council and transpose legislation from the EU into national law. The food sector is represented, for instance, by FoodDrinkEurope (the European food and drink industry organisation). The most important stakeholder group is made of consumers and their organisations; BEUC is the European Consumer Organisation.

The EC has the power to propose legislation, and the EP and Council are in charge of passing legislation. The EC is then responsible for enforcing legislative acts. National Member State governments are responsible for transposing EU legislation into national laws. Two important advisory organisations concerned with food safety are the European Food Safety Authority (EFSA) and the Scientific Committee on Food:

- The EFSA is an independent agency responsible for risk assessment (Jongen & Meulenberg, 2005)[24]. Its mission is "*to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks*.'' In general, the EFSA gives independent scientific advice on food safety, operates rapid alert systems, communicates with consumers about food safety and health issues, and networks with national agencies and scientific organisations. EFSA's Scientific Panels and Scientific Committee (whose members are appointed through an open selection procedure) provide scientific advice on food safety issues.
- The Committee on the Food Chain and Animal Health was established to replace committees on foodstuff, plant health, feeding stuffs and the Standing Veterinary Committee. It decides whether the EC can go ahead with its proposals. If the Committee does not reach a positive decision, the EC is obliged to present its proposal to the Council, where ministers decide.

Recent regulatory initiatives in the sector: introduction and implementation

Until the BSE crisis in the mid-1990s, European food law developed with a focus on the creation of a European internal market for food. Along with other food crises, BSE changed the focus of food legislation towards food safety law. The design for this transition was published in the White Paper on Food Safety published in 2000 (COM 1999, 719 final) which was aimed at restoring and maintaining consumer confidence. A considerable number of laws and policy initiatives were part of the plans in the White Paper. It reviewed existing food legislation aiming to make it more coherent, comprehensive, up to date, and to strengthen enforcement. Furthermore, the establishment of the EFSA (see above) was planned, giving it the role of providing the EC with analysis.

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[23] In this report, the name 'food industry' or 'food sector' is used for what officially – using NACE nomenclature – is called the food and drinks industry

[24] Jongen, W. and Meulenberg, W. (eds.) (2005). Innovation in Agri-Food systems. Product quality and consumer preferences. Wageningen Academic Publishers

In the White Paper, a new legal framework was proposed to cover the whole food chain, including animal feed production. The primary responsibility for safe food was attributed to industry, producers and suppliers. In addition, an important issue was the ability to trace products through the whole food chain. Two years after the White Paper was published, the new food law was set out, in form of Regulation 178/2002. This regulation is often referred to as the General Food Law. Its main objectives are to lay down the principles of food law in the EU, the establishment of the EFSA, and the setting up of procedures for food safety crises. The Rapid alert system for food safety crises was implemented by COM Regulation 16/2011 in January 2011, *"laying down implementing measures for the Rapid alert system for food and feed".*

Alongside the General Food Law and Regulation 16/2011, more than 75 other Directives, Regulations and Decisions related to food safety exist at EU level. The most important areas of food legislation are presented below:

Labelling and nutrition. With reference to food labelling legislation, Regulation 1169/2011 entered into force in December 2014. As regards nutrition and health claims, rules have been established by Regulation 1924/2006, which is the legal framework used by food business operators when they want to highlight the beneficial effects of their products in relation to health and nutrition. Nutrition and health claims are listed in separate regulations. Health claims must be authorised by the EC based on an assessment done by the EFSA.

Biological safety. Since the food crises in the 1990s, new measures have been taken by the EC to increase food safety levels. Regarding food safety, biological hazards include viruses, bacteria, parasites and prions. Key factors in the new measures include a coordinated and holistic approach to food hygiene, covering all levels of the food chain and applying a transparent hygiene policy to all food and feed operators; and increasing knowledge of sources and trends of pathogens by monitoring zoonotic agents throughout the food and animal feed chain.

Chemical safety. This area deals with contaminants and food contact materials. The principles referring to contaminants are laid down in Regulation 315/93/EEC (as from 1993) while maximum levels for certain contaminants in food are set out in Regulation 1881/2006. Regulation 1935/2004 lays down the general principles of safety and inertness for FCMs, and Regulation 2023/2006 ensures that the manufacturing process is well controlled so that the specifications for FCMs conform with the legislation. There are also regulations concerning specific substances, such as hormones in meat.

Food improvement agents. These include additives, enzymes, flavourings and extraction solvents. The Scientific Committee on Food and/or the EFSA assess which additives are safe and can be placed on the EU list. Regulation EC 1333/2008 sets out the rules on food additives, and Regulation 1334/2008 states general requirements for the safe use of flavourings. The list of flavouring substances was adopted in 2012[25].

Novel food. Novel food can be newly developed, innovative food, food produced using new technologies and production processes, or food traditionally eaten outside the EU. Authorisation and the use of novel foods were harmonised in Regulation (EC) 258/97 in 1997. Novel foods must undergo an assessment after which an authorisation decision may be taken. The Member State issuing the application must make an initial assessment and determine whether an additional assessment is required. In 2008, the Commission presented a proposal to amend the 1997 regulation with a simpler, clearer and more efficient authorisation procedure fully centralised at EU level. The new Regulation was adopted on 25 November 2015 (EU 2015/2283) and will be applicable from 1 January 2018.

Intellectual property rights. These are related to novel food. The renewed Novel Food Law (which was adopted in 2015 and entered into force at the end of 2017) gives companies five years to protect the (scientific) data they had to produce to get a permit to bring a novel food product on to the market, after the product is launched on the market. The data cannot be used for a new application without the permission of the first applicant which used this data.

Food for specific groups. Recently, an important topic in the food industry has been food for specific groups, such as people with gluten intolerance or infants. Furthermore, throughout the EU there is a lack of uniformity on certain aspects, such as the substances that can be added to food for special groups. Compositional and labelling rules are also lacking for various foods for special groups, along with insufficient consistency and clarity on gluten-free foods. The new Regulation 69-2013 addresses these issues and has applied since 20 July 2016.

25 See: https://www.fsai.ie/uploadedFiles/Reg872_2012.pdf

Packaging. Since 2004, Regulations 1935/2004/EC and 450/2009/EC have set the legal basis for their correct use, safety and marketing of food-packaging materials.

Food Waste. Prevention of food waste has become an integral part of the Commission's Circular Economy Package, consisting of an EU Action Plan for the Circular Economy (adopted by the Commission on 2 December 2015). This plan holds legislative proposals on waste, including a revised proposed directive on waste (Directive 2008/98/EC).

3.2.3. Snapshot of the food sectoral innovation system

Research interest in the innovation behaviour in companies has mainly focused on high-tech industries. However, innovators in low- and medium-tech industries are of comparatively greater importance for their national economies: figures for the food industry show that they generate new products and processes that contribute more to the economic growth of countries than the high-tech industries[26].

Sectoral innovation system dynamics

The food and drinks sector accounted for EUR 1,089 billion of turnover, 1.8 % of EU gross added value and 4.25 million jobs in the EU-27 (2016 data). With 15.6 % of turnover in total EU manufacturing, it is one of the major European manufacturing industries (2016).

The economic and innovation performance of the food and drinks sector should be seen in close relation to and dependent on the performance of other parts of the food and drinks value chain, which includes agriculture, biotechnology (for food testing, safety, ingredients, and nutritional research), material sciences (for packaging), ICT (for transport and logistics), wholesale and retail trade, and food services (catering, bars, canteens and restaurants).

Overall, the European food and drinks sector is a low innovative industry with an R&D intensity of 0.27 %.[27] In 2016, the sector's R&D expenditure amounted to EUR 2.5 billion (in 2012 it was EUR 2.8 billion).

The sector is dominated by small and medium-sized enterprises (SMEs)[28]: they comprise more than 90 % of the total number of companies and accounted for almost half of total sectoral turnover (49.5%) and 62.8% of total employment (2016 data).. There are considerable differences in innovation performance between large firms and SMEs. The share of large companies engaged in innovation is more than twice that of small companies. This applies for innovation activities in goods, services and processes, and for the market introduction of new or significantly improved products and services and the introduction of new production methods. The share of large firms introducing new products on the market is twice as high as the share of small firms doing so. The differences are less pronounced for the introduction of products new to the firm but not new to the market. Leis et al. (2011) conclude that large companies are the innovation leaders as they bring new products to the market, whereas SMEs seem to adopt successful products and processes.

Specific parts of the food and drinks sector are more innovative than others. In terms of the share of total food innovations in Europe, the dairy sector (also active in food ingredients) and ready meals, soft drinks, savoury frozen products and biscuits were the largest innovators – 2014 EU R&D Scoreboard). In 2015, the leading reasons for innovation in Europe were reported as pleasure (57 %), health and convenience (both 18 %)[29].

However, it should also be noted that many product innovations in this sector are characterised by a low level of replicability – it is very easy for other companies to copy products and market them. Retailers often practice this approach with their own labels.

Moreover, not all innovative ideas become successful innovations. About one out of three newly launched consumer food products fail on the market[30]. Prior to a potential market entry, innovations can fail, for instance due to certain regulations (e.g. medicinal functional foods, the use of nano-sized particles as food ingredients or genetically modified ingredients are all difficult to

26 See for instance the data from EUROSTAT on the food sectoral, available on their website and also published in the 'Economic Bulletins of FoodDrinkEurope', see: http://www.fooddrinkeurope.eu/publications/category/key-data/ and the data on low-, medium- and high-tech industries presented in: Sandven, T. et al. (2005). Structural change growth and innovation: the role of medium-sized and low-tech industries, 1980-2000. In: Hirsch-Kreisen, H. et al. (eds.), Low-tech Innovation in the Knowledge Economy. Peter Lang, Frankfurt-am-Main

27 Respective R&D intensity levels were for Japan (2009 data) 0.73 %, USA (2010 data) 0.57 % and Korea 0.36 %

28 According to the EC's definition, SMEs are companies with an annual turnover of less than EUR 50 million and fewer than 250 employees

29 World Innovation Panorama (2016). See: http://www.xtcworldinnovation.com/default.asp?id=84

30 Van Poppel, A. (1999). Nieuwe producten. Te veel missers. Trends 13 May, 78-79

implement), or may be too expensive to develop (e.g. new processing methods for improving a product's healthiness or to reduce energy consumption during processing). Regulation may also act as a driver for innovation – for example, research into natural preservatives to reduce the consumption of certain 'artificial' ingredients (Leis et al. 2011).

Food speciality ingredients

European companies that develop and produce food speciality ingredients for the so-called business-to-business market tend to be quite innovative. They spend between 4-6 % of their turnover on R&D. In Europe, about 200 companies are active in the food ingredients sub-sector, and the EU market value for speciality ingredients is about EUR 14 billion[31].

In terms of regulation, companies in this sub-sector often deal with the Novel Food Regulation, as well as regulations on claims and labelling, since some of their products are new foods and sold with health claims (such as healthy ageing products, and ingredients that replace dietary fibre or remove allergenic properties).

Compared to other food categories, the development of speciality ingredients is both time consuming taking from four to 10 years and rather expensive. Development costs of new (novel) food products with health/nutrition claims range from EUR 15-20 million, new ingredients with health claims between EUR 3-5 million, new ingredients without health claims range from EUR 2-3 million, and new formulations of existing products cost about EUR 0.2-2 million[32]. On average, these products are on the market between five to 15 years, while some even stay up to 20 years. For more simple reformulations of existing products, the market life may be much shorter (one to three years).

Challenges impacting innovation in the food industry

Apart from the regulatory challenges impacting on innovation in the food industry (see below), the food and drinks industry faces the following key challenges:

- **Growing dominance of the retailers** (and their own private labels). Retailers – which are both clients and competitors of food-producing companies – copy product concepts from these companies which has resulted in a situation whereby certain product categories have disappeared from the market in some countries. If a large retailer is not willing to bring a new private label product on to the market, the market for such a new product outside large retailers is often too small and the financial risk too high for the food company. The dominant role of retailers has a negative effect on innovation in the food industry, especially for SMEs.
- **Sustainability** is an important issue, not only in terms of reducing specific resources such as energy but also creating less food waste. Industry is asking for clear regulation concepts and rules on how sustainability can create a level regulatory playing field. They are also recommending integrating sustainability in the food sector's innovation agenda.
- **Perceived consumer mistrust** in the food industry. Some consumer groups are very critical and in their communications, give very negative connotations to the processed character of the food industry's products[33]. Also, food product ingredient lists which include the chemical terminology of ingredients (for natural products, too), scares some consumers (chemophobia). Because of this, companies have withdrawn products from or refrained from putting new ones on the market. Labelling was introduced to inform the consumer about the quality of the food product so they are able to make an informed choice. The industry has introduced logos, too, but the current label and logo overload is also confusing for the consumer.
- **Fragmented R&D&I** in Europe. In the past, the EU has stimulated collaboration across Europe between companies in the sector in its Framework Programmes. However, the budget for food innovation projects in H2020 is limited. ETP Food for Life has developed a Strategic Research and Innovation Agenda[34]. The large – most often multinational – companies in this sector that have worked together in EU programmes would like to start large-scale projects on innovation which are closer to the market than research projects (i.e. allow for higher TRL levels).

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31 Brooks, G. (2016). Economic impact assessment of EU food-related regulations on research, innovation and competitiveness in the specialty food ingredients. For the Federation of European Specialty Food Ingredients Industries (ELC). Graham Brooks. GBC Ltd. January 2016

32 See footnote 31

33 Given the various food scandals, there seems to be mistrust not only by consumer protection groups but also directly from the consumers themselves

34 Available at: http://etp.fooddrinkeurope.eu/

3.2.4. Regulatory impacts on the food sectoral innovation system

This section addresses the central question of the study: what is the impact of regulation on innovation in the food sector? Two complementary methods were used: a survey followed by a series of interviews. The survey respondents were asked questions on the impact of general regulations (not specific for a sector) and sector-related regulations on innovation activities in their sector. The response rate from the food sector was rather low: 48 respondents answered the food-sector-related questions. The interviewees were also asked some of the other questions in the survey; and the interviews were used to interpret the survey outcomes of the survey.

Impact of general regulatory measures

When comparing the results of the food sector with those of the other three sectors in this study, it can be seen that overall they are similar. However, the food sector can be distinguished by the respondents' rather contrasting perception of types of regulation. In considering 'conflicting requirements' and 'environmental protection regulation', the food sector respondents appear to be the most negative among the four sectors. They are also the most extreme when it comes to 'labelling' (most negative, but also second most positive), 'product safety' (most positive, but also second most negative) and 'trade agreements' (most positive and most negative).

The respondents belong to three sub-groups (primary production, i.e. agriculture, food manufacturing, other[35]). It is to be expected that perceptions would differ between the agriculture sub-group and the manufacturing sub-group. When analysing the responses in more detail, it was found that the outcomes for several regulations show considerable differences between the primary sector (agro) and the food manufacturing companies. This applies to:

- Procurement: the food manufacturers are only positive, while respondents from the agricultural group are mainly negative;
- Trade: the agricultural respondents are mostly negative, but the food manufacturing part is somewhat more positive;
- Environmental policies: the food manufacturing part is split between very positive and very negative perceptions while the agricultural part is mainly very positive and much less negative;
- Competition law and labelling: again, the food manufacturing part is split into more positive and more negative views than the sector's agricultural sub-group;
- Dedicated sectoral policies: here, the agro part is divided into more positive and more negative opinions than the food manufacturing group.

Impact of food-sector-related regulatory measures

In the survey, specific food sector legislation and regulations were listed under the following six headings:

Biological safety	Labelling and nutrition
Chemical safety	Novel food legislation
Food improvement agents	Animal nutrition

Asked about the possible impact on innovation, the respondents' opinions were rather similar as to whether it is a barrier, a driver, or is neutral. One exception applies to legislation relating to food improvement agents where less than 25 % of respondents identified this as a barrier to innovation.

There are – sometimes considerable, but also comprehensible – differences between the food manufacturing sub-group and the agro sub-group:

- In terms of biological safety, the agro sub-group is more negative than the food manufacturing representatives.

[35] Food - primary refers to those survey respondents who report being in the food sector while at the same time are in the group of NACE sectors corresponding to primary sectors: sectors 01–03 Agriculture, forestry and fishing. Food - manufacturing includes those survey respondents who report being in the food sector while at the same time are in the group of NACE sectors corresponding to food manufacturing sectors: sectors 10–12 Manufacture of food products, beverages and tobacco products

- Regulations in food improvement agents, labelling and nutrition, as well as novel food legislation: here, the food manufacturing respondents are less positive and, in some cases, much more negative than the primary sub-group sector respondents.

In addition, interviewees mentioned specific examples of regulations that had a **positive impact** on innovation in their sector:

- The General Food Law
- Food safety regulations
- The Regulation on Food for Specific Groups 609/2013/EU. Article 11(2) of the regulation has the potential to play an important role in developing innovative products for specific groups[36]
- Infant formula regulation (Commission Delegated Regulation EU 2016/127). The directions given in the regulation fostered research projects which have led to an improvement in the stability of specific food supplements used in infant foods
- Limiting the use of trans-fatty acids, which is currently being discussed in Europe, will create the need to develop or find other ingredients or replacements.

A positive role of regulations for innovation in the food industry – especially the General Food Law and the food safety regulations – was also identified in several other studies[37]. The strict food safety requirements and the high quality of products provide a comparative advantage for EU manufacturers.

Regulations with a **negative impact** on innovation in the food sector mentioned by the interviewees are:

- Novel Food Regulation. The need for consecutive authorisation procedures to use a novel food ingredient in a composed food product (food supplement, fortified food, food for specific groups) creates a lengthy and burdensome exercise compared to the practice carried out in non-EU countries and regions. It has been the case that, despite a positive risk assessment by the EFSA and the Commission's proposal to approve the use of a certain substance/material, the European Parliament has rejected the approval[38]. The scope of the recently revised Novel Food Regulation (to be implemented by the end of 2017) is not very clear, requires a lot of data, and needs clarification by means of a Commission Guidance.
- Claims legislation. Protection of the data companies must provide when they apply for a health claim for their product is rather limited, which hampers firms, especially SMEs, trying to develop such products. In addition, this legislation has eliminated some products that were already on the market with a claim communicated before the claim regulation came into force but which could not be substantiated. Also, the criteria for nutrition claims do not allow for the possibility to inform consumers in case of a small reduction in sugar, salt and fat (see 'Need for European Nutrition Policy Framework').
- Labelling. As consumers are afraid of food ingredients with a chemical name, food companies are not inclined to use such ingredients in their food products as they must be mentioned on the label. Food additives must always be called by their chemical names. This does not apply to food flavours that are added to food; here it is sufficient to include the name 'flavour' on the label.
- Pesticide Regulation. Regulation 396/2005/EC on maximum residue levels of pesticides in or on food and feed of plant and animal origin has laid down harmonised levels for pesticide residues in food and feed in the EU. The definition of "residues" in Article 3 is too broad and has led to several problems in the case of substances which may have more than one source. Multiple-use substances are by default treated as pesticide residues (e.g. chlorates) and thus create unjustified compliance issues.
- The too-narrowly-defined conditions for the use of sweeteners (Directive 94/35/EC of 30 June 1994) prevent the utilisation of sweeteners to contribute to innovative product reformulation of products with an improved nutrition profile, with very few exceptions. The regulation is a hurdle for sugar and energy-reduction initiatives and for innovation/reformulation in various

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36 It empowers the European Commission to update delegated acts on food for specific groups by "taking into account relevant technical and scientific progress, including data provided by interested parties in relation to innovative products", for instance with respect to the legal requirements of their composition

37 Leis, M., Gijsbers, G., Van der Zee, F. (2011). Food and Drinks sector. Final Report. Sectoral Innovation Watch, TNO and EASME (2015) Competitive position EU F&D industry

38 As one interviewee indicated: "As a company one needs to have a very strong business case in order to allow investments in a novel food product; it needs a strategic investment decision"

product categories (most commercial breakfast cereals do not meet the conditions of use as currently stipulated).

- The lack of regulation at EU-level on food-contact materials (EC No 1935/2004). Several packaging materials (such as paper and carton, adhesives, varnishes and coatings, printing inks) are not regulated at the EU level, which has resulted in regulations being developed at the national level. In particular for SMEs, but also for other companies with limited capacity to analyse the national requirements, this is having a negative effect on the development and marketing of new and improved products.

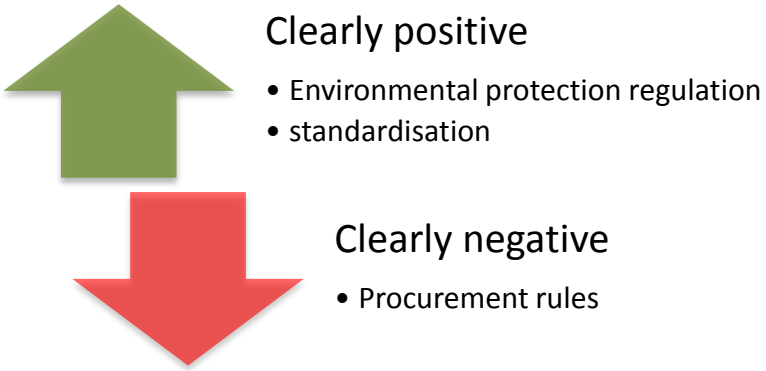
Apart from the effects mentioned by interviewees and in the survey, desk research revealed a negative impact of some broader regulations such as fiscal measures and taxation regimes.

Explanations for the neutral effect of regulation on innovation

One of the striking results from the survey is that the answers to most questions on the role of a specific regulations show that they can both hinder and drive innovation. This does not only apply to the food-specific regulations but includes some general regulations such as competition law (state aid rules), dedicated sectoral policies, labelling and trade agreements.

A clear positive or negative impact on innovation in the food sector could only be established for a few regulations listed in our survey (see Figure 8).

Figure 8: Clear impact of specific regulation in the food sector



Source: Technopolis Group

Interviews with representatives of companies and organisations in the European food sector were used to find an explanation for this outcome.

The most common answer to the question "How can a specific regulation have both effects?" was that this should be interpreted from a sequential perspective: when a new legislation is introduced, it often works as a 'ban effect'. For instance, in cases where ingredients in products or specific processes are forbidden due to safety reasons, or no science-based health claims can be made, or the chemical name of an ingredient must be mentioned on the product label, this often leads to these products being withdrawn from the market. However, once the regulation has been implemented, harmonisation becomes a fact (i.e. a new level playing field is created) and companies have adapted to the new situation, this is the point when the new situation becomes both a challenge and an opportunity. As companies have the capacity to innovate, they will develop new or improved products and processes (depending on their position in the supply chain). Entrepreneurs look for new opportunities and start new, innovative activities. As consumer confidence is crucial in this sector, companies that stick to the new legislation tend to gain consumers' trust.

Interviewees also noticed the positive impact of the strict, solid and sometimes also restrictive EU regulation. They observed that European food products are seen as high-quality products, which is key for facilitating exports outside of the EU. Since border control of these goods happens quite quickly, the strict EU regulation helps the sector with its exports. It seems that the stringency of EU food regulation is also being adopted by other regions: interviewees observed that the softer US regulations are moving closer to Europe's more stringent rules.

Impact of non-uniform EU regulation implementation

The interviews indicated that non-uniform implementation within Europe is an important hurdle to innovation. The non-harmonised internal market is perceived as one of the main problems for the food sector.

- Uniform implementation of EU regulation in all Member States provides for a level playing field for competing food companies. Examples of a lack of EU regulation were mentioned in the limited character of the EU's harmonised food-contact materials legal framework, missing nutrient profiles in the Nutrition and Health Claims Regulation, or the missing maximum limits for vitamins and minerals in the Food Supplements Regulation. In addition, the non-harmonised interpretations of EU Food Law must be added here.
- Existing conflicting requirements between EU regulations and national Member State regulations hamper innovation. Some Member States are currently developing rules on the country of origin labelling of food even though this area is regulated at EU level in the EU Food Information to Consumers Regulation (the so-called EU-FIC).
- Examples of conflicting requirements between EU regulations that were mentioned by interviewees are the Nutrition and Health Claims Regulation which, in some aspects, is neither aligned to the EU-FIC nor to the Directive on Natural Mineral Waters. Regulating is lacking on the use of mineral oil in paper and cardboard used for food packaging: recycled paper can contain significant quantities of mineral oils that might migrate from the cardboard to the foodstuff and therefore are not suitable for food packaging.

Innovative firms struggle with **a lack of clarity concerning European regulations**:

- Complicated and complex legal texts. The wording of some regulations is complex, and appears to be incoherent or difficult to interpret and apply. Examples mentioned include the Additives Regulation (latest version Regulation (EC) 231/2012)), where new exceptions are added rather frequently, making it highly complex.
- Definitions that are too broad. Definitions provided in legislative texts are sometimes formulated rather ambiguously or too broadly. Companies mentioned that for new ingredients they had developed, they were unable – due to the multi-interpretability of terms – to answer the simple question: is this new ingredient a novel food, yes or no? They went to both their Member States and to the EU to ask for clarification and it was apparent that the answers they received were not coherent. Interviewees also mentioned the biocide regulation here.

Non-stringent regulations bring uncertainty to the sector, in particular when different interpretations in Member States hamper EU-wide harmonisation, or when definitions are in the process of being clarified or changed. As one interviewee indicated: "Uncertainty can kill a product". Predictability and legal certainty are important foundations for developing innovations.

Gaps in EU legislation

The interviewees mentioned several gaps in EU legislation which impact negatively on innovation. One frequently mentioned gap concerns the **missing nutrient profiles** in the Nutrition and Health Claims Regulation 1924/2006/EC. This regulation states in Article 4 that by 19 January 2009 the Commission shall establish specific nutrient profiles – which still has not been done. The setting of such profiles would encourage food companies to reformulate their food products or to even develop new innovative ones to fulfil the requirements of the nutrient profiles and thus to be able to make nutrition and health claims on them. Interviewees also mention the **very limited data protection** that is laid down in the claims regulation, which acts as a barrier for companies to invest significantly in R&D to substantiate the health claim for a new ingredient/product.

A similar example is the **lack of setting harmonised maximum limits for vitamins and minerals** in the Regulation on the addition of vitamins and minerals and of certain other substances to foods 1925/2006/EC as well as the Directive on food supplements 2002/46/EC. When these regulations were introduced, 10 and 14 years ago respectively, the setting of such limits was announced. The missing European limits led to a situation whereby Member States developed different national rules with widely diverging requirements. Food companies had to respond by developing different variants of their products (sometimes also without the supplements) for each Member State, which increased the costs of product development (with specific recipes) considerably.

Several regulations **lack specifications** for food for young children or other groups, such as older people. This applies for the Food for Specific Groups (FSG) Regulation 609/2013/EU, the Food Information to Consumers Regulation 1169/2011/EU and the Annex to Nutrition and Health Claims Regulation 1924/2006/EC.

The food industry **needs a European Nutrition Policy Framework**. Such a framework would set out what levels of salt, saturated fats and added sugars are acceptable from a health perspective. It would "*not only guide healthier recipes, but also bring the long-term predictability needed to support investments in health-related innovation across the industry*"[39].

In addition to consumer protection, **sustainable development will become an important basis for regulation** in the food industry. This requires new regulations with clear definitions (such as for the 'circular economy', 'eco designs', or 'waste'), rules that have to be agreed upon between the various parts of the value chain, and new financial models which must be developed. Questions on liability have to be answered; for instance, who pays for the degradation of the cardboard boxes used to transport food products: the box producer, the food industry that uses these boxes, or the company recycling them?

EU response to company feedback on regulation

Interviewees also reflected on the question as to if and in what way the EU has dealt with the problems with regulation European food companies are experiencing in their sector.

- They appreciate the reorganisation within DG SANTE (Health and Food Safety), bringing together the two units which previously dealt with food (and feed) safety regulations separately in one unit, the Directorate E Food and Feed Safety, Innovation.
- The EU is aware of the problems the food industry has with some of the regulations, especially the Novel Food and Claims Regulations. The Novel Food Regulation has been simplified and a time frame for the approval procedure set. This will lift the uncertainty about how long an approval period will last. In addition, all approvals follow the same procedure. It has taken seven years to develop this simplification process, but the new regulation will come into force by the end of 2017/beginning 2018.
- The EC writes so-called Guidance Documents to explain a regulation and help companies to interpret the text. Sometimes there are even Guidance documents on a Guidance document. The Commission's DG SANTE has a helpdesk and organises one-to-one meetings if necessary, with Member States also providing help.

These developments are the results of many workshops[40] and other events held with Member States, stakeholders[41] and the Ispra-based Joint Research Centre of the EC (which also includes safety of consumer products and food security) designed to make regulations more transparent and simple for the sector.

3.2.5. Economic impact and projections

Impact of regulation on innovation expenditure and jobs

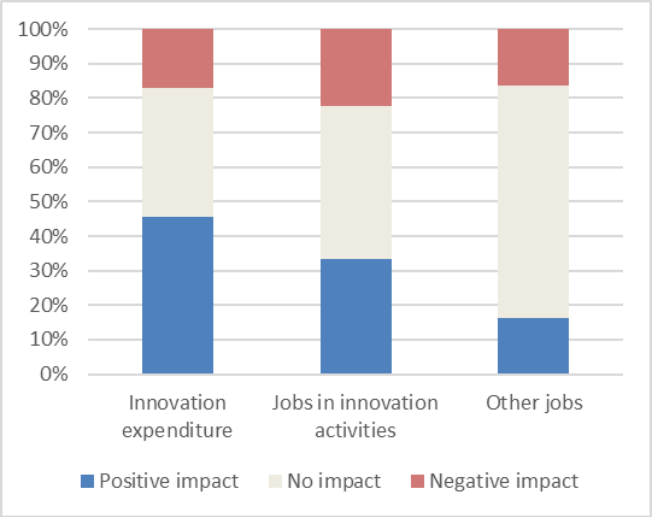
In the survey, respondents were asked about the impact of regulation on their innovation expenditure, on jobs in innovation activities and other types of jobs in their company (in full-time equivalents), over the past three years (2013-2015). The results show that the net impact of regulation on all three indicators was positive (see Figure 9).

[39] See also: http://www.foodnavigator.com/Policy/Nestle-calls-for-strictly-regulated-EU-nutrition-policy and http://www.foodnavigator.com/Market-Trends/Nestle-Reformulation-could-stall-without-EU-wide-nutrition-strategy

[40] See for instance: http://ec.europa.eu/dgs/health_food-safety/information_sources/events/20151010_food_innovation_en.htm

[41] For one of these meetings, FoodDrinkEurope prepared the document 'Framework conditions for sectorial research and innovation' on regulatory barriers to innovation in the food sector and recommendations on how to address them

Figure 9: Impact of regulation on expenditure and jobs in the food sector (2013-2015)



Source: Technopolis Group

Note: impact on innovation expenditure: N = 35; on jobs in innovation activities: N = 36; on other jobs = 37

Impact on innovation expenditure until 2030

Calculations of the potential impact of addressing regulatory barriers to innovation expenditure until 2030 (in thousands of euros, for five-year periods) show that the removal of existing regulatory barriers to innovation in this sector by 2030 could lead to an increase of about EUR 3-7 billion in innovation expenditure.

Table 7: Future impact of barrier removal on innovation expenditure (EUR billion)*

	Direct full impact from 2017		Progressive impact over 15 years	
	Low estimate	High estimate	Low estimate	High estimate
Annual average	0.4	0.8	0.2	0.5
Total 2016-2020	1.4	3.3	0.3	0.6
Total 2021-2025	1.9	4.5	1	2.2
Total 2026-2030	2.1	4.9	1.8	4.2
Total 2016-2030	5.4	12.6	3	7

Source: Technopolis Group
Note: direct full impact: the percentages above are directly applied for each year over 2017-2030; progressive impact: the percentage of impact in 2016+n is the percentage above multiplied by n/14 (linear progression)
** An initial number for innovation expenditure of EUR 9 992 992 thousand euros in 2012 was used. This is the sum of the different types of innovation expenditure by innovative companies, including R&D, for sectors NACE 10-12 from CIS. The evolution of annual innovation expenditure was calculated for the sector over 2016-2030.*

Impact on job growth until 2030

The removal of barriers to innovation in the food sector would have a positive impact on job creation, leading to an increase of 4-9% of jobs in innovation activities by 2030, compared to a situation with barriers. In absolute figures, by 2030, the total potential impact on employment in innovative firms over the period is calculated at close to an increase of up to 200 000 jobs (using the higher estimate).

Table 8: Future impact of barrier removal on job growth (in thousands)*

	Number of jobs created (in thousands)	
	Low estimate	High estimate
Annual average	5	13
Total 2016-2020	8	18
Total 2021-2025	27	64
Total 2026-2030	46	109
Total 2016-2030	80	191

Source: Technopolis Group

** The calculation was done by estimating the number of jobs in innovative companies in 2030 and the difference in a situation without barriers, using as initial number of jobs in innovative companies of 2 375 627 jobs in 2012 (Source: CIS)*

3.2.6. Conclusions

The main conclusions on the impact of regulation on innovation in the food sector are:

- The overall impact of regulation ranges from neutral to positive; a small net positive impact on innovation expenditure and job growth was measured;
- A lack of EU regulation which provides for harmonised rules for a number of important issues has been recognised;
- New regulations can have considerable negative impacts, often leading to the withdrawal of products from the market place;
- However, as soon as the playing field has been levelled, the new situation creates new challenges and – given the entrepreneurial and innovative capacities available – new opportunities;
- Lack of clarity and stringency in a regulation, rendering the texts as complex constructions, often with unclear definitions, and requiring layers of Guidance documents) create uncertainties which negatively affect innovative activities in the food sector;
- Economic projections show that the removal of regulatory barriers in Europe will lead to a rise in innovation expenditure of EUR 3-7 billion and an increase in innovation jobs by 4-9 % by 2030.

3.3. The health sector

3.3.1. Introduction

The following section provides a snapshot of recent EU legislation and regulatory impacts, health sector performance, an assessment of the drivers of and barriers to innovation and finally, an economic analysis, including projections.

3.3.2. Snapshot of regulatory initiatives in the health sector

To understand innovation in health, it is important to bear in mind that the nature of the EU's regulatory capacities in this field are quite limited in scope compared to other sectors. For this reason, an explanation of the current policy framework at EU level provides important context for this sectoral study.

The EU's strategic direction in the field of health is primarily elaborated in the EU Health Strategy 'Together for Health'. The strategy outlines four core principles: i) shared health values; ii) health is the greatest wealth; iii) health in all policies; and iv) strengthening the EU's voice in global health – and three main objectives: i) fostering good health in an ageing Europe; ii) protecting citizens from health threats; and iii) supporting dynamic health systems and new technologies.

Implementation of the EU's policy objectives can happen through various ways, including: i) implementing legislation; ii) providing financial instruments for investment; and iii) supporting and facilitating cooperation both between and within Member States. Of key importance to this sector are **EU actions implemented through legislative measures**. As stipulated in the Health Strategy, the EU can adopt health legislation under the Treaty of the Functioning of the European Union (TFEU).

Regulatory actors and governance in the sector

At EU level, legislation attempts to provide harmonised rules to ensure the quality, safety and efficacy of healthcare products which can be placed on the market. However, as evidenced by the TFEU, the EU has limited powers to act in the field of health, with a majority of health responsibilities resting with the Member States, and not the EU.

In addition to the limited powers, the EU's Commissioner for Health and DG Health and Food Safety (SANTE) are only responsible for part of the EU's health powers, which are fragmented across the European Commission. DG Research and Innovation (RTD), DG Internal Market, Industry, Entrepreneurship and SMEs (GROW), DG Competition (COMP), DG Communications Networks, Content and Technology (CNECT), DG Employment, Social Affairs and Inclusion (EMPL), DG Justice and Consumers (DG JUST), DG Regional and Urban Policy (REGIO) and DG Trade (TRADE) also play important roles. This differs significantly from the situation in Member States where, typically, health ministries are responsible for the majority of health-related public-sector activities.

Recent regulatory initiatives in the sector

The EU has implemented legislative measures specifically related to healthcare matters, as well as ensuring such issues are covered by legislation in other areas. The most extensive area within which the EU has provided legislation relates to pharmaceuticals and medical devices. Examples include: clinical trials pharmacovigilance; falsified medicinal products; medicines for children; advanced therapy medicinal products (ATMP); medicinal products for human use (including marketing authorisation); orphan medicinal products; medical devices and *in vitro* diagnostic medical devices; price transparency; and parallel imports of proprietary medicines.

The most recent EU foray into the regulation of the pharmaceuticals industry comes in the form of the Clinical Trials Regulation (No 536/2014), the responsibility of DG SANTE, which will enter into force towards the end of 2018. This regulation aims to foster an environment that is favourable for conducting clinical trials across all EU Member States, respecting the highest standards of patient safety. In addition, the Commission's revision process of the directives related to medical devices has reached the advanced trilogue stage[42]. Medical devices is an area seen as a key source of innovation in healthcare and the medical device industry is considered to be one of the most innovative sectors in Europe[43].

Other areas of legislation that have an impact in the health sector include:

- Patents
- Patients' rights in cross-border healthcare
- Coordination of social security systems
- Biocidal products
- Chemicals (Registration, Evaluation, Authorisation and Restriction of Chemicals – REACH)

More general regulations that will have important implications for EU healthcare, as noted by representatives of DG RTD interviewed for this sectoral analysis, also include the General Data Protection Regulation (GDPR)[44]and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)[45].

3.3.3. Snapshot of the health sector innovation system

The healthcare sector accounts for 8 % of the total European workforce and 10 % of the EU's GDP; and in 2010, public spending on healthcare accounted for almost 15 % of all government expenditure.[46] Although healthcare has high potential for innovation and growth, the European Commission has identified a number of innovation challenges affecting the healthcare sector in the EU[47]. For example, getting a new medicine from bench to bedside can take between 10 and 20 years and may cost more than EUR 1 billion[48] (although such cost estimates remain controversial).

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[42] For more information see: http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision_en

[43] SWD(2012) 273 final

[44] http://ec.europa.eu/justice/data-protection/reform/index_en.htm

[45] http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

[46] EC (2013). Investing in Health. Commission Staff Working Document Social Investment Package: http://ec.europa.eu/health/strategy/docs/swd_investing_in_health_en.pdf

[47] EC Innovation in Healthcare From Research to Market to Health-systems to Patient, Main conclusions from 2010, 2011, 2012 conferences https://ec.europa.eu/research/health/pdf/innovation-in-healthcare-overview-report_en.pdf

[48] Ibid

For every new drug or medical device that hits the market, hundreds of potential medicines or fledgling technologies fall by the wayside.

It is reported that the pharmaceutical industry believes that EU research priorities have focused too much on fundamental research at the expense of projects which have greater potential to result in new products[49]. In addition, too many ideas fail to make the leap from research to commercialisation.

The EU is trying to boost innovation in health through a number of programmes and initiatives. These activities include funding instruments such as Horizon 2020 (H2020), particularly SC1 and the dedicated SME instrument[50], or the Innovative Medicines Initiative (IMI); collaboration networks such as the European Innovation Partnership on Active and Healthy Ageing (EIPonAHA), the Expert Panel on Effective Ways of Investing in Health (EXPH), European Reference Networks (ERNs), and the EIT-Health (in the framework of the European Institute of Innovation and Technology), among other initiatives encompassing innovation in health.

Innovation performance

According to Eurostat, a number of data sources can be used to measure innovation, including R&D expenditure and patent statistics. An analysis of these data is presented below.

R&D expenditure

In terms of R&D expenditure, the 2015 EU R&D Scoreboard provides data on two relevant industrial sectors: 'Pharmaceuticals & Biotechnology' and 'Health Care Equipment & Services'. In the EU, both of these health-related sectors have seen significant R&D growth. Pharmaceuticals & Biotechnology have registered growth on the previous year of 6.5 %, while Health Care Equipment & Services recorded a growth of 8 % – two of the top three industries in terms of R&D growth. When combining these sectors, the EU comprises 37 % of global R&D expenditure, compared with 46 % for the US. A comparison reveals a gap between the US and EU health industries, particularly in the field of biotechnology. In fact, the US contributes 54.7 % of global R&D investment in the biotechnology sector while the EU contributes …..

R&D expenditure for entities producing pharmaceutical products in the EU-28 has increased significantly since 2005, peaking in 2011, falling again in 2012 before rising in 2013. The biggest contributors to this EU-28 figure in 2013 were Belgium, Spain, the United Kingdom, Austria and the Netherlands. Incomplete data are also available for Switzerland, showing that, for the two years for which figures are available, Switzerland spent 73 % (2008) and 104 % (2012) of the EU total on R&D. These data suggest a keen focus on R&D in Switzerland in comparison to the EU, which makes sense since large pharmaceutical companies such as Novartis or Roche are based in this country. Investment per inhabitant has been steadily increasing since 2005, peaking in 2013 at EUR 831 per individual. In 2013, the largest contributors to this figure were Denmark, Belgium, Sweden, Slovenia and Germany.

The pharmaceutical industry had been facing a crisis in R&D productivity for over 20 years[51]. For a long time, significant investment increases in R&D have not corresponded to a greater output of new, approved drugs. One of the reasons for this trend was reported to be the increased strictness and fragmentation of the regulatory framework across the EU, which results in more expensive testing[52]. More recently, industry representatives have reported that the pharmaceutical industry is emerging from this crisis. For example, a recent European Federation of Pharmaceutical Industries and Associations (EFPIA) report[53] has shown that the number of new therapy drugs (NTD) per year nearly doubled from 2010-2014[54]. However, converting R&D expenditure into innovation and new products remains an ongoing concern for pharmaceutical companies.

Other relevant health industries have reported R&D and innovation challenges as a result of regulatory frameworks. In biotechnology, for example, it has been stated that two stages of the value chain – R&D, comprising basic and translational research and product development, and manufacturing – are greatly influenced by the state of regulatory frameworks, with differences in national implementation causing particular challenges. Challenges that intersect with and can be addressed by the EU regulatory framework, according to representatives of the European

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49 Ibid

50 https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020

51 Pammolli, F., Magazzini, L. & Riccaboni, M. (2011) The productivity crisis in pharmaceutical R&D, *Nature Reviews Drug Discovery* 10, 428-438 (June 2011)

52 ECORYS (2009) Competitiveness of the EU Market and Industry for Pharmaceuticals, Volume II: Markets, Innovation & Regulation

53 EFPIA (2015) Growth and competitiveness of the pharmaceutical industry

54 Asher, M. (2015). 2014 FDA drug approvals. *Nature reviews drug discovery*, 14, pp. 77-81

biotechnology industries, include: difficulties regarding the cross-border provision of highly innovative products (e.g. ATMPs) due to non-harmonised product classifications; ensuring Europe is an attractive and appropriate location for bio-manufacturing; and facing the global competition for clinical trials work, given the European Commission estimate that the number of clinical trials conducted in the EU fell by 25 % between 2007-2011[55].

Patents

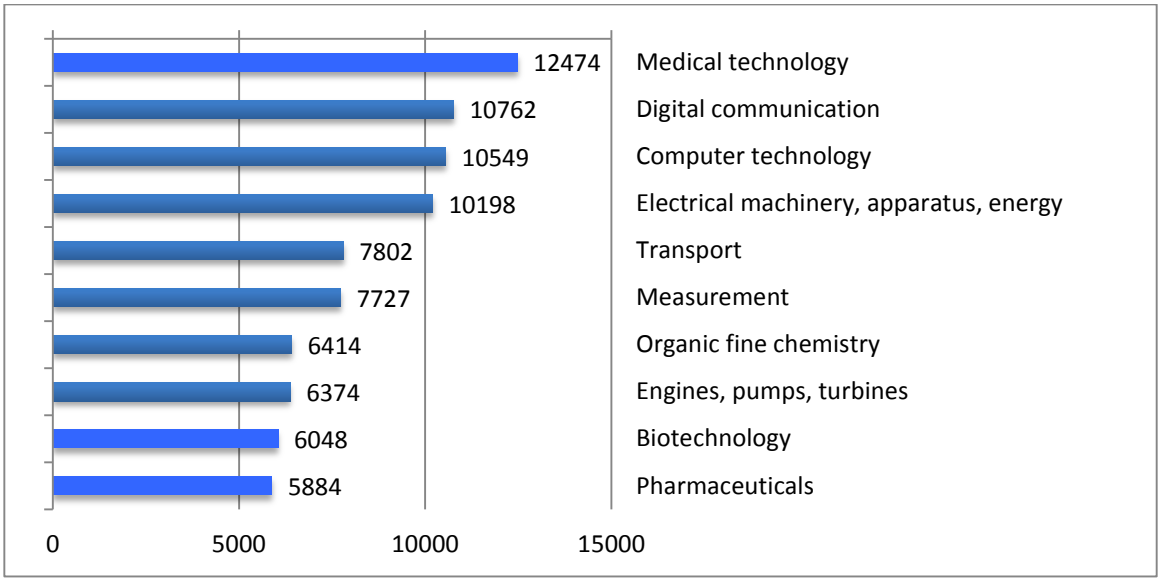
In terms of patents, the 2011 Innovation Union Competitiveness report states that, in the field of health technologies, the US accounted for almost half of all health-related patents in the world, for both pharmaceutical products and medical technologies[56]. The 2013 Competitiveness report documents a very similar situation. Beyond the US, however, individual Member States, including Denmark, the Netherlands, Sweden and Germany, are leaders in health-related technologies. These countries are generating patents at a similar rate to, or above, those seen in China, South Korea, Russia, India and Brazil.

With regard to health-related patent applications under WIPOs Patent Cooperation Treaty (PCT), the 2013 Competitiveness report states that Germany and the UK are the largest producers within the EU, but Denmark and Sweden have a higher number of PCTs per GDP[57]. Globally, the US and Japan have the greatest concentration of PCT patents in health, while Israel and Iceland have the highest number of PCT applications per billion GDP. The report also illustrates the significant outputs that India and China, emerging global players, already have in terms of total number of patents in health.

According to the European Patent Office (EPO) and WIPO priority patents data[58], half of the top 20 countries in number of patent applications are EU Member States, but the leading EU patent applicant, Germany, is a long way behind the US, the global leader. At company level, most patent applicants in EU-MS are European companies. Globally, although the company with the highest number of patent applications is located in the EU (the Dutch company Philips), only six other EU-based companies or organisation make it into the top 25 companies globally, compared with 10 US and six Japanese companies.

In terms of the fields within health, data from the EPO show that medical technology was the leading technology field in 2015 with 12 474 patent applications submitted. Biotechnology and pharmaceuticals were also among the top leading patenting that year.

Figure 10: Leading patenting industries/sectors (EPO applications, 2015)



Source: EPO

Applications in the field of medical technology have been increasing over the years, whereas the biotechnology and pharmaceutical applications have remained relatively stable, with slight fluctuations over the nine-year period. In 2015, the number of pharmaceutical applications fell

55 Information provided by representatives of EuropaBio
56 European Commission (2011) Innovation Union Competitiveness report
57 European Commission (2013) Innovation Union Competitiveness report
58 Frietsch et al. 2016

slightly compared to 2006, while biotechnology applications rose slightly. A similar trend can be found in terms of the patents granted by the EPO in the three sub-sectors. Given the significant increases in R&D expenditure, the data suggest there are challenges for R&D productivity in these health industries, as discussed above.

Looking at the number of patents applications by firm in Europe, the leading companies in 2015 are Philips for medical technology, Merck & Co for pharmaceuticals, and DSM for biotechnology.

Medical technology

According to the medical technology (medtech) industry, there are almost 25 000 medical technology companies in Europe. Most of them are based in Germany, followed by the UK, Italy, Switzerland, Spain and France. Although most of the above firms are large companies, 95 % of Europe's 25 000 companies are SMEs[59]. According to their own data, the industry provides over 575 000 jobs in Europe and in 2014 delivered a positive trade balance of EUR 14 billion. The industry estimates that 7.5 % of health expenditure in Europe is on medical technologies (6.7 % on medical devices and 0.8 % on *in-vitro* diagnostics). The industry also estimates that the largest medtech markets in Europe are Germany (28 %), France (16 %), UK (12 %), Italy (10 %) and Spain (5 %). Worldwide, the biggest markets are the US (39 %), Europe (31 %) and far behind Japan (9 %) and China (6 %).

Within the European medtech sector, the medical devices field is considered one of the most innovative sectors in Europe[60]. On average, innovation in this sector becomes available in Europe around 18 months earlier than in the US and more than two years earlier than in Japan.

The above information suggests that the European medtech sector has been performing well under the current medical devices/medical technology regulatory framework. However, a recent impact assessment undertaken to explore options to update the regulatory framework recognises that it is necessary to improve safety and prevent Member States from adopting varying product regulations that could result in further fragmentation of the internal market[61]. The proposed revision aims, among other things, "to provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry".

The proposed changes to the regulation do not aim to significantly alter the current framework by, for example, introducing a market authorisation process, and it is expected that new measures will not impact the speed with which medical devices are approved in the EU. Studies comparing the approval system in the US and the EU note that the Federal Drugs Administration (FDA) system has received criticism for being too slow, risk adverse, and expensive compared with to the European system[62]. However, they also note that there is an increased risk of post-marketing safety alerts and recalls for devices that have been approved first in the EU[63].

Sorenson and Drummond (2014) note that although the two regulatory systems are different in many respects, both jurisdictions face similar challenges for ensuring that only safe and effective devices reach the market, monitoring real-world use, and exchanging pertinent information on devices with key users such as clinicians and patients[64]. Some of these challenges may be addressed by the EU with the proposed changes to the legislation, but it remains to be seen how these changes may impact innovation and whether the new proposed system drives innovation rather than hindering it.

Pharmaceuticals

According to an EFPIA report, the European pharmaceutical industry grew considerably between 2000 and 2014[65]. Production increased from EUR 126 316 million in 2000 to EUR 221 088 million in 2014 (estimate for 2015 is EUR 225 000 million). The largest share of pharmaceutical production in 2014 is attributed to Switzerland (EUR 35 819 million), followed by Germany (EUR 30 401 million), Italy (EUR 28 696 million), France (EUR 20 981 million) and the UK (EUR 17 483 million). The

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59 MedTech Europe. The European medical technology industry in figures. Available from: http://www.medtecheurope.org/sites/default/files/resource_items/files/MEDTECH_FactFigures_ONLINE3.pdf

60 SWD(2012) 273 final

61 Ibid

62 Kramer, D. B., Xu, S., & Kesselheim, A. S. (2012). Regulation of Medical Devices in the United States and European Union. *New England Journal of Medicine*, 366(9), 848-855: https://doi.org/10.1056/NEJMhle1113918

63 Hwang, T. J., Sokolov, E., Franklin, J. M., & Kesselheim, A. S. (2016). Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study. *BMJ*, *353*, i3323: https://doi.org/10.1136/bmj.i3323

64 Sorensen, C. & Drummond, M. (2014). Improving Medical Device Regulation: The United States and Europe in Perspective. *The Milbank Quarterly*, *92*(1), 114-150: https://doi.org/10.1111/1468-0009.12043

65 EFPIA (2016) The Pharmaceutical Industry in Figures. Key figures 2016

trade balance also grew from EUR 22 094 million in 2000 to an estimated EUR 86 500 million in 2015 (EUR 73 025 million in 2014). Again, the European country with a larger trade balance is Switzerland (EUR 31 609 million) followed by Germany (EUR 22 643 million) and Ireland (EUR 17 726 million).

The EFPIA report also states that the pharma industry invested EUR 30 887 million in R&D in 2014 (rising to EUR 31 500 million estimated for 2015), and that it directly employs more than 723 000 people. The total pharmaceutical market value at ex-factory prices was estimated at EUR 192 000 million in 2015 (EUR 183 924 million in 2014). However, although all these indicators show that pharmaceuticals are becoming high performers, the industry is facing important challenges, especially with regard to driving innovation in the sector:

- There is rapid growth in the market and research environment in emerging economies such as Brazil, China and India, leading to a gradual migration of economic and research activities from Europe to these fast-growing markets.
- During the period 2010-2015, 58 % of sales of new medicines launched were on the US market, compared with 23 % on the European market, and from 2011-2015, the number of new chemical or biological entities brought to market in the US (89) is higher than for Europe (75).
- The industry argues that the fragmentation of the EU pharmaceutical market has resulted in a lucrative parallel trade, estimated at EUR 5589 million (value at ex-factory prices) in 2014, depriving the industry of additional revenues which, at least in part, could also be resources to fund R&D. Fragmentation, however, has also created opportunities within the industry in terms of, for example, allowing a differentiated pricing strategy

Marketing authorisation of new medicinal products is considered a critical step in giving the public access to innovative therapies that are needed to fill unmet medical needs[66]. Although the trend is towards rising R&D expenditure, the number of newly developed medicines submitted to regulatory agencies has not increased. The study also recognises that the determinants of successful marketing authorisation are still not clear even when good regulatory tools have been developed.

According to the data presented in the study, the number of approved new active substances remained relatively stable since the introduction of Regulation (EC) No 726/2004 until 2011 when 25 new active substances entered the European market and 32 new active substances were made available in the US. However, the trend may be changing as, in 2015, the European Medicines Agency (EMA) recommended 93 medicines for marketing authorisation, including recommendations for 39 new active substances[67]. Recommendations for medicines containing active substances that had never been used in medicines before were 41 in 2014, 38 in 2013 and 35 in 2012[68].

In the EFPIA report mentioned above, the pharma industry points out some important challenges in terms of the pharmaceutical development process, although these are only partially related to the market authorisation process in the EU:

- By the time a medicinal product reaches the market, an average of 12-13 years will have passed since the first synthesis of the new active substance (10 years of R&D, plus two to three years of administrative procedures);
- The cost of researching and developing a new chemical or biological entity was estimated at EUR 1926 million in 2013[69];
- On average, only one to two out of every 10 000 substances synthesised in laboratories will successfully pass all stages of development required to become a marketable medicine.

Clinical trials are an important factor affecting the time it takes to develop new drugs in the EU. The impact assessment on the revision of the Clinical Trials Directive 2001/20/EC has acknowledged that problems with the clinical trials regulatory framework in the EU had greatly reduced Europe's competitiveness in the field of clinical research, negatively impacting on the development of new and innovative treatments and medicines[70]. The new Clinical Trials Regulation EU No 536/2014 has tried to address the issues but, since it has only recently come into force, its

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66 Putzeist, M. (2015). Marketing authorisation of new medicines in the EU: towards evidence-based improvement. Available from: http://apps.who.int/medicinedocs/documents/s21298en/s21298en.pdf

67 EMA (2016) Annual Report 2015

68 EMA (2015) Annual Report 2014

69 DiMasi, J. A., Grabowski, H. G. & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47, 20–33, in: EFPIA: The Pharmaceutical Industry in Figures. Key figures 2016

70 SWD(2012) 201 final

effects are still to be measured. Stakeholders' views and expectations about the regulatory changes are presented below.

Biotechnology

According to the European Commission, around 20 % of the medicines currently in the European biopharmaceutical sector are derived from biotechnology, as well as up to 50 % of new medicines[71]. In recent years, the US has strengthened its science and technology leadership in relation to health and biotechnologies, with the EU falling further behind in these areas[72].

An Ernst & Young and Europabio 2014 report shows that the US and Europe are the largest biotech markets in terms of number of healthcare biotech companies, ahead of Canada and Australia, the other two established biotech centres[73]. The industry employed 51 740 people in Europe, which is almost half of the 100 100 people employed in this sector in the US in 2012. The EY-Europabio reports also notes that while revenues of European publicly traded healthcare biotech companies grew between 2010 and 2012, R&D expense declined by 1 % in 2012, probably an effect of the 2008 global economic crisis.

Two areas of healthcare biotechnology regulated at EU level are rare diseases and ATMPs. For example, in the case of rare diseases and orphan medicines, the trend also seems to be improving, showing that although the impact of regulation is difficult to measure, in the long term, implications of the regulations tend to be positive[74].

In 2000, the EU developed its Orphan Drug Regulation after the US (1983) and other countries such as Japan (1993), Singapore (1997) and Australia (1998) did the same[75]. The legislation in both the US and EU follow similar principles, such as granting prolonged market exclusivity to orphan drugs. There are, however, some differences: while in the US the emphasis is on demonstrating the scientific rationale and disease prevalence, in the EU there are two additional requirements: i) that the condition is life-threatening or seriously debilitating, and ii) that there is currently either no satisfactory method (of diagnosis, prevention or treatment) or that the new product will be of significant benefit over the existing method. This means that in the EU the applicant needs to provide a solid argument as to why the new method is expected to be superior to what is already on the market. An additional challenge in the EU is that the criteria for authorisation require demonstrating prevalence in the European Community, not only in one or two countries, and that there may be very little information available for many rare diseases. The process of orphan designation in the EU, which can take up to six month, is considered more complicated than that in the US.

In 2014, the EMA recommended the highest number of orphan designated medicines for marketing authorisation in a year. Of the 82 medicines for human use recommended that year, 17 were intended for the treatment of a rare disease[76]. Several studies have also concluded that orphan drug legislation in the EU has contributed enormously to promoting drug development for rare diseases, and they also show a strong relationship between orphan drug development and pharmaceutical innovation performance in Europe[77].

In contrast to this positive assessment, stakeholders also recognise that the orphan medicines regulations allow for a certain level of opportunistic behaviour by companies. It is considered that in some cases companies apply for a medicine to be granted orphan status before switching its application once the status is granted. However, stakeholders representing patients with rare diseases find that the level of this behaviour is not significant when compared to the benefits afforded to patients with rare diseases as a result of these regulations.

To summarise, the EU is a strong global player with regard to innovation across a number of health industries. However, the dominance of the US in certain areas and the increasing presence of emerging players, such as China, is an ongoing challenge for and threat to the EU.

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71 http://ec.europa.eu/programmes/horizon2020/en/area/biotechnology

72 European Commission, DG RTD (2013) Innovation Union Competitiveness report

73 EY & Europabio (2014) Biotechnology in Europe. The tax, finance and regulatory framework and global policy comparison

74 Blind, K. (2012). The Impact of Regulation on Innovation. NESTA Working Paper 12/02

75 Europe and the US. Intractable & Rare Diseases Research, 3(1), 1-7

76 EMA (2015). Record number of medicines for rare diseases recommended for approval in 2014

77 See for example: Mizoguchi, H., Yamanaka, T. & Kano, S. (2016). Research and drug development activities in rare diseases: differences between Japan and Europe regarding influence of prevalence. *Drug Discovery Today*. and Heemstra, H. E., de Vrueh, R. L. A., van Weely, S., Büller, H. A. & Leufkens, H. G. M. (2008). Orphan drug development across Europe: bottlenecks and opportunities. *Drug Discovery Today*, *13*(15-16), 670-676

3.3.4. Regulatory impacts on the health sectoral innovation system

In relation to the healthcare sector, the EC[78] has found that regulatory obstacles are an important barrier to getting bright ideas to patients. This is particularly relevant for SMEs. Although regulation is perceived as necessary to meet high patient safety standards, it is also acknowledged that innovators are faced with expensive, complex and fragmented systems for approving new products.

Some of these issues have been raised, and expanded upon, through the survey undertaken as part of this study. Respondents were asked to identify specific EU legal/regulatory instruments that hamper innovation in health. The most prominent health themes where barriers are perceived include: medical devices/technology; pharmaceuticals (including clinical trials, HTA and ATMP regulation); patenting rules; and data protection and privacy issues. The main barrier reported across these themes concerns *inconsistent application of regulation* among the Member States. Respondents state that this results in uncertainty over national requirements and, therefore, it is very costly to become familiar with, and adapt to, different regulatory environments. Furthermore, respondents have highlighted EU funding instruments as a barrier to innovation spanning these health themes. For example, one respondent pointed out the "strict financial viability rules" as a barrier for SMEs, while another stated that EU funding mechanisms focus on academia and public services but do not stimulate the presence of R&D and innovative technology products in the market.

In contrast to the discussions on barriers presented above, the survey findings, illustrated below, demonstrate that the net impact of EU legislation is perceived as positive. As regards expenditure on innovation, for example, only 18 % of respondents consider that EU regulation has had a negative impact over the past three years. The majority (52 %) consider that no impact has been experienced with almost a third (30 %) reporting that EU regulation has had a positive impact on innovation expenditure. Similarly, for jobs in innovation activities, only 15 % reported that EU regulation has had a negative impact, with 49 % reporting no impact and 36 % reporting a positive impact.

When broken down by health themes, legislation is perceived to act more as a driver of innovation than a barrier in all themes except 'blood, tissues and organs'. In seven of 15 themes, EU legislation was viewed primarily as a 'driver'. The most prominent examples include medical devices/technologies; patient safety; pharmaceuticals (including clinical trials); and rare diseases. For four themes, the primary perception of respondents on the impact of EU legislation on innovation activities was 'neutral'. This perception is only particularly strong for preparedness and response. In the four remaining themes: one (EU legislation on 'blood, tissues and organs') is primarily perceived to be a 'barrier'; and three elicit responses of 'not applicable' (EU legislation on 'illicit drugs', 'tobacco' and 'vaccination').

The survey received responses from a wide range of stakeholders, including 196 health-specific responses from entities including for-profit and not-for-profit private organisations, as well as public and academic institutions. These entities span at least 21 EU Member States and Switzerland.

In the interviews conducted as part of this sectoral study, and echoing the survey findings mentioned above, **EU-level regulation** is not perceived in general as hindering innovation. In fact, for several stakeholders, regulation is not only necessary for safety issues, but also **generally drives innovation**.

It has been mentioned that barriers to innovation transcend the regulatory framework in the health sector, and issues affecting innovation may be related to: limited EU competences in health; other policy issues beyond legislation; low level of funding at EU and national level; national implementation of the EU regulatory framework; the slow pace in which the health sector innovates; or the interplay between protecting safety and promoting innovation. Stakeholders have referred to some of these issues as "structural barriers" affecting innovation. According to them, structural barriers related to regulation in the pharmaceutical sector include, for example, extra requirements for vaccines to prove efficacy once they are on the market, or pricing and reimbursement regulation for innovative medicines, which forces the comparison of new products with existing ones. Lack of both harmonisation and regulation in some areas (e.g. health technology assessments) has also been perceived as problematic.

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78 EC Innovation in Healthcare From Research to Market to Health-systems to Patient, Main conclusions from 2010, 2011, 2012 conferences, see https://ec.europa.eu/research/health/pdf/innovation-in-healthcare-overview-report_en.pdf

Below are the collected views on a number of regulatory measures specifically referred to across the interviews:

Medicinal products: all stakeholders noted that the EU regulatory framework for medicinal products has generally acted as a driver and has provided pharmaceutical companies with a unified framework for market authorisation for products (Marketing Authorisation Regulation (EC) No 726/2004). However, some stakeholders noted that the current process allowing for different authorisation mechanisms remains complex. They pointed out that the implementation of EU legislation on, for example, pharmacovigilance and paediatrics medicines, which they have qualified as "non-pragmatic", has led to a high regulatory burden, taking up unnecessary resources. Other stakeholders noted, however, that the main barriers included in the legislation are due to safety issues and the protection of intellectual property rights. They also noted that high standards of safety are important as currently many patients and carers do not trust drugs, which can be an issue, and that the framework in which the European pharmaceutical industry operates is negotiated internationally. They also remark that the industry has experienced strong economic growth in recent years.

Clinical trials: stakeholders welcomed the introduction of the new Clinical Trials Regulation 536/2014 for its aims to streamline the process of applying, assessing and conducting a trial as this creates a more transparent, predictable environment, ensures patient safety and accelerates access to innovative treatments. However, these stakeholders also identified some areas where the new regulation may hamper innovation. A succinct summary of these areas was provided in a written response by relevant industry associations (EFPIA, EBE and VE). Although they welcomed the EU Clinical Trials Regulation, they raised "*significant concerns that changes introduced to Annex VI of the EU Clinical Trial Regulation could risk product quality by increasing the handling required to effect* [sic!] *shelf life extensions to investigational medicinal products (IMP) labelling, potentially increasing the risk to patients. The provisions in Annex VI may also adversely impact EU competitiveness by limiting innovation, such as use of interactive response technology (IRT) and increasing administrative burden and cost.*"

Orphan medicines: this is an area where stakeholders pointed out that regulation (Regulation (EC) No 141/2000; Regulation (EC) No 847/2000) has acted as a driver for innovation, demonstrated by growing approval rates of medicines for rare diseases since the legislation came into effect. It was noted that only eight products were available on the market for rare disease patients when the legislation was introduced. In the 15 years since, this number has increased beyond 100. Stakeholders also expressed concern over some of the provisions in the current proposed update, stating that they may raise the regulatory burden for companies without "clearly stated benefits for the patient". It was also noted that some evidence requirements might be unattainable for certain rare diseases.

As mentioned in the previous section, stakeholders have recognised that the orphan medicine regulations allow for a certain level of opportunistic behaviour by companies. Nevertheless, the stakeholders consulted in this study found that the level of this behaviour was insignificant when considered against the benefits afforded to patients with rare diseases as a result of these regulations.

Advanced Therapy Medicinal Products: stakeholders noted that while regulatory efforts (Regulation (EC) No 1394/2007) in this area can be considered as innovation drivers, the divergent and non-harmonised implementation of exemptions in Member States acts as a barrier to innovation by "*creating secondary regulatory pathways and by creating conditions that can distort markets (Art 28 (2) 'hospital exemptions*)".

General Data Protection Regulation (Regulation (EU) 2016/679): in this area, stakeholders noted that the final provisions relating to the use of data for health and research-related activities leaves the regulation of many data movements to national legislation. Further harmonisation and pan-European standards in this field would be welcomed, especially by the pharmaceutical industry, but also by other stakeholders who consider that data protection in the health sector is somewhat misunderstood and that rules protecting data could be relaxed when it is "used for a good cause", while still protecting patient identity.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS): according to stakeholders, the 'due diligence' obligation to ensure a genetic resource has been accessed and is being used in compliance with the laws in the country from where it originates, included in the recently passed EU regulation relating to the enforcement of the Nagoya Protocol, may not be possible in many cases and users of genetic resources may stop using them, creating a negative impact on innovation.

3.3.5. Economic impact and projections

The following projections have been produced by relating perceived impacts by the survey respondents on the role played by regulatory factors (i.e. driver, barrier, neutral factor). The rationale behind this exercise is to estimate the difference in the quantified impact of regulation between a respondent who identifies a given factor as a barrier and a 'similar' (in the econometric sense) respondent who does not consider the factor as a barrier.

The approach does not assume that regulation has an overall net negative impact, but rather that this impact can be either less positive or more negative due to regulatory barriers. The impact, observed in relative terms (i.e. percentages) at the level of the survey respondents, can then be extrapolated to EU level figures using CIS data to get absolute figures.

For the purpose of the projections, data from CIS until 2030 were estimated (based on estimated future growth rates calculated by CEDEFOP for employment or based on recent trends for innovation investments) as a baseline scenario from which the impact in absolute value of addressing barriers has been calculated.

The estimated impact of addressing barriers to innovation for health companies will be approximately:

+2.9 % to +4 % of **innovation expenditures** per year
+1.8 % to +5.1 % of **jobs in innovation activities** compared to a situation with barriers

These rates have been applied to statistics for the sector in order to determine projections until 2030.

Innovation expenditure

To extrapolate this relative impact to absolute figures at the EU level, data on innovation activities from CIS were used. The health sector is not available as a separate category in the CIS statistics. Therefore, statistics for the pharmaceutical sector are used as a basis for measuring the potential impact of addressing regulatory barriers on innovation expenditure (in thousand euros). This potential impact is presented in Table 9 where the data is based on the sum of different types of innovation expenditure, including R&D.

It is projected that regulatory barriers to innovation will cost companies approximately EUR 11-30 billion in terms of innovation expenditure.

Table 9: Health sector (pharmaceutical sector only): estimated projected impact of addressing regulatory barriers on innovation expenditure to 2030 (EUR billion)

	Direct full impact from 2017		Progressive impact over 15 years	
	Low estimate	High estimate	Low estimate	High estimate
Annual average	1.3	2	0.8	1.2
Total 2016-2020	5.2	7.7	0.9	1.4
Total 2021-2025	7	10.5	3.5	5.3
Total 2026-2030	7.7	11.6	6.7	9.9
Total 2016-2030	20	29.9	11.1	16.6

Source: Technopolis Group

Note: direct full impact: the percentages above are directly applied for each year over 2017-2030; progressive impact: the percentage of impact in 2016+n is the percentage above multiplied by n/14 (linear progression)

Jobs in innovation activities

As above, the following projections are based on data from CIS, on this occasion on the number of jobs in innovative companies in the pharmaceutical sector.

It is predicted that the total potential impact on jobs in innovative firms over the period would be around 20 000-30 000 additional jobs. This figure is determined by estimating the number of jobs in innovative companies in 2030 and calculating the difference with the situation without barriers to innovation. This total difference can be averaged by year, as shown in the table below.

Table 10: Health sector (pharmaceutical sector only): estimated projected impact of regulatory barriers on the number of jobs

	Number of jobs created	
	Low estimate	High estimate
Annual average	1500	2100
2016-2030	23 000	32 000

Source: Technopolis Group

3.3.6. Conclusions

The data and information presented in this sectoral study has shown that the EU is a strong global player with regard to innovation across a number of health industries. However, US dominance in certain areas and the increasing presence of emerging players, such as China, are ongoing challenges for and threats to the EU. Although, in the EU, medical technology is the leading technological field in terms of patent applications and patents granted, the sector is dominated by globally operating companies. The US accounted for almost half of all health-related patents in the world, for both pharmaceutical products and medical technologies. In biotechnology, the EU seems to be taking a stronger position in terms of the number of patent applications, as well as R&D investments and the number of biotech companies.

In these areas, several regulations seem to have had an impact on innovation, although it has not been possible to establish clear direct links. For example, the medical technologies/medical devices market in the EU is considered highly innovative, yet the current legislation is being revised to address safety concerns and disparities in the Single Market. Although one of the objectives of the proposed policy options to amend medical device regulation aims at driving innovation, it remains to be seen how this is implemented. In the field of pharmaceuticals and biotechnologies, the regulations for market authorisation, clinical trials and orphan drugs have also been assessed in the light of the EU's innovation performance. The Clinical Trials Regulation, identified as a barrier to innovation, has been recently reviewed and once again its effects need to be assessed. The orphan drugs regulatory framework is widely considered to be innovation-friendly and, according to the patent data analysed and data provided by the industry, it is a market where the EU is playing an increasingly important role. The evolution of the regulatory landscape in the EU seems to have played an important part in bringing about these changes, although this is not the only factor that should be considered.

The survey data analysed for this sectoral study has shown that the net impact of EU legislation is perceived as positive. The most prominent health themes where barriers to innovation are perceived include medical devices/technology; pharmaceuticals (including clinical trials, HTA and ATMP regulation); patenting rules; and data protection and privacy issues. However, the main barrier reported across these themes concerns the inconsistent application of regulation across the Member States. These findings are consistent with the information obtained through interviews with key stakeholders at EU level. For those interviewees, EU-level regulation is not perceived as generally hindering innovation while, for several stakeholders, regulation is not only necessary for safety issues but generally drives innovation, too.

Finally, in terms of the economic projections undertaken for this study, the impact on innovation expenditure is projected at around EUR 11-30 billion and the impact on employment in innovation companies equates to the creation of approximately 100 000 jobs.

3.4. The water sector

3.4.1. Introduction

This analysis of the water sector aims to better understand the EU legal and regulatory framework and to assess its economic effects with regards to innovation. To this end, a broader scoping exercise was performed, including identification of core actors and functions within the innovation system as well as the main governance aspects and framework conditions. Quantitative methods have been used to assess the economic effects of this framework with regards to innovation, as well as complementary interviews with stakeholders. The following sections will summarise the results with a description of the regulatory framework and governance in the field of water in the EU, as well as a snapshot of innovation and challenges in the sector (section 4.4.2). This sets the scene for the analysis of the interactions between the legislative framework and innovation in the sector (section 4.4.3). Section 4.4.4. provides an economic analysis of the effects of investment in innovative solutions, and economic projections for additional investment, innovation potential and job creation in Europe based on the results of the survey of companies and other stakeholders conducted for this study (see chapter 2). Short, in-depth illustrations of challenges facing

innovators in specific innovation areas will be highlighted. The main conclusions on the impact of regulation on innovation in the water sector are provided in the last section.

The overview of regulatory governance and regulation screening builds on a previous screening study on the impact of regulation on innovation in the water sector, which was undertaken for the European Commission in 2013 (see Technopolis Group, 2013). The following regulatory landscape description provides an update of regulatory governance and policy initiatives from 2013-2016.

3.4.2. Snapshot of regulatory initiatives in the water sector

The regulatory governance of the European water sector evolved in 'waves', focusing on regulating water quality (between 1975-1980), then moving to emission limit values (in the 1990s). The third regulatory wave initiated an integrated, river-basin approach with the Water Framework Directive (WFD) in 2000 (see Kaika, 2003).

The WFD sets the framework for water protection and water-quality standards covering the entire water cycle and catering to the cross-border and cross-sector character of the policy issues in the water sector. The WFD set the target that all European surface waters should have achieved 'good ecological quality' and 'good chemical quality' status by 2015, meaning that they should achieve minimum standards for ecological protection (e.g. for protecting the biological community, hydrological characteristics) and minimum quality standards for chemical characteristics (based on standards agreed at European level) (see Annex V of WFD). In the case of European groundwater – aside from common standards for monitoring and managing its quantitative status – the WFD stresses the importance of the water not being polluted at all. Therefore, only a very few minimum standards for the chemical status of the groundwater have been set for specific issues (nitrates, pesticides, biocides), which must be adhered to. For groundwater, the WFD uses the precautionary principle and prohibits direct discharges to groundwater. The Directive also sets requirements for monitoring to detect changes in the chemical composition and ensures measures to prevent contamination. The targets are set at different governance levels: in the case of the most hazardous substances, goals for minimum standards for the chemical status are set at the EU level, while the national level sets goals for less hazardous substances. Ecological status goals are set at the sub-basin level (Green, 2013).

To achieve the WFD priorities, important governance instruments are the river basin management plans, which include programmes of measures to protect and improve the status of the river basins and recurrent assessments of the water status. The programmes of measures also integrate requirements of other water sector regulations and are based on the ecological and chemical status of water targets and other environmental quality standards. Moreover, the WFD requires six-year cycles of monitoring and assessment to track the implementation status and distance from targets.

However, the WFD also offers the possibility of exemptions or postponing the achieving of targets. In this context, the WFD targets set for 2015 have yet to be reached as implementation of the WFD is lagging behind in some Member States. The WFD's fourth implementation report illustrates the large gap remaining in achieving "good" water quality status by 2015. Based on the existing and planned basic measures taken by Member States in a 'business as usual scenario', the water quality status reached is 50 % away from target, while the objective of "good" water status could have been reached if Member States had implemented the supplementary measures recommended by the WFD (European Commission, 2015).

The WFD is accompanied by a stream of related Directives which provide specific requirements for drinking water, bathing water, marine environment, as well as for assessing the risks of floods and drought, or dealing with urban waste water. Furthermore, the complexity of the water system regulation does not stop at water sectorial level, but EU-level legislations in connected sectors, such as waste, energy and agriculture, are equally relevant.

For example, the Urban Waste Water Treatment Directive (UWWTD) focuses on the collection, treatment and discharge of urban waste water and the treatment and discharge of waste water from certain industrial sectors, aiming to protect the environment from the adverse effects of these discharges (91/271/EEC amended by 98/15/EEC). Its 8th Implementation report, published in 2016, mentions the high compliance of the EU-15 Member States with the regulation, but also highlights the poor progress in achieving compliance in EU-13 Member States[79] (see European Commission, 2016).

A recent policy initiative that guides EU governance in the water sector is the Communication on 'A Blueprint to Safeguard Europe's Water Resources' (European Commission, 2012). The Blueprint sets the framework for the EU's policy action with regard to further implementation of the WFD and follows up on the 2011 Resource Efficiency Roadmap (COM(2011) 571). Moreover, the European Innovation Partnership on Water was launched in 2012, building on the Blueprint, in order to

[79] i.e. the EU MS that joined in 2004, 2007 and 2013, with the caveat that Italy and Poland did not provide sufficient workable data, while Croatia did not have to comply until 2012, therefore their progress is slower

mobilise stakeholders and facilitate the development of innovative solutions in the sector in line with the policy objectives set out at EU level.

In December 2015, the European Commission proposed to the Council and the European Parliament a new Circular Economy Package including an Action Plan to provide an integrated framework for the EU's transition towards a circular economy (European Commission et al., 2015a). One of the Action Plan's key proposals in the water sector is to take **measures to promote water reuse** in 2016-17. Specifically, the measures foreseen include: an upcoming regulation on minimum requirements for reused water; a guidance document for Member States to integrate water reuse in water planning and management; and a review of the Best Available Techniques Reference Documents for industrial sectors to promote water reuse in industrial activities, etc.

Another recent key legislative action point is **the update on the fertilisers regulation** launched in 2016 – COM (2016) 157. The proposed policy actions are to "incentivise large-scale fertiliser production in the EU from domestic organic or secondary raw materials in line with the circular economy model, by transforming waste into nutrients for crops". The purpose is to ease access to the market for the fertilisers produced, based on circular economy principles[80].

3.4.3. Snapshot of the water sectoral innovation system

Governance

The water sector is a prime example of EU policy coordination across multi-level governance levels, involving European, national, regional, and territorial actors at the river basin level. This multi-level governance comes with inherent implementation and enforcement challenges. Here, we consider the water sector governance as defined by the actors involved in the decision-making and policy development processes, and the principles for governing the water sector.

At EU level, water has been regulated according to the principles of subsidiarity, which means that the water sector decision-making is a shared responsibility between the Member States and the European institutions, whereby the EU can take action if the results cannot be achieved by national-level actions only. The regulatory process defining EU legislation and regulation in the water sector implies that any legislative initiative in the water sector takes the ordinary legislative procedure approach, involving co-decision from the European Commission, the Council and the European Parliament.

Article 3 of the WFD called for the establishment of international districts for river basins that cover the territory of more than one Member State. Member States must ensure common administrative structures to identify international river basins and administrative structures for them. Therefore, as bodies coordinating international river-basin districts, the International River Basin Commissions and Conventions are important actors in the governance and coordination of implementation of the WFD in the EU Member States. Active River Basin Commissions are, for example, the River Odra, Elbe, Meuse, Danube, Rhine, etc.

Overall, the interlinkages between the European, national and local institutions in the field of water management pose cross-border coordination challenges and require openness to cooperation. The sector needs to be organised according to the physical and geographical configuration of the water resources (for example, across an international river basin).

The national-level management and regulatory responsibilities are allocated based on the territorial configuration of the country's public administration. For instance, in the Netherlands, the water policy institutional stakeholders have water policy and spatial planning responsibilities at the national level, but also regulatory competences at the province level. The regional and municipal levels are generally responsible for the operation and management of the water system and further specific water policy implementation and control activities. However, other countries have chosen a top-down coordination process spanning geographical or public administration boundaries, as in the example of water-sector governance in Portugal. The latter is more centralised, without additional regional layers in the configuration of water management authorities.

The institutional actors in the governance of the water sector at European level are complemented by networks of stakeholders, branch organisations, lobbying associations and innovation platforms. Their role has been in communicating and bridging the gap between the EU-level legislative actors, the national regulators and the voice of the water sector stakeholders. In addition, this type of governance has been characterised as "adaptive", enabling the sharing of management responsibilities and the promotion of participatory practices. However, its success also depends on the networks' management and innovation capacities (Green, 2013).

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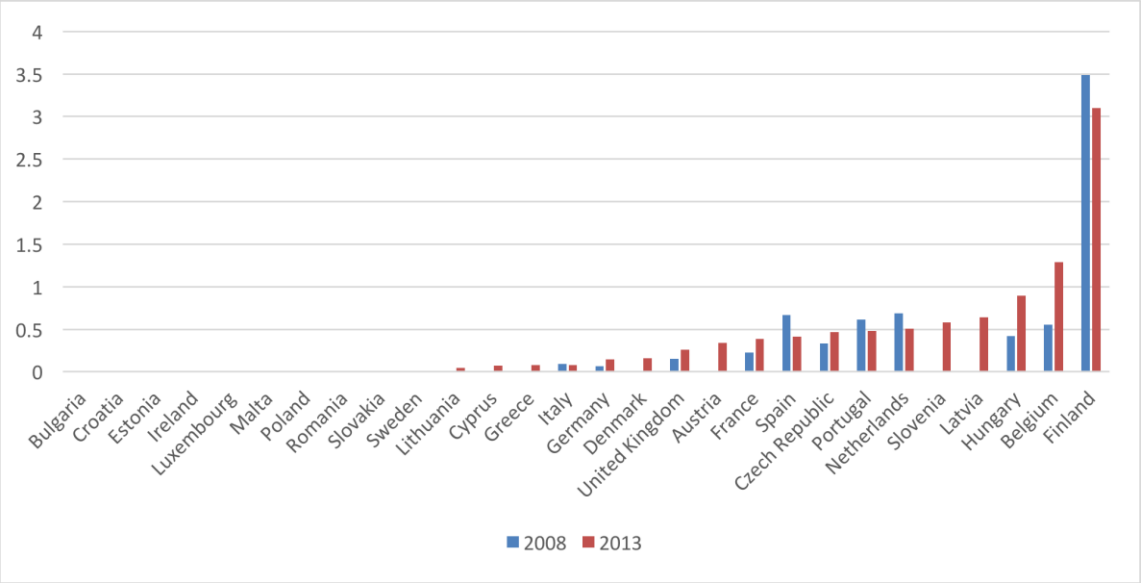
80 The proposal is undergoing the EU legislative co-decision process at the time of writing the report (November 2016), which is why changes may be made to its final provisions

The sector's innovation performance

The countries where companies are investing the most in R&D in the water sector in relation to their population are Spain, Finland, Belgium and Hungary. However, even if Finland is the top investor in R&D in water, the two countries are catching up. Between 2008 and 2013, the business enterprise R&D expenditure (BERD) in Finland decreased by 11 %, while Belgium and Hungary doubled theirs. In recent years, Latvia and Slovenia have also invested heavily in water, spending more per million inhabitants than the Netherlands in 2013.

Figure 11 BERD in water in million PPS 2005 per million inhabitants



Source: Eurostat, World Bank

Innovation activities in the EU water sector have been stable and among the highest in the world, competing with the US and BRICS[81]. The EU's performance reached 2.5 patents per million inhabitants in 2013, having been steady since 1990 (Patstat, Eurostat and World Bank).

Within the EU, the number of patents per country reveals that Member States situated in the north and west of Europe tend to innovate more in the water sector, whether in water supply or water treatment. Overall, in both fields, countries such as Denmark and the Netherlands rank in the top 20 % while others like Croatia and Poland come in the lowest fifth. However, some countries are more innovative in one or other of these two fields, which is the case of Cyprus, a country significantly more innovative in water and waste water than in sewerage.

The water innovation sector is broadly dependent on large manufacturing companies. For instance, in 2011-2013, the top patent applicant firms in Europe were Veolia, Siemens, BASF and Kemira.

Overall, it seems that at EU level the wider innovation system challenges are broadly related to imbalances in innovation performance among Member States, measured by patenting activity. However, it should be noted that innovation performance in the water sector depends on a country's characteristics in terms of economic specialisation, geography, climate and population size. These factors also have an impact on the country's needs in terms of water and can therefore either impede or contribute to innovation. For example, Cyprus, Ireland and the Netherlands, two islands and a country renowned for their water risks, are top innovating countries.

Water sector challenges and technological bottlenecks

A potential challenge in the water innovation system is **matching the pace of innovation to the challenges in the water sector**. There has been an increase in water use in some EU Member States' (such as in Belgium, Spain and Lithuania), which is a growing threat to the water sector (EPRS, 2015). According to the UN World Water Development Report, Europe is not expected to meet 40 % of its water demand by 2030 (UN, 2015). While water quality has improved in the EU following legislative measures such as the Urban Waste Water Treatment Directive, other pollution pressures monitored through the Directive are on the rise, such as agricultural fertilisers or pharmaceuticals (see EEA, 2012).

[81] BRICs countries include Brazil, Russia, India and China. When considering relative numbers of patents, Japan appears the most innovative region by far, reaching 12.3 patents per million inhabitants in 2013 (dropping from a peak of 63.4 in 2000)

The **water challenges** identified by the 2015 WFD fourth implementation review include **pollution** caused by agriculture, **infrastructure challenges** in households with old sewerage collection and treatment systems, and industrial emissions; **over-abstraction** of water affects 10% of surface water bodies and 20% of groundwater bodies; and human interventions in the shape of water bodies that change their flow and physical form.

The European Water Supply and Sanitation Technology Platform (WssTP) identified **technological bottlenecks** in the EU water sector that need to be tackled to help **solve the environmental issues and tackle supply and demand challenges** in this sector. Many interviewees mentioned the need for new and low-cost solutions to improve the real-time collection of intelligence on different aspects of the water sector, and to integrate them within water management and water-treatment processes. For instance, the high water-treatment costs and old infrastructure would benefit from improved and cheaper technologies, particularly new digital technologies for connecting the water sector in the cyber-physical world, such as low-cost sensors and key enabling water-treatment technologies. The development of technologies facilitating the 'internet of things', like software for big data generation, processing, modelling and analysis in the field of water is another growing area (see WssTP, 2016).

There are further challenges related to the need to upgrade European water infrastructure with green and hybrid grey infrastructure solutions, where research and innovation actions from the public and private sector are also needed. The solutions needed are related to new integrated natural and human-built systems (including new materials), novel maintenance technologies and strategies, and systems that enable multiple loops for multiple types or streams of waters (e.g. different water-treatment systems at all levels) (WssTP, 2016).

The European Innovation Partnership on Water has also identified areas where innovations that tackle the challenges facing the water sector and support economic growth must be accelerated. These areas include the fields of water reuse and recycling, water and wastewater treatment, including recovery of resources, water-energy nexus, flood- and drought-risk management, and ecosystem services.

The following addresses the question as to what extent the current regulatory framework either fosters or hampers innovation in the water sector.

3.4.4. Regulatory impacts on the water innovation system

Within our general survey (see chapter 2), there were also specific questions for respondents who identified themselves as belonging to the water sector. Thus, 48 responses were provided by this water sector. This section provides an overview of the respondents' perceptions of barriers and drivers and the effect of specific regulations.

The key results from the survey whereby water-sector companies responded to the question whether general regulations are drivers or barriers to innovation can be summarised as follows:

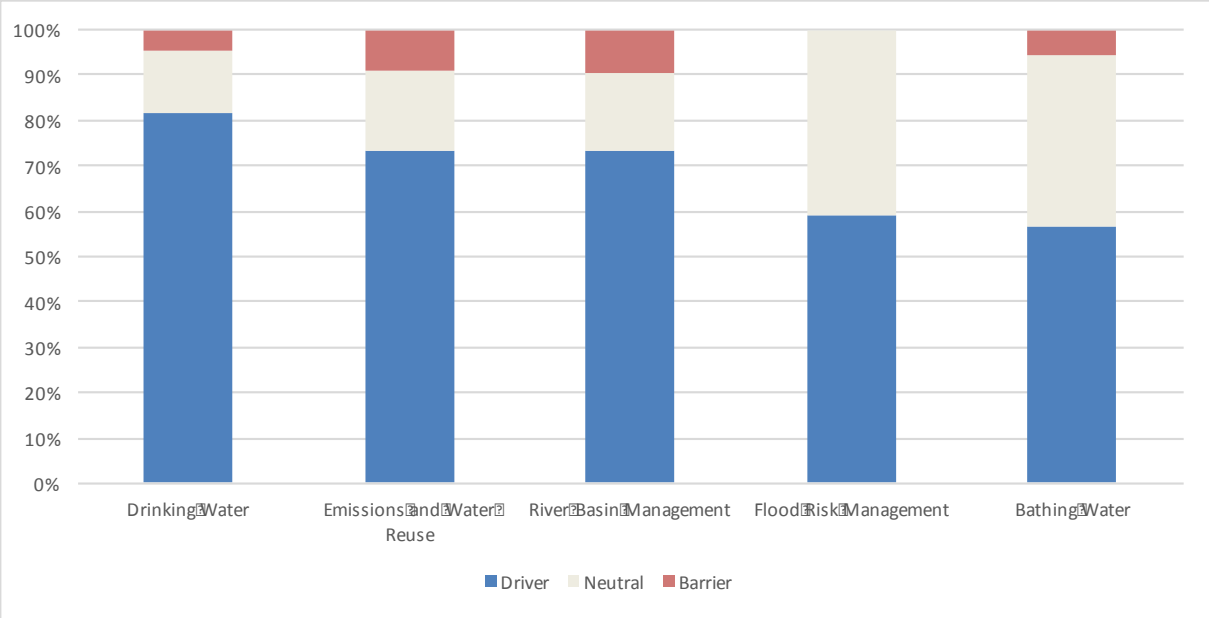
- Barriers to innovation (where over 50 % of respondents agree) include: conflicting requirements of different regulations (75 %);
- Majority of respondents identify drivers for innovation as: labelling (over 60 %); environmental protection regulation (60 %); standardisation (50 %).

The majority of survey respondents considered the following as having neutral effects on innovation: existence of private dominant positions (68 % neutral); existence of state/semi-state dominant positions in the sector (59 % neutral); competition law (53 % neutral); procurement rules (65 % neutral on this aspect); product safety regulations (47 % neutral); and trade agreements (60 % neutral).

In terms of overall dedicated sectoral policies, respondents appear to be more divided: 30 % indicate they are a driver and 30 % perceive them as a barrier to innovation. The remaining 40 % of respondents are neutral on this. Therefore, it can be claimed that 70 % of the water-sector respondents see the sectoral legislation as not hampering innovation.

When asked about specific EU-level legislation in the water sector, the overwhelming majority of respondents mentioned that **EU legislation in the field of water is a driver of innovation**, while less than 10 % (on average) mentioned them as barriers (see Figure 12). This is the case for fields related to drinking water, emissions and water reuse, and river basin management, on which over 70 % of respondents shared this opinion. No respondents mentioned that flood-risk management was a barrier to their respective innovation activities. Regulations on emissions and water reuse and river basin management posed barriers for only about 10 % of respondents.

Figure 12: **Regulations as drivers or barriers to innovation in the water sector**



Source: Technopolis Group

Deepening the analysis of how sectoral regulations impact on the water sector by types of innovation and companies, SMEs perceive the sectoral regulations as imposing barriers to a larger extent than large enterprises and micro-enterprises**.** In addition, a larger share of companies developing product or process innovations perceive regulatory barriers when compared to companies developing marketing or organisational innovations, or those not innovating at all.

Since 30% of respondents mentioned overall sectoral policies as barriers, but only 10% of them considered those listed as barriers, there are other sectoral policies that could be hampering innovation activities. Respondents provided more details in open questions; specific EU legal/regulatory instruments that were found to hamper innovation in the water sector include:

- Biocidal Products Regulation (2012) - BPR Regulation (EU) 528/2012. As one respondent explained, BPR "is stopping innovation especially in the disinfectant business, because of the high regulatory costs of launching new activities and products"
- Difficulties posed by regulation in the field of water reuse:
  - The lack of both standards and a common Directive on water reuse: "this was to be developed, but at the end only guidelines are being prepared as a recommendation, but not as more binding legislation";
  - There is a need for better regulation on nitrates in groundwater and on sewage sludge as feedstock for raw material recovery;
  - The end of waste criteria and related legislation (especially the conditions for reusing waste-based products);
- Lack of clarity and the need to update the Drinking Water Directive.

Several aspects that pertain to the **non-uniform or conflicting implementation** of EU regulations in Member States were considered by 23 respondents to be hindering innovation:

- Implementation of the Biocides Directive is conflicting in different countries;
- There are different 'attitudes' to the Nitrates Directive in different countries (e.g. on nitrate limited zones);
- "Sewage sludge treatment and final disposal are difficult topics as Member States differ on how best to deal with secondary sludge";
- "There is a gap between the implementation of water-quality rules for waste-water treatment effluents in the different European countries: "Investments in new technology (e.g. for water treatment) to improve the water quality are not implemented when older and cheaper technologies are accepted".

Further broad points raised by the survey respondents include:

- **Lack of proper enforcement** of EU legislation – for instance, Eastern European countries are mentioned as Member States where "there is very low control of how the rules are applied, and also very little action against violated permits. This decreases the chances for

successful business because there is no or reduced demand. A solution should be provided in countries where enforcement is not up to standard."

- **Contradicting legislation**, for example between nitrates/energy/ Natura 2000 legislation, specifically mentioning that there is little room for exemptions on environmental impact for testing new technologies during the experimental phase. Since experimentation and testing are crucial phases of the innovation process, it may be said that this is a case where regulation imposes burden on the innovators. However, the environmental legislation imposes specific limitations on the environmental impact of technologies even for the testing phase. The specific problem identified is experienced by first user/appliers of the technology: "they both have to prove impact [on] first application and comply with regulation". The suggestion was to "provide temporarily less strict regulations for first full-scale applications" and "to consider allowing a small decrease in quality when a large impact can be achieved in another area" in the first stages of application[82]. Also, a further set of contradicting legislations were mentioned by a larger number of respondents for the case of the Biocidal Products Regulation (BPR, 2012) as being incompatible with the Drinking Water and Bathing Water Regulations, thereby hampering product development.
- **Difficulties in adapting the regulation** to new or unforeseen problems, and to the cross-sectoral pathways for market development (across energy, water, nature): "The EU is okay with developing regulations, however, procedures to adjust and deal with specific unforeseen practical problems are poor. This is posing particular difficulties for innovative enterprises." A proposed solution was to "add in each regulation an appendix on how to deal with unforeseen barriers".

Respondents pointed in particular to innovation-driving legislation with the Groundwater Directive and changes to the EU Waste Directive. Non-regulatory driving factors for innovation were also mentioned, such as the economic crisis, the over-consumption of water, the recovery of raw materials from waste, and the United Nations Sustainable Development Goals.

Insights from interviews with stakeholders largely emphasised the fact that EU- level legislation in the water sector is not a problem for innovation. On the contrary, most interviewees claimed that existing legislation in the field of water is rather a driver for achieving better solutions to reach environmental outcomes, hence it pushes companies to innovate. Thus, the interviewees' perception is that **there are strong drivers for innovation in the water sector**, including regulation and businesses' intrinsic need to reduce the costs of their operations, processes and resources, as well as health considerations.

However, while the legislative framework has played a major role in driving innovation mainly to ensure the health of water ecosystems, the interviewees considered that **water legislation needs to be updated to tackle the current water challenges** such as water scarcity, climate change and new forms of pollution.

Further suggestions of specific key issues that need to be tackled in the short term to improve the legislative framework to promote innovation in the sector include:

- **Reassess the pathway through which current regulation is accounting for the impact of other industries on water**. For instance, the use of pharmaceuticals and chemicals and their interaction with food chains and water-use chains challenge water quality and human health. Both the survey respondents and the interviewees identified gaps in the regulation in this respect. A specific difficulty seems to be related to who pays and is responsible for better technologies – which industry should invest in improved technologies, for instance, when water/pharmaceuticals or water/industry/agricultural chains interact? A REFIT exercise was considered necessary to dissect these issues at a deeper level.
- **Provide guidelines on liability**. In the case of water reuse, it remains unclear who is accountable for the potential risks of reused water – for example, when the agricultural industry is reusing water sourced from the textiles industry, which industry should be liable for potential hazards?
- **Clear legislation on water reuse**. Survey respondents and interviewees pointed out that proposed EC initiatives on water reuse are guidelines for quality standards on water reuse. However, these soft measures are not legally binding. In addition, the guidelines do not cover all types of water reuse, which could have a larger impact on driving innovations in more areas of water reuse.
- **Water pricing** has been regarded, ultimately, as a tool that could be a solution to several of the challenges mentioned above, since it regulates consumption and could influence industries towards more sustainable practices. For instance, a suggested EU intervention is

82 As verified in an interview with representatives of the European Innovation Partnership, the case of such contradictions is under evaluation and is being tackled by DG Environment.

not necessarily meant to ensure similar pricing levels across the EU, but rather the transparency of water prices across the EU.

- **Adjusting the end of waste criteria**. Interviewees and survey respondents pointed to cross-EU differences in implementing sewage sludge treatment and disposal. Adjusting the end of waste criteria to include sewage sludge could provide an appropriate framework for reuse and allow more innovative technologies to enter the market.
- **Improved coordination of legislation**. Several interviewees mentioned the need to ensure better coordination between the EU's water policy and the common agricultural policy (CAP), with EU energy policies and climate and environmental objectives. By ensuring that at least the standards set in the WFD for good water status are being respected in other policies and that, for instance, "best available techniques" – as set out in the Industrial Emissions Directives – are taken into account when investing in new technological solutions, the legislative framework would support the commercialisation of innovations. Further specific examples of regulatory barriers identified within this stream include:
  - In the field of agriculture, few links were made in the formulation of the current River Basin Management Plans requested by the WFD and the Rural Development Plans requested by CAP. This has been confirmed by an EU Court of Auditors' report which recommended greater cross-compliance: "*the Commission has not ensured that good agricultural and environmental conditions standards in relation to water are appropriate at Member State level or formulated in such a way that they promote good farming practices*" (ECA, 2014).
  - The lagging implementation of the WFD, UWWTD, Nitrates Directive, the Sustainable Use of Pesticides Directive and the rather mild enforcement tools used to reach the goals set out in the Directives have been mentioned as key current issues in governing the water sector that need to be tackled. The interviewees pointed out that there is a need for stronger communication and "marketing" of water legislation and especially of the WFD, including within the framework of related policies like the CAP or the Energy Union. These gaps can still be bridged which could reinforce the water legislative framework as a driver for innovation. This could also help the diverging national implementation of EU legislation and the lack of proper enforcement. Both are considered as barriers to innovation.
- **Provide room for disruptive technologies**. Interviewees mentioned that the essential innovations in the water sector for driving change are disruptive ones. The current regulatory governance arrangements at MS level allow for incremental innovations. Currently, one of the key risks is that water management systems are locked-in within old infrastructure that is costly to replace. Interviewees believed that disruptive innovations have the potential to be more efficient than existing technologies and infrastructure systems and to reduce costs along the water value chain. This is not limited to the Water Framework Directive or EU-level legislation, as national legislations could also play a role.

To sum up, a clear message from both the survey and the stakeholder interviews was the need to ensure that water legislation is tackling the growing global challenges (such as water scarcity, climate change, pollution) and that it drives innovation towards tackling these challenges. The latter remark is important – if the legislation in place and the coordination framework at EU level are not adapting quickly enough to the current and rising global challenges and market developments, regulation can easily be regarded as a barrier for innovation. By not adapting to these challenges or providing room for adaptation, the regulative framework is not providing incentives to the public and private sectors to innovate and adopt innovations which address those challenges. The water legislative framework is a driver for (often incremental) innovations, but more needs to be done in light of adjusting to new unforeseen challenges and global trends.

3.4.5. Economic impact and projections

This section is based on the results of a large survey that addressed the impacts of regulation on innovation (see chapter 2.4). Here, the focus is on those respondents who indicated they were active in the water sector – numbering 48 out of 2013 responses.

3.4.5.1.Economic impact

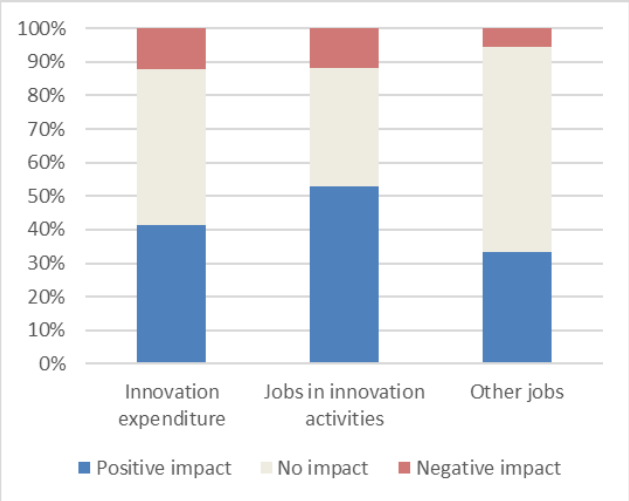
The survey asked: "Based on your perceived barriers/drivers to innovation, please estimate how regulation has impacted over the past three years the following indicators: innovation expenditure, jobs in innovation activities and other jobs.

According to 46 % of respondents, regulation has had no impact on innovation expenditure during the last three years, while 41 % mention it had a positive impact. Only 12 % of respondents felt that regulation had negative impacts on innovation expenditure and on jobs in innovation activities.

Moreover, the impact on jobs in such activities was rated as positive by 53 % of respondents. The impact of regulation on other jobs in the water sector was perceived mainly as either neutral (61 % of respondents) or positive (33 %). Only a minority of 6 % perceived a negative impact on other jobs.

Overall, the survey results show that the net impact of regulation (or in other words, the global impact of regulatory factors presented in the previous section) is perceived as positive in the water sector.

Figure 13: **Impact of regulation on specific economic indicators**



Source: Technopolis Group

Figure 14: Impacts of regulation in the field of water

Economic indicators	Negative impact	No impact	Positive impact
Innovation expenditure	5 (12 %)	19 (46 %)	17 (41 %)
Jobs in innovation activities	4 (12 %)	12 (35 %)	18 (53 %)
Other jobs	2 (6 %)	22 (61 %)	12 (33 %)

Source: Technopolis Group

3.4.5.2.Economic projections

Projections in this section are based on the methodology detailed in the methodological section of the study. The projections use the information provided by respondents on the perceived impact of regulation on their activities, which they identified via quantified ranges (as a percentage of their innovation investments and jobs). Estimates are produced by relating this impact with their responses on the role played by regulatory factors (i.e. driver, barrier, neutral factor). The rationale behind this exercise is to estimate the difference in the quantified impact of regulation between a respondent who identifies a given factor as a barrier and a 'similar' (in the econometric sense) respondent who does not consider the factor as a barrier. This approach does not assume that regulation has an overall net negative impact, but rather that this impact can be either less positive or more negative due to regulatory barriers. The impact, observed in relative terms (i.e. percentages) at the level of the survey respondents, can be extrapolated to EU figures using CIS data in order to get absolute figures. For the purpose of the projections, data from CIS until 2030 were estimated (based either on estimated future growth rates for employment calculated by CEDEFOP or on recent trends for innovation investments) as a baseline scenario from which the impact in absolute value of addressing barriers has been calculated.

In the case of the water sector, the survey respondents identified a low level of barriers to innovation from the current regulation in place. When asked about specific EU-level legislation in the water sector (i.e. in the fields of drinking water, emissions and water reuse, bathing water and river basin management), an overwhelming majority of respondents mentioned that the **legislation in the field of water is a driver for innovation**, and less than 10 % (on average) mentioned it was a barrier.

Based on the econometric analysis of the survey responses[83], the estimated impact of addressing barriers for water companies has been estimated to be about:

- +1 % to 2 % increase in innovation expenditure per year
- +1 % to 2 % increase in the number of jobs in innovation activities compared to the same situation with barriers.

In other words, innovation expenditure and the number of jobs in innovation activities would increase by 1 % to 2 % per year if the above-mentioned regulatory barriers were addressed in the water sector (including the factors assessed in the survey).

The initial figure for innovation expenditure was of EUR 2 581 851 thousand in 2012. It was calculated based on the sum of different types of innovation expenditure, including R&D (sourced from CIS data). Evolution of the sector's annual innovation expenditure has been estimated over 2016-2030 for this exercise.

Table 11: Potential impact of removing regulatory barriers on companies' innovation expenditures (EUR billion)

Period	Direct full impact from 2017		Progressive impact over 15 years	
	Low estimate	High estimate	Low estimate	High estimate
Annual average	0.03	0.06	0.02	0.04
Total 2016-2020	0.12	0.24	0.22	0.04
Total 2021-2025	0.16	0.33	0.82	0.16
Total 2026-2030	0.18	0.36	0.15	0.31
Total 2016-2030	0.46	0.92	0.26	0.51

Source: Technopolis Group

Note: in order to calculate the direct full impact, the percentages above (+1% for low bound and +2% for high bound) are directly applied for each year over 2017-2030; progressive impact: the percentage of impact in 2016+n is the percentage above multiplied by n/14 (linear progression)

The potential impact of addressing regulatory barriers on innovation expenditure (in billion euros) is shown in the table below, based on estimating **the sum of the annual increase in innovation when addressing barriers over the period of 2016-2030.** On average, companies would invest up to **EUR 1 billion per year more on innovation in 2012-2030** if regulatory barriers were addressed by 2030.

By 2030, the total potential impact on employment in innovative firms over the period is estimated to be close to 14 000 jobs, in a scenario of +2 % growth of jobs in innovation activities. This is achieved by estimating the number of jobs in innovative companies in 2030 and calculating the difference between that figure and the number of jobs created in a scenario without regulatory barriers. This total difference can be averaged by year, as shown in the table below. In 2012, the initial number of jobs in innovative companies in the water sector was 743 429 (sourced from CIS – Eurostat).

Table 12: Potential impact of removing regulatory barriers on companies' job creation

	Number of jobs created	
	Low estimate	High estimate
Average per year	500	1000
2016-2030	7000	14 000

Source: authors' calculations

Nevertheless, the figures should be treated with caution as few firms reported regulatory barriers, and if they did, the estimated impact of removing those barriers is not large.

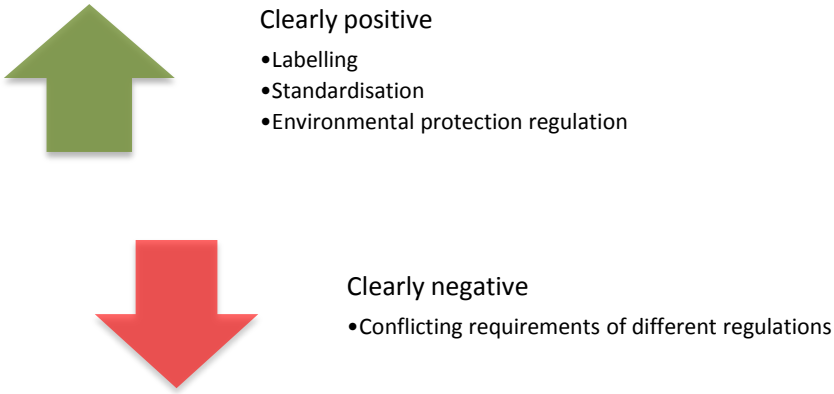
3.4.6. Conclusions

Analysis of the regulatory framework and innovation in the water sector indicate clearly both drivers and barriers (see Figure 15). A large number of regulatory tools appear to be neutral to

[83] See methodological note in the Task 1 report of this regulatory impact assessment study. This estimation does not include the qualitative answers to the open questions in the survey, where stakeholders pointed to other potential barriers to innovation that were not mentioned in the survey's multiple-choice questions

innovation: existence of private dominant positions (68 % neutral); existence of state/semi-state dominant positions in the sector (59 % neutral); competition law (53 % neutral); procurement rules (65 % neutral on this aspect); product safety regulations (47 % neutral); and trade agreements (60 % neutral).

Figure 15: Clear impact of specific regulation in the water sector



Source: Technopolis Group

In terms of overall dedicated sectoral policies in the water sector, 30 % of the survey respondents considered them as driver for innovation, 30 % as barriers, while 40 % remained neutral. It could be said that for 70 % of the companies' sectoral legislation is not hampering innovation. However, there is a difference in perception when it comes to the size of the firm: around 40 % of SMEs perceived sectoral policies as imposing barriers while less than 20 % of large enterprises and micro-enterprises share this perception. Regulatory barriers are more often perceived by companies developing product or process innovations than those developing marketing or organisational innovations, as well as non-innovating ones.

The overwhelming majority of respondents considered the specific EU-level legislation in the sector mentioned in the survey (i.e. the Drinking Water Directive, regulations in the field of emissions and water reuse, river basin management regulations, flood risk management and the Bathing Water Directive) as a driver for innovation. On average, less than 10 % mentioned (one) it as a barrier.

The study also took into account the answers and comments provided through some open questions as well as stakeholder interviews to identify further potential specific regulatory issues or other water-sector regulations affecting innovation. The study's results show that the regulatory framework has only been a disincentive to innovation in particular cases:

- The Biocides Products Regulation (528/2012) imposes regulatory costs on companies wanting to launch new products and thus is a disincentive for them to innovate in the field; its implementation also conflicts in different countries.
- The flexibility of the Water Framework Directive has resulted in different implementation pathways in the Member States and does not incentivise the use of innovative technologies at the local level. This has been a problem in commercialising innovative water-treatment technologies in different Member States – newer Member States do not impose the highest water-quality standards and invest in less innovative and/or less sustainable technologies which often do not tackle emerging pollution challenges such as the presence of pharmaceuticals in water.
- The lack of regulation stringency in the field of water reuse has been found to be a barrier to the spread of innovation. In particular, the guidelines for "minimum quality" requirements for reused water that are being developed do not impose strict implementation rules and should thus only be seen as recommendations. With greater stringency in implementation, the regulation could incentivise the adoption of innovations that comply with the minimum quality standards.
- More needs to be done in terms of increasing the transparency of water pricing, to reduce information asymmetry in the water markets and drive water consumption down, while also tackling the trend in water over-abstraction. In the long run, this would boost the promotion of more water-efficient technologies.
- The survey respondents did not always specify clearly the conflicting issues in the existing regulations, apart from the need to tackle the interactions between the energy/water or agriculture/water industries. Several interviewees mentioned the need to ensure better

coordination between the standards set in EU water policy and the CAP, and EU energy policies.

According to the survey respondents and interviewees alike, strong drivers for innovation in the water sector include legislation and businesses' intrinsic goal to reduce the cost of their operations, processes and resources, water scarcity, and health considerations. Both groups pointed to the need to 'upgrade' the legislation to more recent water-sector challenges, and to the cross-sectoral pathways for market development in the water industry (catering for energy, water, agriculture, and natural environment interactions in the water industry). In the past, EU legislation has driven innovation towards tackling environmental challenges but it must stay up to date with the current cross-sectoral challenges in a more targeted way.

The majority of the survey respondents said that regulation in the water sector had net positive impacts on both innovation expenditure and jobs.

Based on the econometric analysis of the survey responses, the estimated impact of addressing the existing barriers to innovation is a +1 % to 2 % increase in innovation expenditure per year, and +1 % to 2 % increase of jobs in innovation activities compared to a situation with barriers.

In other words, innovation expenditure and the number of jobs in innovation activities would increase by 1 % to 2 % per year if regulatory barriers were addressed in the water sector (including the factors assessed in this survey). This complements the sector study findings that the EU's legislative framework and regulations in the water sector do not pose major barriers to companies' innovation activities, and are largely considered neutral. Positive incentives for innovations are offered especially by environmental protection, standardisation and labelling regulations. However, the legislative tools' slow pace of adjusting to the societal challenges has been highlighted as a risk, as they are not driving innovation to any great extent towards achieving societal goals, which should be kept in mind for designing future legislation.

3.5. General comparison of the economic and sectorial analysis: lessons to be learned

Innovation processes are complex and diverse. It is essential to analyse interaction between new or revised EU legislation and innovation in order to make legislative proposals more forward looking and innovation-friendly. While regulations provide for the main framework conditions, their effects on innovation processes vary over time and with the development of industries, technologies, processes and products. If a technical standard helps to establish a new market, after some time or some years it can become rather outdated and – if not adapted or abandoned – a barrier for new developments. Examples of hampering and outdated regulation seem to be numerous – yet, this perception is a function of time the complexity addressed (the level of information), and the stringency of the regulation.

When regulations are designed, they serve specific purposes, such as consumer health and well-being, market access and competition, or environmental protection and sustainability aspects. Under these broad goals, regulations create compliance costs (often a burden to firms which need to comply) although they can also create compliance innovation. Examples of costs and innovations in the field of environmental goods and services are numerous and are often used to demonstrate the positive impact of regulation – as linked to the literature in the so-called Porter Hypothesis.

The four sectoral case studies are showcases: water can be seen as an example of public sector regulated fields, where several regulatory levels can be identified ranging from supra-national to the local level. Energy is a showcase for a rather transversal sector. In both energy and water, innovation does not come predominantly from the utilities or network owners, but from companies in technologically close but also rather distant industries. Energy and water are key inputs for numerous industries which may have very different approaches to energy efficiency, water saving, or water reuse issues.

The food sector is a classical manufacturing sector and a typical consumer product industry with a few large, innovative multinational companies and a large majority of small less-innovative producers. Innovation in the food sector has benefited tremendously from very distant industries, namely packaging and cooling, while incremental food innovations are numerous, with a constant flow of new products being commercialised. While consumers appear to benefit from a wide choice, only a smaller share of products remains non-amended on the market for more than a year.

The health sector as such required a useful delineation. Innovation comes from pharmaceutical and medical companies, although to a large extent they depend on national health systems, clinical trials, approvals, (often) regulated prices, and a number of other factors which can be subsumed under 'framework conditions' – which makes health a very large but also unique 'sector'.

The study was able to obtain industry-specific views on the impact of different types of regulation on innovation. The perception of regulation being a burden cannot be confirmed with the results. Instead, at the aggregate level, many types of regulations are either neutral – and thus have no direct effect on innovation – or are more often perceived as a driver rather than a barrier. The highest consensus among the respondents concerns the negative effects of conflicting regulation. While a regulation on its own can be sound, it rarely works alone but is linked to other regulation in one way or the other. This lack of a regulatory alignment seems to be the main barrier and can be addressed in particular when it comes to new regulation: here an in-depth analysis on the impacts of new or revised initiatives on innovation[84] can be used in *ex-ante* impact assessments. However, a new regulation can be expected to be a barrier in one sector but a driver in another. If both positions are taken into account, the regulation will most likely be less stringent. However, stringency is a key characteristic for fostering radical innovation. While stringency requires higher compliance costs, the long-term benefits of a stringent regulation are often acknowledged a couple of years after the regulation is put in place. In particular, in the energy and water sectors, stringent regulation made the difference, although monitoring is required for its enforcement. The latter is most often associated with the administration or 'red tape' part of regulations. While several respondents and interview partners pointed out that innovation is hampered by poor stringency and its enforcement, there seems to be a lack of understanding regarding the need and use of administration data (which comes from the various processes linked to compliance with the regulation). A proportionality test on what is needed for what purpose and at what cost, could be linked to the impact assessment analysis to prevent excessive administrative requirements.

Nonetheless, barriers exist in many sectors and their removal would release a substantial amount of investment in innovation. Some of these barriers were clearly mentioned by both survey respondents and interview partners.

For the four sectoral analyses, specific EU regulations were assessed by firms from within the sector. In particular, in energy and water, the EU regulations were seen as drivers of innovation. For health and food, respondents were more critical and pointed out a number of aspects where the legislation is hampering innovation. Pieces of regulation were mentioned where amendment after amendment was simply added – which renders the regulation as complex and hard to understand and apply. The lack of regulation was also clearly mentioned in the food sector, indicating that the industry needs a reliable regulatory framework. Since the regulatory decision-making – for example, to allow certain food ingredients, setting minimum and maximum requirements, labelling, etc. – must take into account consumer protection objectives, EU regulations in the same way as those at the national level take into account company perspectives. Identification of (potentially) conflicting regulation can be included fairy easily at the public consultation phase.

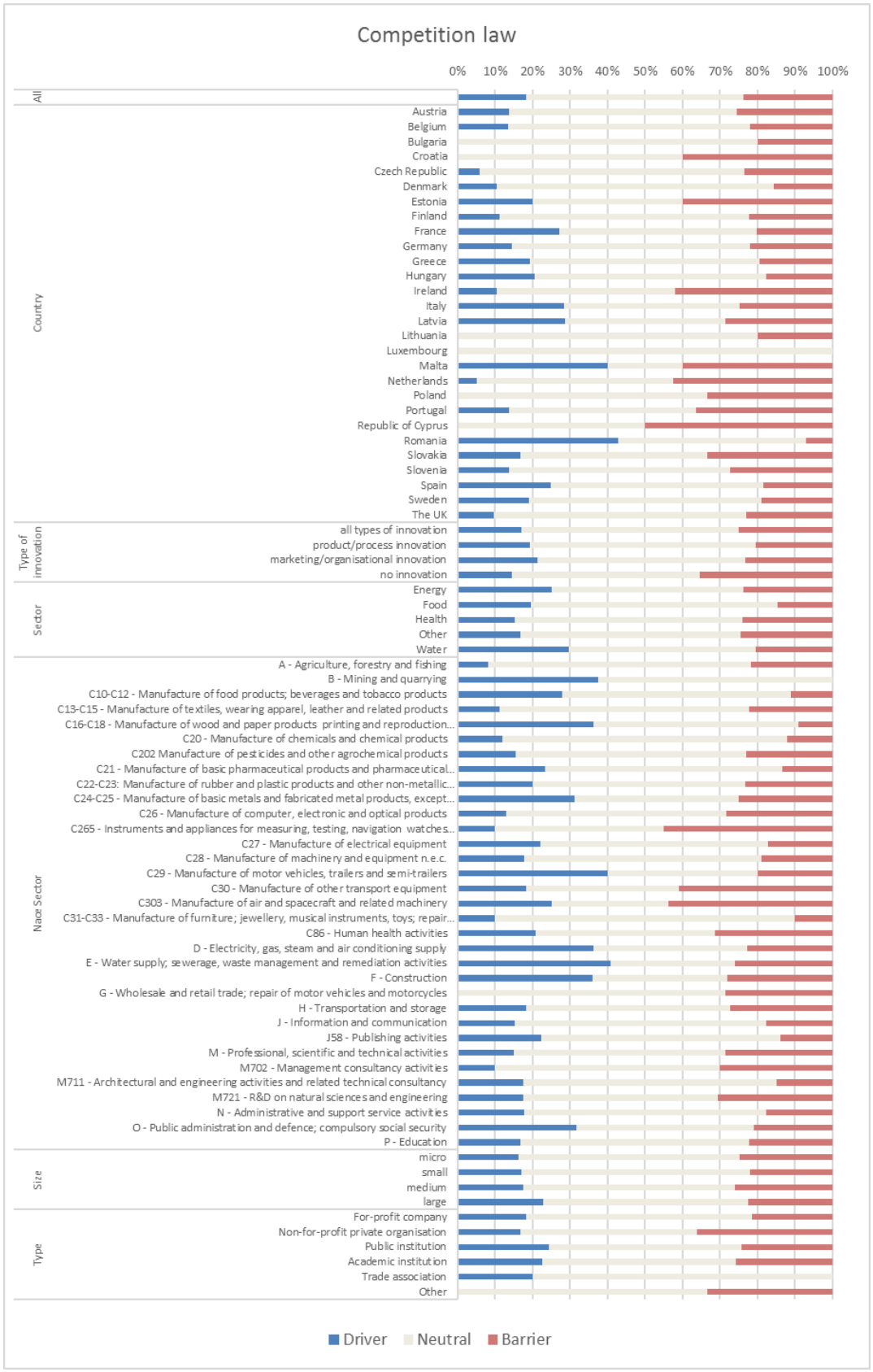
When it comes to existing problematic regulation, it could be more effective to revise the regulation thoroughly instead of simply adding special clauses. This may take more time and resources at the regulation-setting level but may have clear benefits at the user side.

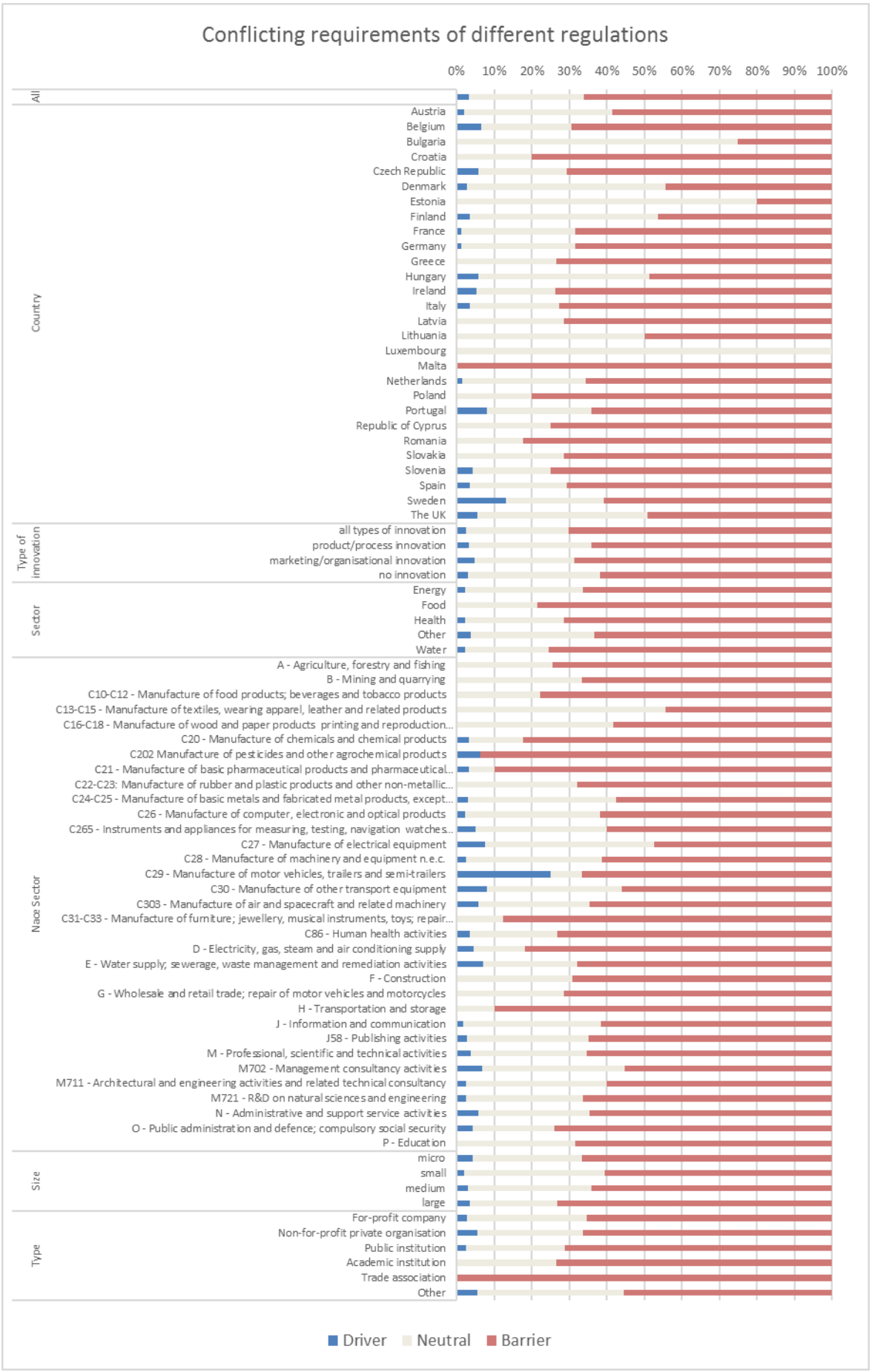
[84] See the European Commission's R&I tool available at https://ec.europa.eu/info/files/better-regulation-toolbox-21_en .

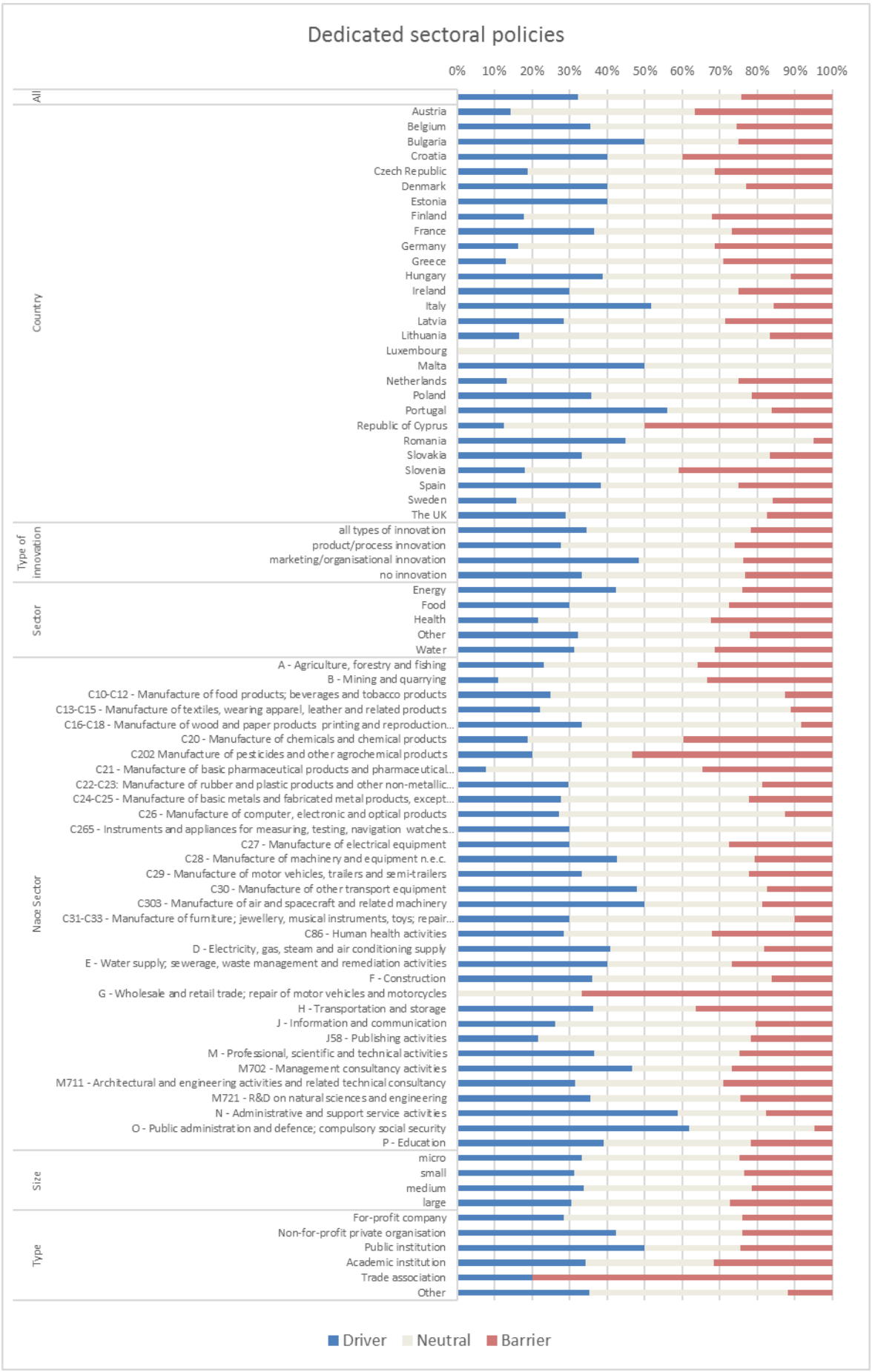
Appendix A Supporting evidence

A.1 Economic analysis

Percentage of respondents considering the different regulatory factors as acting as drivers, barriers or having a neutral effect for their innovation activities




Conflicting requirements of different regulations
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
All
Country
Austria
Belgium
Bulgaria
Croatia
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Republic of Cyprus
Romania
Slovakia
Slovenia
Spain
Sweden
The UK
Type of innovation
all types of innovation
product/process innovation
marketing/organisational innovation
no innovation
Sector
Energy
Food
Health
Other
Water
Nace Sector
A - Agriculture, forestry and fishing
B - Mining and quarrying
C10-C12 - Manufacture of food products; beverages and tobacco products
C13-C15 - Manufacture of textiles, wearing apparel, leather and related products
C16-C18 - Manufacture of wood and paper products printing and reproduction...
C20 - Manufacture of chemicals and chemical products
C202 Manufacture of pesticides and other agrochemical products
C21 - Manufacture of basic pharmaceutical products and pharmaceutical...
C22-C23: Manufacture of rubber and plastic products and other non-metallic...
C24-C25 - Manufacture of basic metals and fabricated metal products, except...
C26 - Manufacture of computer, electronic and optical products
C265 - Instruments and appliances for measuring, testing, navigation watches...
C27 - Manufacture of electrical equipment
C28 - Manufacture of machinery and equipment n.e.c.
C29 - Manufacture of motor vehicles, trailers and semi-trailers
C30 - Manufacture of other transport equipment
C303 - Manufacture of air and spacecraft and related machinery
C31-C33 - Manufacture of furniture; jewellery, musical instruments, toys; repair...
C86 - Human health activities
D - Electricity, gas, steam and air conditioning supply
E - Water supply; sewerage, waste management and remediation activities
F - Construction
G - Wholesale and retail trade; repair of motor vehicles and motorcycles
H - Transportation and storage
J - Information and communication
J58 - Publishing activities
M - Professional, scientific and technical activities
M702 - Management consultancy activities
M711 - Architectural and engineering activities and related technical consultancy
M721 - R&D on natural sciences and engineering
N - Administrative and support service activities
O - Public administration and defence; compulsory social security
P - Education
Size
micro
small
medium
large
Type
For-profit company
Non-for-profit private organisation
Public institution
Academic institution
Trade association
Other
Driver
Neutral
Barrier


Dedicated sectoral policies
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Type of innovation
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product/process innovation
marketing/organisational innovation
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Sector
Energy
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Nace Sector
A - Agriculture, forestry and fishing
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N - Administrative and support service activities
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P - Education
Size
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Academic institution
Trade association
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Driver
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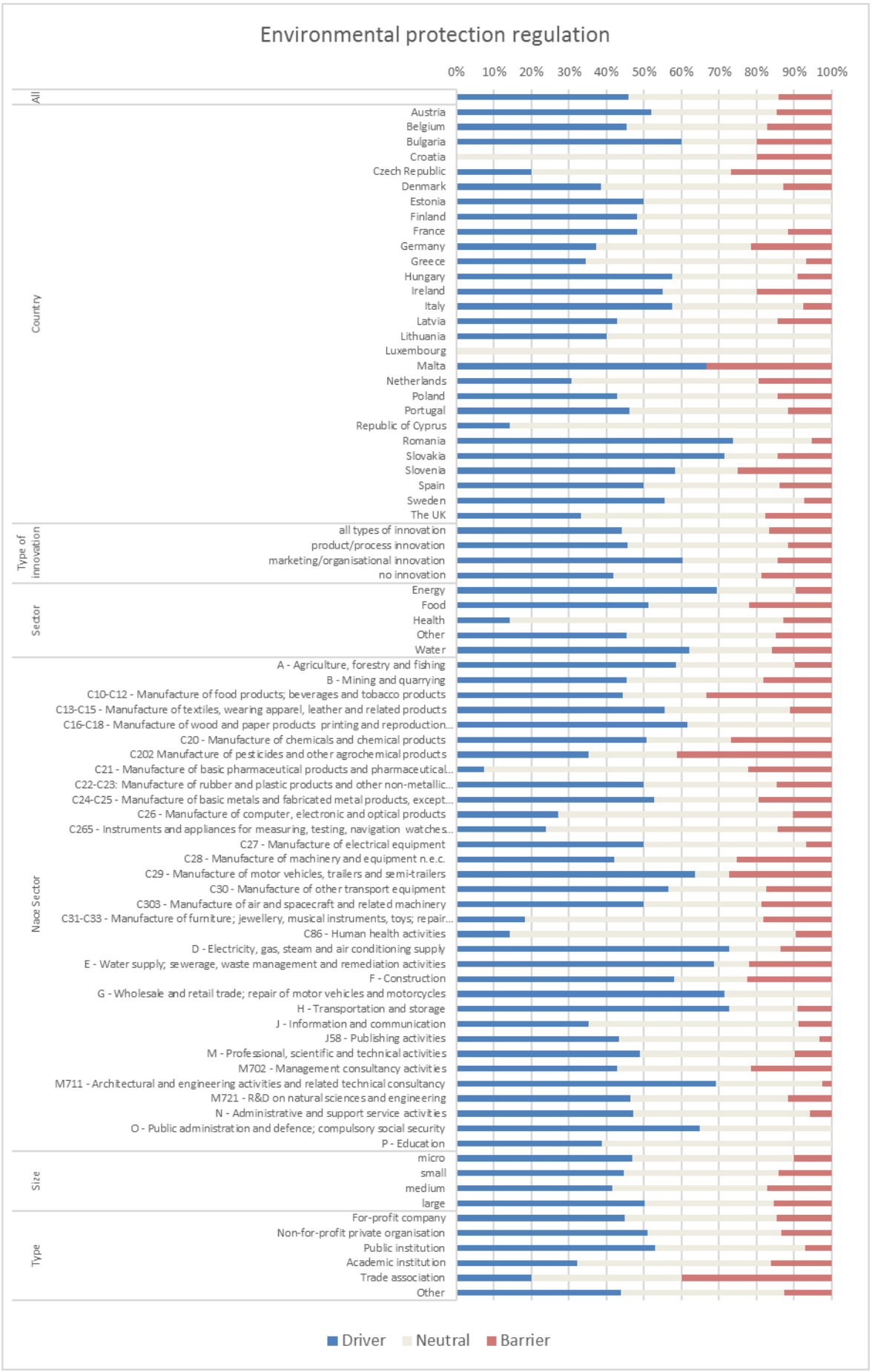
Environmental protection regulation
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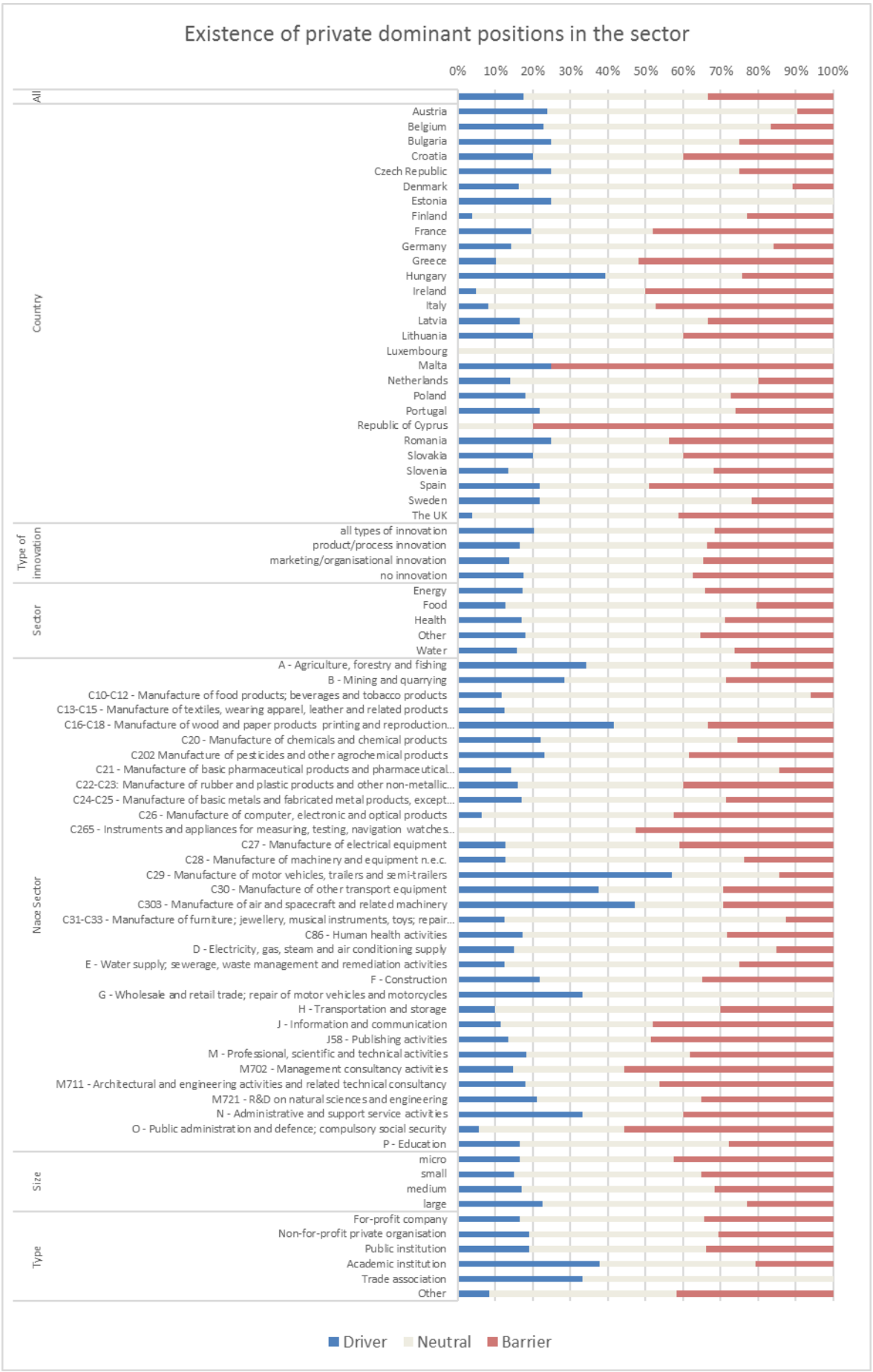
Existence of private dominant positions in the sector
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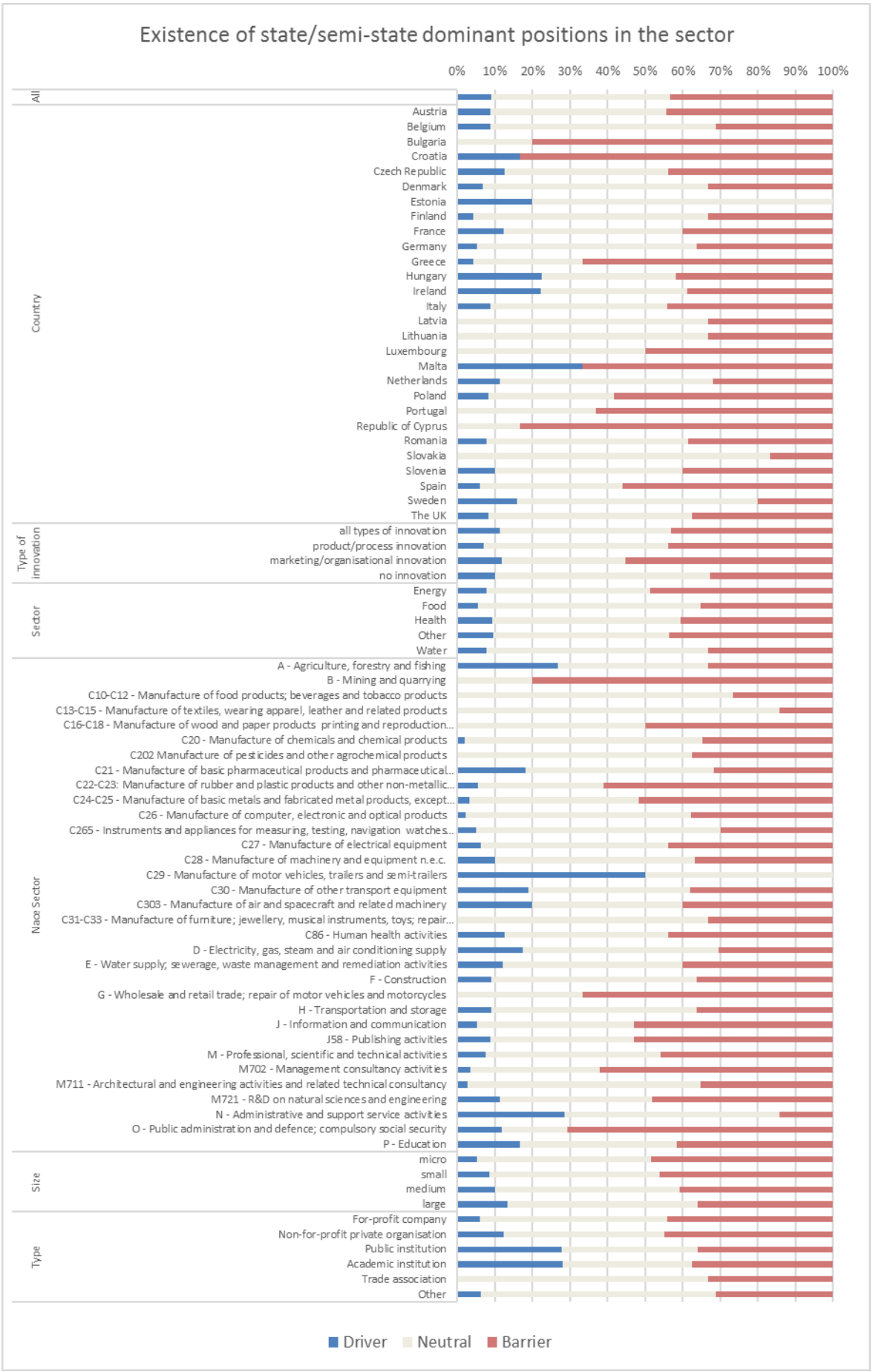
Existence of state/semi-state dominant positions in the sector
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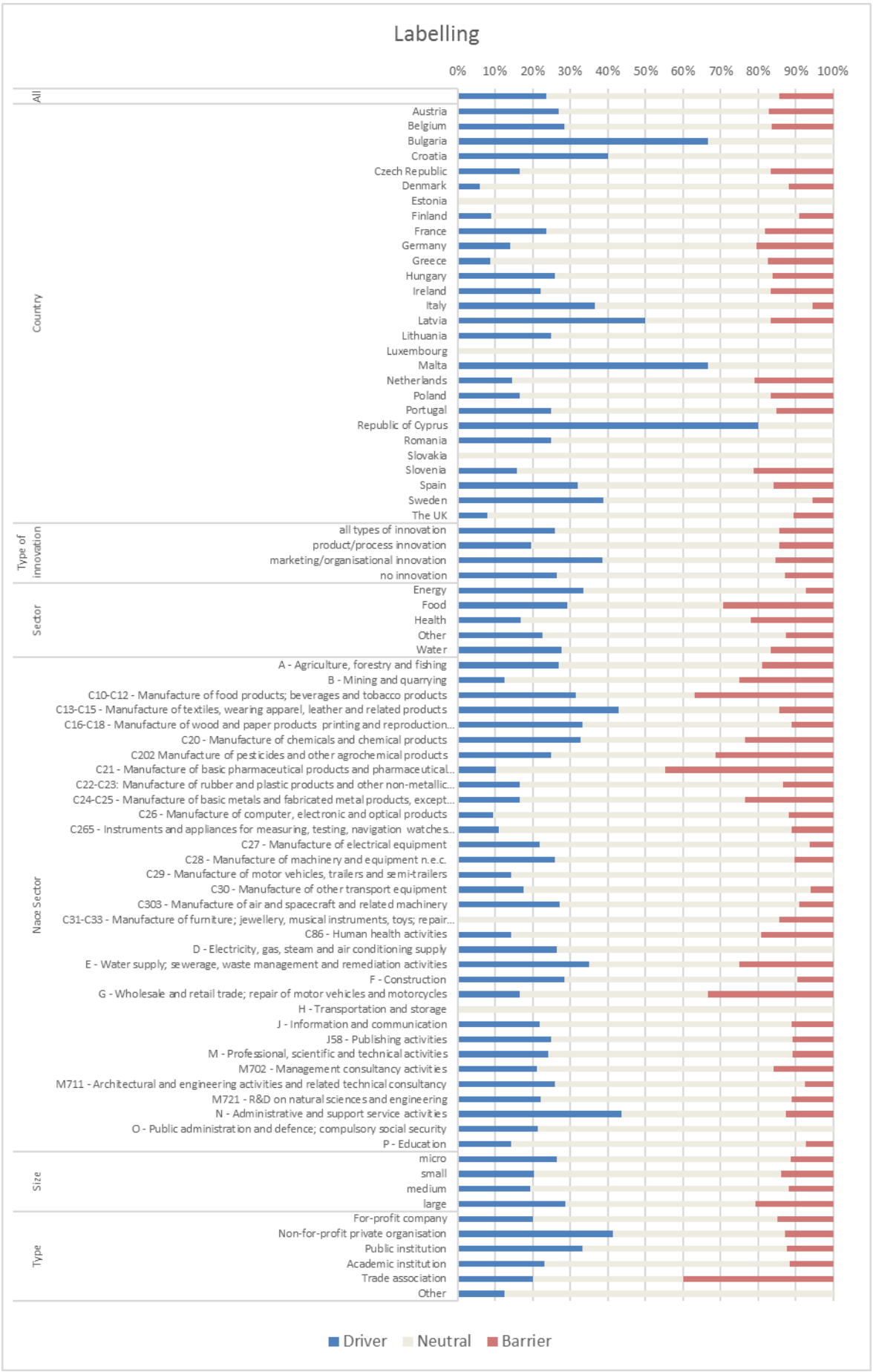
Labelling
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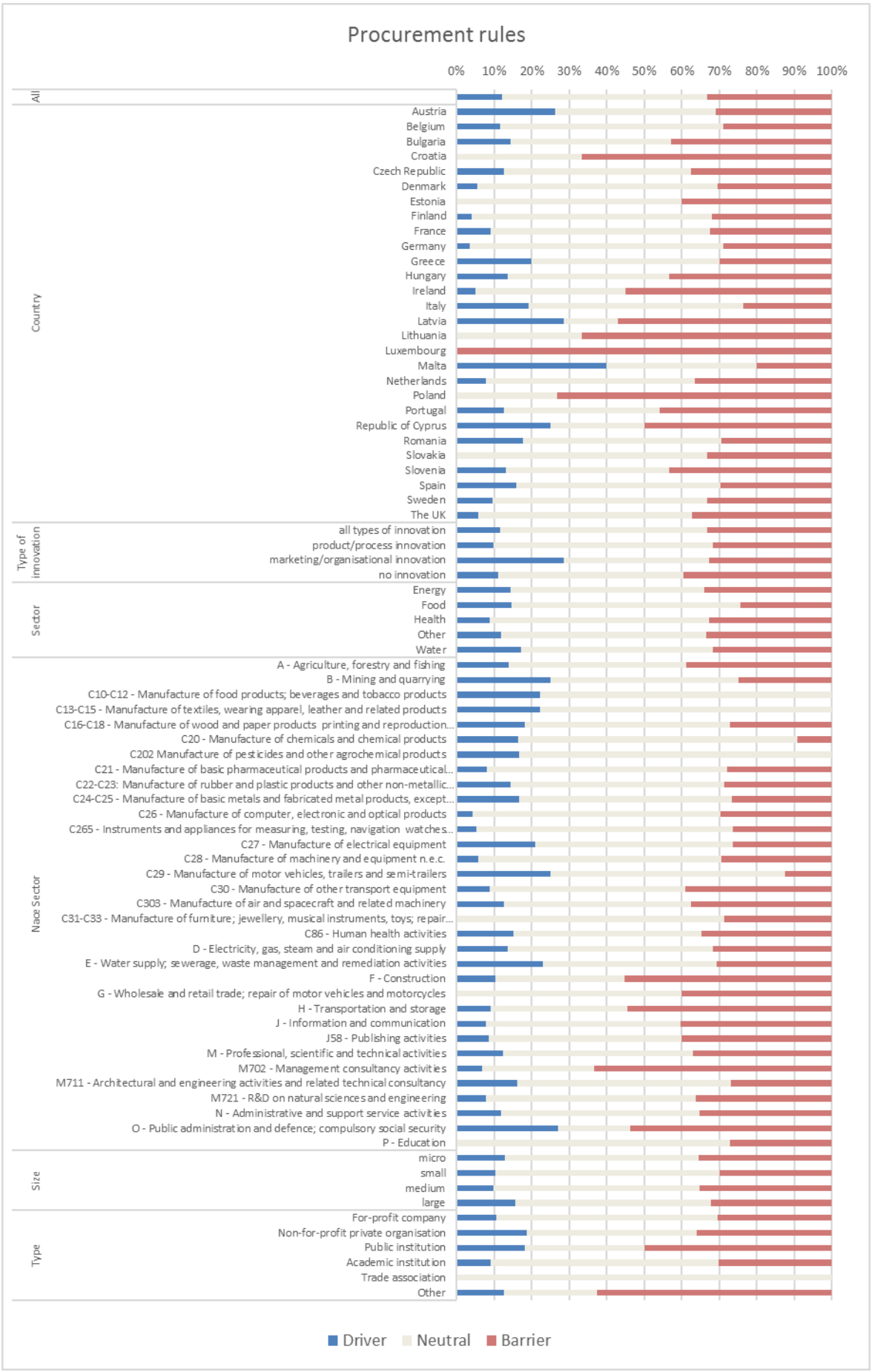
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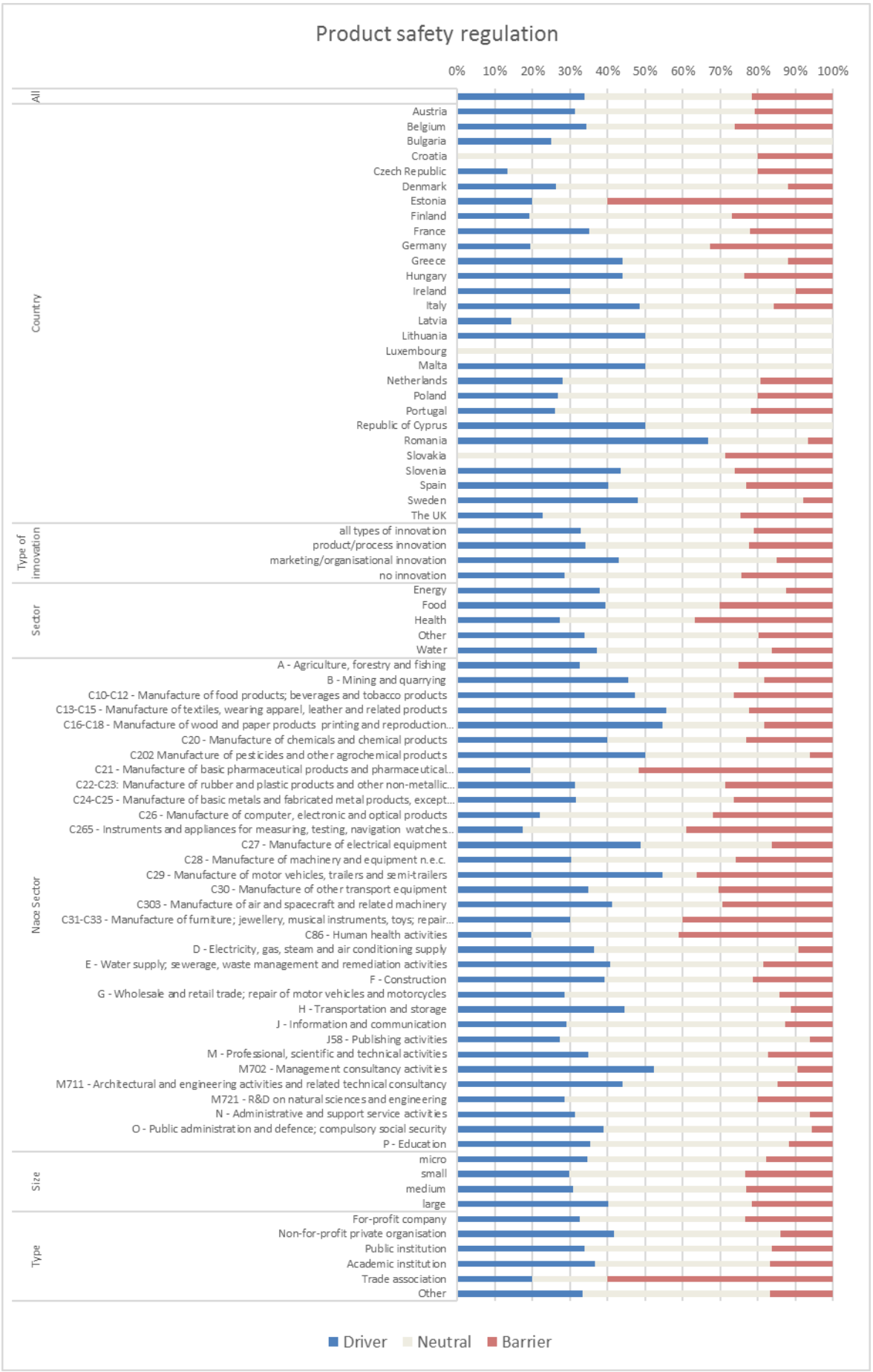
Product safety regulation
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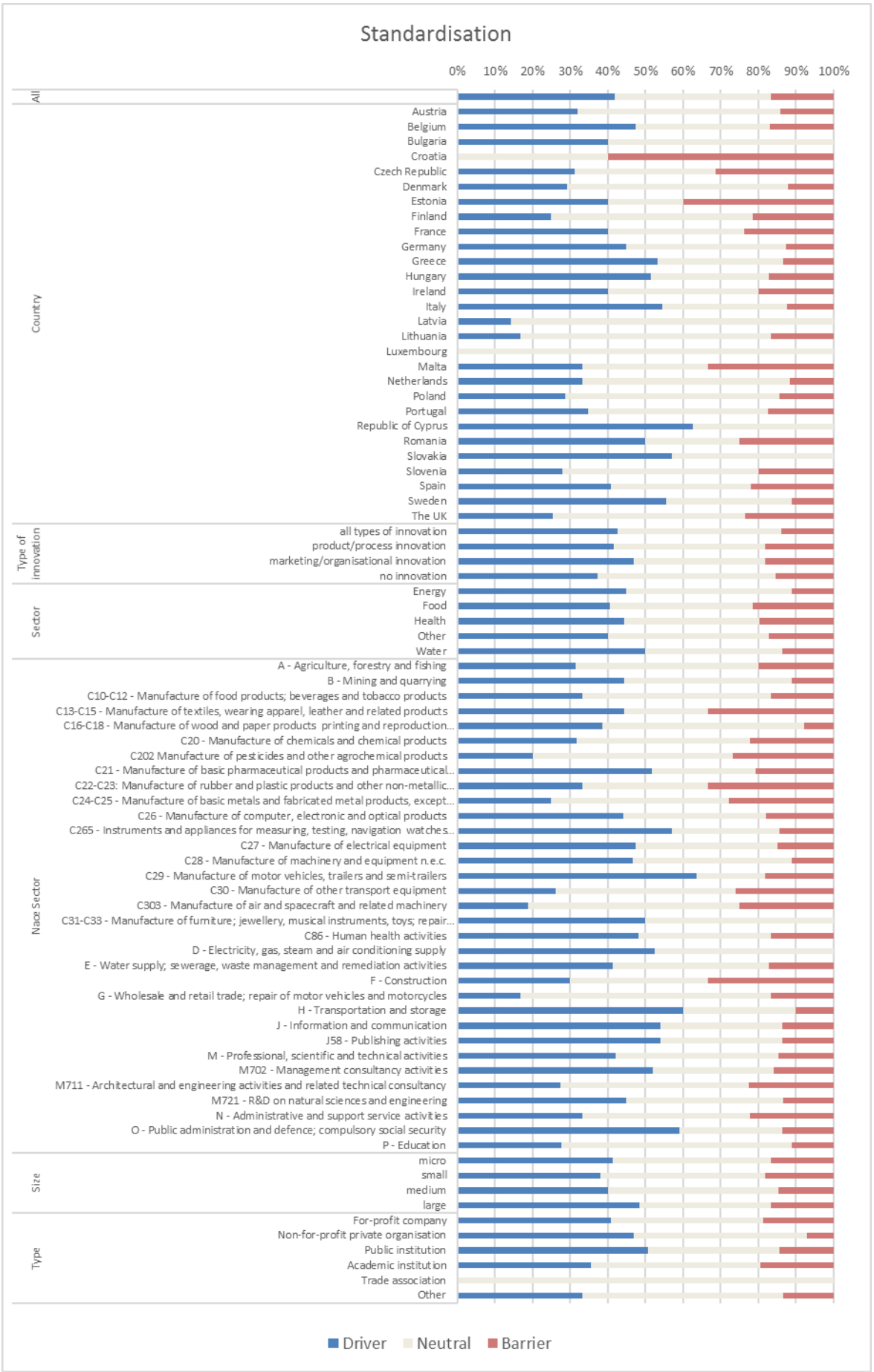
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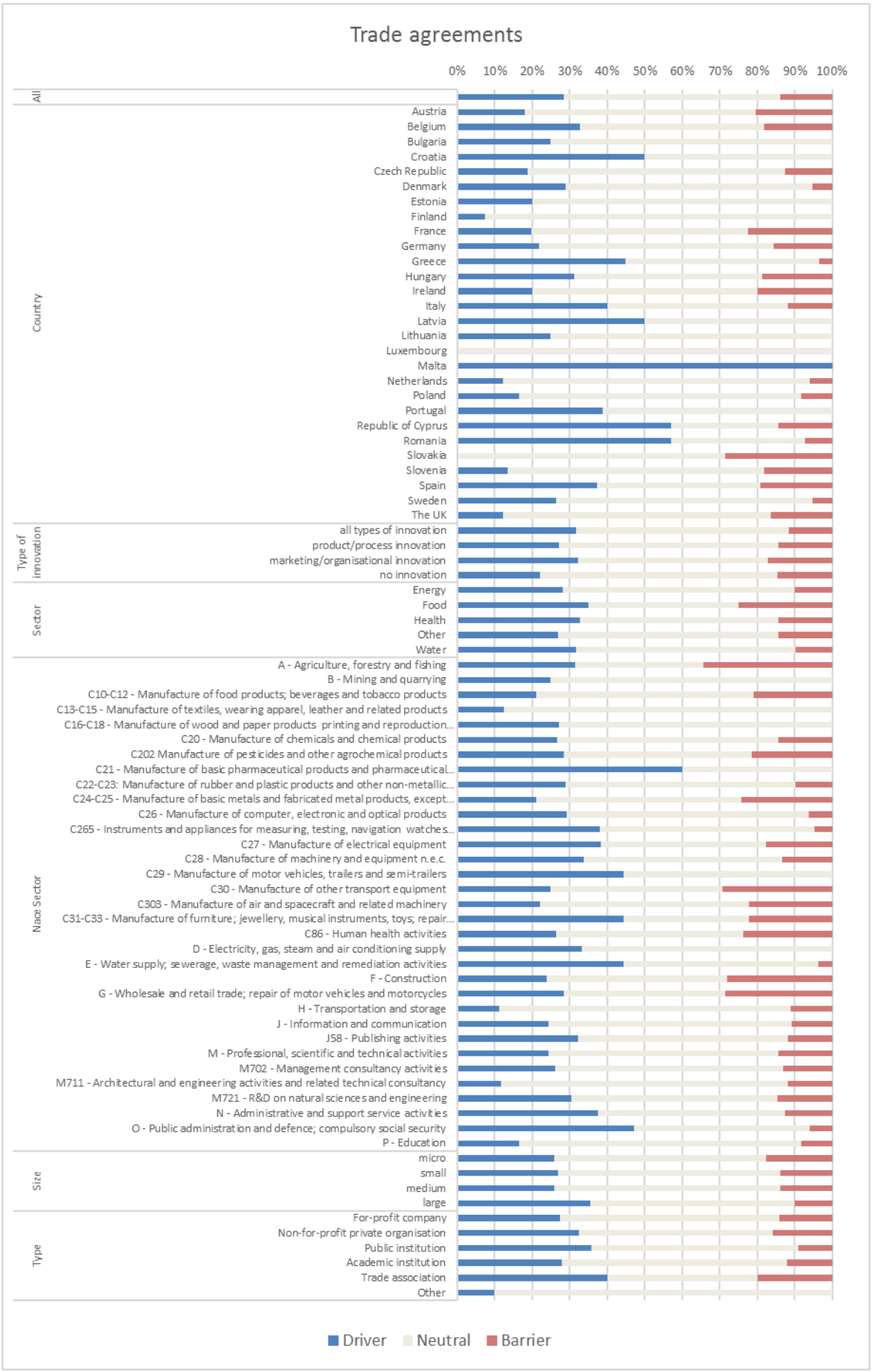
Trade agreements
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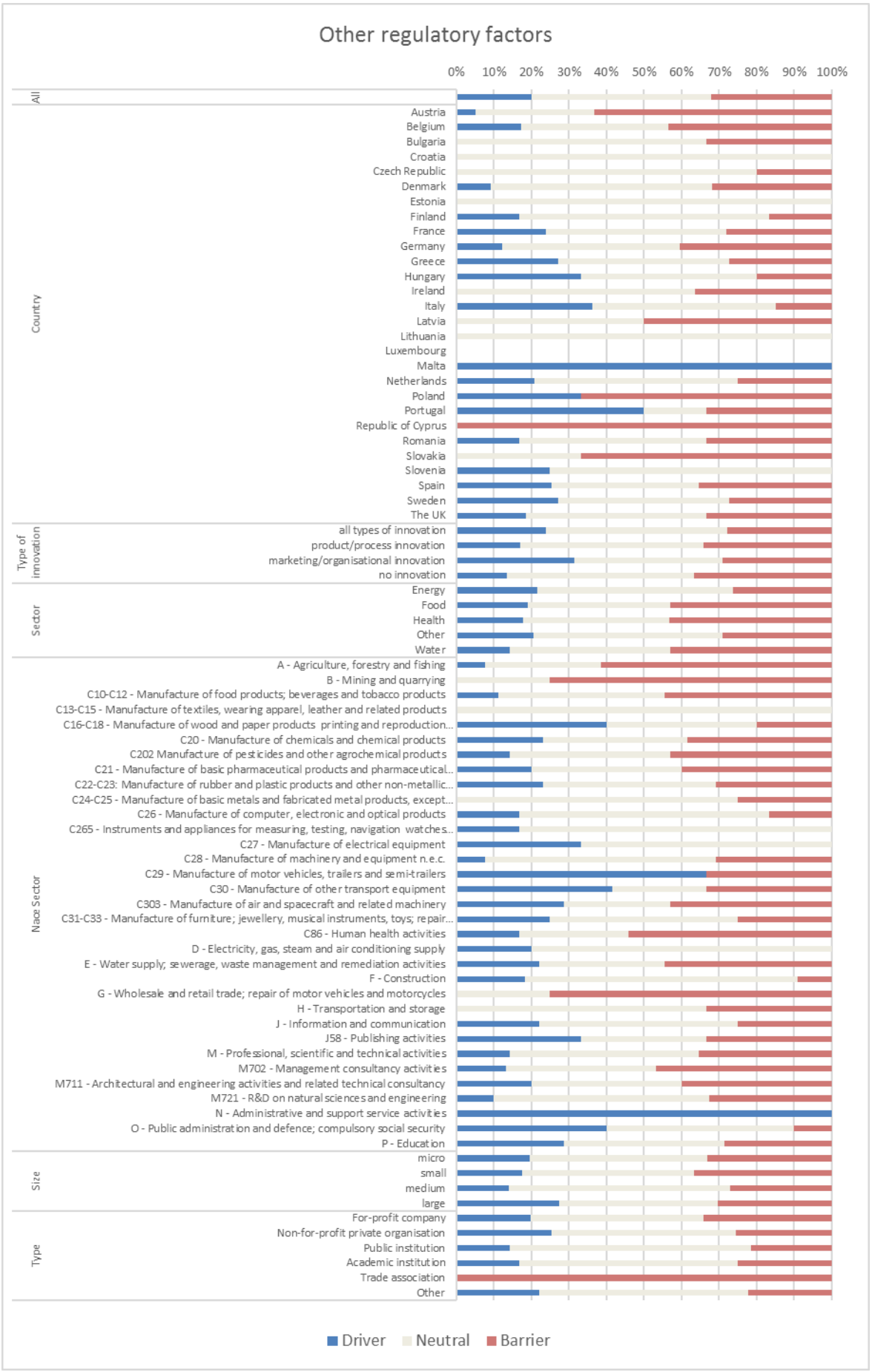
Other regulatory factors
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A - Agriculture, forestry and fishing
B - Mining and quarrying
C10-C12 - Manufacture of food products; beverages and tobacco products
C13-C15 - Manufacture of textiles, wearing apparel, leather and related products
C16-C18 - Manufacture of wood and paper products printing and reproduction...
C20 - Manufacture of chemicals and chemical products
C202 Manufacture of pesticides and other agrochemical products
C21 - Manufacture of basic pharmaceutical products and pharmaceutical...
C22-C23: Manufacture of rubber and plastic products and other non-metallic...
C24-C25 - Manufacture of basic metals and fabricated metal products, except...
C26 - Manufacture of computer, electronic and optical products
C265 - Instruments and appliances for measuring, testing, navigation watches...
C27 - Manufacture of electrical equipment
C28 - Manufacture of machinery and equipment n.e.c.
C29 - Manufacture of motor vehicles, trailers and semi-trailers
C30 - Manufacture of other transport equipment
C303 - Manufacture of air and spacecraft and related machinery
C31-C33 - Manufacture of furniture; jewellery, musical instruments, toys; repair...
C86 - Human health activities
D - Electricity, gas, steam and air conditioning supply
E - Water supply; sewerage, waste management and remediation activities
F - Construction
G - Wholesale and retail trade; repair of motor vehicles and motorcycles
H - Transportation and storage
J - Information and communication
J58 - Publishing activities
M - Professional, scientific and technical activities
M702 - Management consultancy activities
M711 - Architectural and engineering activities and related technical consultancy
M721 - R&D on natural sciences and engineering
N - Administrative and support service activities
O - Public administration and defence; compulsory social security
P - Education
Size
micro
small
medium
large
Type
For-profit company
Non-for-profit private organisation
Public institution
Academic institution
Trade association
Other
Driver
Neutral
Barrier

A.2 Inventory of relevant voluntary national or regional initiatives addressing regulatory barriers to innovation in the EU

Introduction

This section presents an inventory of initiatives undertaken at national level across Europe to overcome regulatory barriers to innovation. This exercise involved two main steps. First, the development of the **inventory** itself**,** which consisted in compiling a long-list of initiatives based on their location, success, and more importantly their type. Second, ten specific initiatives have been selected based on factors such as their success, replication level, relevance, sector and type to be the subject of **case studies**.

This section provides (i) the analytical framework for the development of the inventory and selection criteria for the case studies, (ii) a summary of the initiatives included in the inventory and (iii) conclusions.

Methodological approach

In order to develop the inventory, the following steps have been followed:

1. **the screening of different data** sources such as evaluations and impact assessments carried out at European level and identifying relevant initiatives; academic publications; reports from national innovation centres and the Commission as well as databases focusing on innovation related measures;
2. **the analysis of pertinent documents**;
3. **the extraction of data** related to different (voluntary/self-regulatory) measures adopted, mainly at the national level, to address obstacles to innovation, and to develop ways to overcome them;
4. **clarification of the typology of different initiatives** based on the first three steps above; and
5. **the classification of the initiatives identified as relevant** for the scope of the exercise based on evidence related to how and whether such initiatives have means or have identified strategies to overcome the identified legislative obstacles to innovation.

The mapping of the voluntary (or self-regulatory) initiatives started by identifying and sourcing the data through **desk research**. The research mainly targeted:

- Selected country-level sources (with a focus on large EU Member States);
- Official websites of Member States' national authorities responsible for innovation policies in different sectors/policy areas; and
- Databases and websites focusing on innovation related measures;

For identified initiatives, additional information has been gathered through their websites.

This extensive desk research activity allowed for the compilation of a preliminary inventory of voluntary (or self-regulatory) initiatives undertaken at the transnational, national and regional level across the EU. All initiatives have been coded and added to a database with information on title, country, sources, sector/policy area, type of initiative, responsible authority, and type of barriers addressed.

In parallel to the desk research to develop the inventory of initiatives, the research team has developed a framework which has been used to collect, assess and analyse the information available for the proposed case study initiatives (initiative fiches). Figure 16 below illustrates the structure of the fiche as well as the categories of information collected.

Figure 16 Analytical and assessment framework

Categories	Information collected
References	• Title • Country • Sources
General information	• Responsible Agency • Stakeholders/Beneficiaries • Sector • Barriers addressed • Type of initiative

Categories	Information collected
	• Objectives
Impact on innovation	• Qualitative information on implementation process • Qualitative information on impact (e.g. pros and cons) • Replicability (or elements to calculate it) • Any information on implementation costs already quantified
Best practices and lessons learnt	• Lessons learnt

Typology of voluntary initiatives at national and regional level

The 19 included initiatives are different in nature, pertain to different geographies/Member States (e.g. Denmark; Spain; Italy; the Netherlands; the UK), and span different sectors/policy areas (e.g. growth; competition; water; pharmaceuticals; enterprise). The main types of initiatives which have been identified to date include:

- **Regulatory safe havens** – where some of the regulatory burden on companies is waived by competent authorities, expecting that this will foster innovation. Initiatives in this category include: *Project Innovate* in the UK financial services sector; *Startup Visa*, an initiative across Ireland, Spain, Italy, the Netherlands and Denmark to support start-up led by non-EU innovators.
- **Public-private partnerships** (PPP) – where informal or formal arrangements between one or more public entity, and one or more private entity are established to facilitate the production of innovative goods and/or services. Examples compiled in the inventory include: *Sneller Innoveren Innovation Acceleration* in the water sector in the Netherlands; the *Catapult Programme* for research and innovation set up by Innovate UK; the *Lygature Platform for Regulatory Innovation* in the pharmaceutical sector in the Netherlands, as well.
- **Single permitting initiatives** – where a single permit per company allows the operation of more than one facility by the operator, for example the *Batumi Initiative* in Portugal consisting of a single environmental permit.
- **EU voluntary commitments** – where a group of organisations (such as an industry association) develops voluntary commitments. Initiatives identified in the inventory under this category include: *the Smart Energy Demand Coalition (SEDC)* at EU level; *Open and Agile Cities Initiative (OASC)* including several EU cities as well as many others around the world; the *Spanish Network of Smart Cities (RECI)*; the UK *Home Office Digital Strategy*; and *ChemXchange*, an EU-wide voluntary scheme in the field of chemicals.

Other initiatives that do not fall in the above categories, are for example the *Taskforce for Increase Resource Efficiency* in Denmark; *Startup Law* in Italy; the *Green Deals* - the Dutch government's approach to removing barriers to stimulate sustainable innovation; the *Circular Economy toolkit* in Denmark and the *Innovation Deals for a Circular Economy* set up by the European Commission; the UK government's *Productivity Plan*; the *Payment System Regulator* by the Financial Conduct Authority, also in the UK; and the *Opioid Policy Initiative* by the European Society for Medical Oncology (ESMO) and the European Association for Palliative Care (EAPC).

Of the initiatives listed in the inventory, ten have been selected as case studies based on the type of barriers targeted, their specific objectives, and the amount of relevant information publicly available. For each of the selected initiatives, the research team has prepared a detailed fiche that is summarised in

Figure 17 below. The examples have been mostly selected based on the level of information available through secondary research while trying to meet following criteria:

- At least one initiative per type;
- At least one initiative per sector studied as part of this project (i.e. health, water, energy and food); and
- Geographic diversity so initiatives from a number of Member States are selected.

Based on the above criteria, the case study fiches include:

Figure 17 List of case study initiatives

#	Initiative	Type of Barriers Addressed	Sector/policy area	Country	Replication level
1	Task Force for Increase Resource Efficiency	• Existing regulations and underlying conflicts of interest that prevent businesses from utilising their input of materials and water more efficiently, and that ultimately affect resource productivity and circular economy practices.	Growth and environment (cross-sector)	DK	High
2	Startup Law	• Barriers deriving from non-fit for purpose regulatory, administrative, fiscal and financial regimes.	Law	IT	High
3	Innovation Acceleration	• Outdated legislation, regulations and procedures preventing the development of mutual trust between policy makers and public authorities, service providers, and final users. The formal jurisdictions established in the policy framework which lead to a lack of attention for opportunities. • Strict application of laws, rules and procedures, which frustrates innovation. Shortcomings in the intellectual property legislation and related policy framework.	Water	NL	High
4	Project Innovate	• Rules and policies, at the UK or at the EU level, that are restricting innovation or that should be introduced to facilitate innovation in digital and mobile solutions. Structural issues that innovators told to impede the progress of their propositions towards the market.	Financial services	UK	High
5	Escher, the Lygature Platform for Regulatory Innovation	• Gaps in regulatory frameworks that prevent faster and more efficient development of medicines and of medical technology addressing unmet medical needs.	Health	NL	N/A
6	Green Deals	• Regulatory failures (e.g. Confusion about licenses, ambiguous regulations). The Dutch government promised to cut red tape for biogas production, waste management and other renewable energy projects with the exception of costly wind and solar power, so that it can meet targets set by the European Union. Barriers are also identified by applicants and can include a lack of clarity in obtaining relevant permits or in navigating applicable regulations or problems finding business partners.	Energy Water Food Other	NL	High
7	Startup Visa	• Regulatory and administrative barriers faced by non-EU innovators who want to establish or prolong their innovative start-up in the EU-MS concerned.	Growth (cross-sector)	IE, ES IT, NL, DK	High
8	Batumi Initiative - Single Environmental Permit (SEP)	• Simplification, harmonization and coordination's of all environmental permits, which are supported by the concept: one process, one title, one fee.	Cross-sector	PT	N/A
9	Innovation deal for a circular economy	• The objective of an Innovation Deal is an in-depth understanding and clarification of how an EU rule or regulation applies. If a rule or regulation is confirmed as an obstacle to innovations that could bring wider societal benefits, the Deal will make it visible and feed into possible further action.	Circular economy	EU	High
10	Smart Energy Demand Coalition (SEDC)	• Systematic regulatory barriers facing demand response in Europe. • EU-level challenges in the creation of value-add demand side programs for consumers. • Low levels of program development for EU installed technical capability. • Europe's splintered market structures, and historical regulations generating barriers to consumer participation in the markets.	Energy	EU-level association	N/A

Conclusions

In developing this inventory of initiatives, the research team has faced several challenges. The main one is that, while there is a wealth of interesting and successful initiatives at all levels (local, regional, national and EU) to either overcome barriers to or boost innovation, only a few of them have been set up to explicitly address regulatory or legislative barriers. These types of initiatives have not been included in the inventory.

In addition, the data obtained about the initiatives has not allowed making the connections between outputs and outcomes, and how these relate back to the stated objectives, i.e. has the intervention generated improvements in the intended results (been effective), and thus compare them against the costs, and the net benefits of the initiative estimated relative to the status quo. The following issues and challenges that have prevented the analysis need to be acknowledged:

- **Available quality data:** ideally, to conduct an economic analysis of the initiatives, good quality data should be available especially data from a source that has tested the cause and effect of the changes.
- **Impact and attribution**: without good quality data, exploring issues such as the impact of the initiative and attribution has not been possible. The lack of data has not allow to present a narrative that demonstrates a logic behind the intervention employed and the outcomes observed. There are a range of statistical techniques that can be used, but these require the right sort of data to be available, or comparison with historical data if feasible. At the very least, there needs to be a coherent narrative that underpins the links between inputs and results / impacts, but this may not withstand full scrutiny.

In the absence of data that would allow for developing a logic model and conduct economic analysis of the initiatives, information about other important issues has been collected, for example around the replication level of the different programmes and schemes. The information obtained does allow reaching some conclusions about initiatives developed at national and EU level to overcome regulatory or legislative barriers to innovation:

- All sectors have sought to overcome regulatory barriers to innovation, although most of them seem to be in the environmental/waste management sectors, e.g. Green and Innovation deals.
- The initiatives can be found across the EU although there seem to be more in Northern countries (e.g. the Netherlands, Denmark, UK), at least explicitly trying to address regulatory barriers.
- The most common type of initiatives are voluntary commitments, followed by PPP.
- Several of the initiatives have been successful in achieving their goals and 7 out 10 have been replicated or are considered as highly replicable.

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This report summarises the findings of the study "Regulatory barriers to innovation'. The study brought together a number of methodologies such as a large industry survey. Furthermore, available economic data, patent analysis, cases studies and interviews enriched the analysis.

A focus on four areas – energy, food, health, and water – indicated different effects of different types of regulation on innovation in these four areas. While it is broadly acknowledged that EU-regulation has had positive effects on innovation, there are barriers. By removing existing barriers, further positive effects on R&D investment and jobs in R&D in Europe can be expected.

Studies and reports

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